

# 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.

## 6th AU Smart Safety Surveillance Steering Committee Meeting Held in Addis Ababa.

On March 26–27, 2025, The 6th Steering Committee Meeting of the African Union Smart Safety Surveillance (AU-3S) Programme kicked off in Addis Ababa, Ethiopia, bringing together key stakeholders from across Africa to enhance pharmacovigilance and medical product safety on the continent.

Dr. Mekedes Daba (Ministry of Health) highlighted Ethiopia's pivotal role in advancing pharmacovigilance, serving as one of the two entry points for the COVAX facility in Africa. Through digital innovation, Ethiopia has strengthened real-time adverse event reporting and response mechanisms—contributing to a safer healthcare system.

Heran Gerba, Director-General of the Ethiopian Food and Drug Authority (EFDA), emphasized Ethiopia's remarkable progress since joining AU-3S, particularly in submitting extensive safety reports during the COVID-19 vaccine roll out.

She reaffirmed Ethiopia's commitment to strengthening AU member states' safety surveillance capabilities and supporting new countries in adopting the 3S strategy—reliance, data & work-sharing, and prioritization.

This high-level meeting, hosted by EFDA, brought together CEOs of National Medicines Regulatory Authorities from 13 African nations, along with technical partners, including the Medicines and Healthcare Products Regulatory Authority and the World Health Organization (WHO).

### The GATS Ethiopia 2024 study showed that Ethiopia has attained promising outcomes in its tobacco control efforts.

On April 3, 2025, the Ethiopian Food and Drug Authority, in collaboration with the Ethiopian Public Health Institute, the World Health Organization, and other partner organizations, organized a consultation forum in Addis Ababa to discuss the 2024 Global Adult Tobacco Survey (GATS) targeting individuals aged 15 and above.

Speaking at the consultation forum, Excellency Dr. Tadele Burqa, Vice-Chairman of the Standing Committee on Health, Social Development, Culture, and Sports of the House of People's Representatives, emphasized that the House is committed to supporting efforts to protect public health—not only through the enactment and approval of laws but also by ensuring the effective implementation of Proclamation 1112/2011.

He assured participants that the House will continue to stand with them in their mission.

Opening the forum, State Minister of Health Excellency Dr. Dereje Duguma expressed his appreciation for the successful domestic implementation of the national tobacco use survey. He highlighted the importance of using data and scientific research to inform actions that help protect the health of our society.

He further noted that tobacco smoke is a leading cause of various non-communicable and chronic diseases, emphasizing that stakeholders must take an active role in tobacco control efforts, given the significant economic, social, and political burdens it imposes.



In her welcoming speech at the forum, Heran Gerba, Director General of EFDA, stated that while the GATS Ethiopia 2024 study reflects encouraging progress in tobacco control, there are still key areas that need further improvement.

She highlighted that the overall decline in tobacco use, particularly the reduction among women, was a positive outcome of the study. However, she emphasized the need for continued efforts, especially within government institutions, to further strengthen tobacco control measures and enhance performance in this area.

The consultation forum brought together representatives from federal health institutions, regional health regulatory bodies, heads of the Authority's branch offices, and various non-governmental organizations involved in tobacco control and public health.



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### EFDA Unveils 7th Edition of Ethiopia's Essential Medicines List

Addis Ababa | March 11, 2025 – The Ethiopian Food and Drug Authority (EFDA), in collaboration with key stakeholders, has officially launched the 7th Edition of the Ethiopian Essential Medicines List (EML). This milestone aims to improve the availability of safe, effective, and high-quality medicines across the country.

Seyoum Wolde, EFDA Deputy Director General for the Medicines Sector,

emphasized that the new edition is closely aligned with the World Health Organization's (WHO) latest model list, while also taking into account Ethiopia's unique healthcare priorities. He noted the integration of the AWaRe classification system for antibiotics, a globally recognized framework designed to combat antimicrobial resistance (AMR).



“This edition reflects our unwavering commitment to rational medicine use,” Seyoum stated. “It’s built on scientific evidence and aligned with national health priorities to ensure Ethiopians have access to the most effective treatments.”

Dr. Bejoy Namibar, representing WHO, praised Ethiopia’s ongoing leadership in essential medicines policy. He reaffirmed WHO’s support for strengthening pharmaceutical governance, improving medicine accessibility, and tackling major health threats like AMR.

During the launch event, Dr. Shemsu Umer of EFDA presented key updates in the 7th Edition—highlighting newly added medicines

revised treatment protocols, and the prioritization of life-saving drugs tailored to the country’s evolving healthcare needs.

Girma Tekle from Addis Ababa University also shared findings from a nationwide assessment of the 6th Edition’s implementation. His insights revealed gaps in medicine availability and prescribing trends, which directly informed the latest updates. With this launch, EFDA continues to play a leading role in strengthening Ethiopia’s healthcare system and ensuring better treatment outcomes for all.

## Market Authorization Holders Pledge Stronger Commitment to Medicine Safety

Addis Ababa | March 21, 2025 – The Ethiopian Food and Drug Authority (EFDA) convened a national orientation workshop for Qualified Persons for Pharmacovigilance (QPPVs), reaffirming the vital role of Market Authorization Holders (MAHs) in ensuring ongoing medicine safety through continuous reporting and Periodic Safety Update Reports (PSURs).

The session brought together pharmacovigilance professionals from across the country to strengthen collaboration and understanding of regulatory expectations.

Asnakech Alemu, Lead Executive Officer of Pharmacovigilance and Clinical Trials at EFDA, opened the workshop by stressing the importance of proactive safety monitoring. She highlighted EFDA’s pharmacovigilance directive—developed under the Food and Medicine Administration Proclamation No. 1112/2019—which mandates MAHs to take timely action in reporting and managing safety concerns.

“Ensuring the safety of pharmaceutical products is a shared responsibility,” said Asnakech. “QPPVs play a critical role in safeguarding public health by identifying and reporting adverse drug reactions.”

Demeke Amare, from EFDA’s Pharmacovigilance and Clinical Trials office, led an in-depth session on the responsibilities of QPPVs. His presentation outlined best practices for surveillance, regulatory compliance, and risk communication.

Attendees actively participated in discussions, openly sharing the challenges they encounter in the field and reaffirming their commitment to enhancing Ethiopia’s pharmacovigilance system. The workshop concluded with a collective pledge to strengthen collaboration with EFDA and improve the quality and timeliness of safety reporting to protect patients nationwide.

## EFDA Drafts New Fortified food registration Guideline to Fortify Edible Oils and Flour



**Adama, Ethiopia – March 27, 2017** – The Ethiopian Food and Drug Authority (EFDA) has introduced draft guideline requiring edible oil and flour manufacturers to fortify their products with essential vitamins and minerals and registered by the authority. In an effort to ensure the effectiveness and feasibility of the regulations, EFDA hosted a stakeholder discussion forum in Adama, inviting key industry representatives to provide feedback.

To gather input on the draft, EFDA hosted a stakeholder consultation forum in Adama, bringing together key industry representatives and technical experts.

Negash Sime, Deputy Director General of EFDA's Food Sector, emphasized the public health impact of micronutrient deficiencies and the critical role of food fortification.

"Micronutrients such as vitamins and minerals are vital for growth, immune function, and digestion," he stated. "Through these guidelines, we aim to ensure essential nutrients are incorporated into staple food products, benefiting millions of consumers."

Ato Mengistu Asfaw, EFDA's Lead Executive Officer for Food Registration and Licensing, presented the details of the proposed guideline.

The forum featured an open and collaborative discussion where participants shared valuable insights and sought clarification on technical elements of the new regulation. EFDA officials, including Mulatu Tesfaye (Food Inspection and Enforcement), Wondafrash Abera (Technical Advisor), and Negash Sime, addressed stakeholder concerns, reinforcing the authority's openness to feedback in finalizing the guideline.

This initiative is part of EFDA's broader strategy to strengthen food safety, improve nutritional standards, and ensure fortified products meet the needs of the Ethiopian population. Once finalized, the guideline will mandate the registration of fortified edible oils and flour, supporting efforts to reduce micronutrient deficiencies nationwide.

EFDA remains committed to engaging with stakeholders and the public as it moves forward in enhancing national food fortification efforts.

## EFDA Welcomes New Staff with Orientation Aimed at Advancing Institutional Excellence

Adama, Ethiopia | March 20, 2025 – In a bid to strengthen institutional performance and build a more competent and competitive workforce, the Ethiopian Food and Drug Authority (EFDA) launched an orientation training for newly transferred employees to the Adama City branch.

The program was officially opened by Heran Gerba, Director General of EFDA, who welcomed the 34 participants and introduced the authority's regulatory mandate. She highlighted EFDA's ongoing transformation journey over the past 15 years, which includes legal reforms, organizational restructuring, and infrastructure improvements aimed at enhancing regulatory effectiveness.

Heran emphasized the importance of professionalism, ethical conduct, and avoiding conflicts of interest, urging the new team members to contribute meaningfully to achieving EFDA's mission and vision.

"Our progress depends on the strength and integrity of our people. As we move forward, your commitment will play a key role in our transformation," she stated.

The orientation training is designed to familiarize employees with EFDA's structural organization, legal frameworks—including the Federal Personnel Administration Proclamation No. 1350/2017—as well as internal policies, strategies, and core regulatory initiatives. It will also cover essential topics such as ethics, communication, customer service, and conflict of interest management.

With participants from both the head office and branch offices, the training is part of EFDA's broader human resource development agenda to build a capable and mission-driven workforce dedicated to public health protection.



## A grand kick-off meeting was held for the 'Last Mile Authorization Ethiopia' project, aimed at strengthening the EFDA's abridged review process based on the reliance pathway.

The Ethiopian Food and Drug Authority has recently launched multiple initiatives to strengthen its marketing authorization system, including this project, which is funded by the Bill & Melinda Gates Foundation (BMGF).

This project primarily focuses on system evaluation and strengthening of the abridged registration process based on the reliance system.



During the official kick-off of the drug evaluation, registration, and market authorization process on March 28, 2025, the Deputy Director General of EFDA, Abayneh Alemayehu, emphasized the significance of the project in enhancing the current registration system. He also expressed gratitude to the Gates Foundation for its financial support, which has been instrumental in enabling the registration and importation of various medicines. This support has helped address critical gaps in the market authorization process, which previously relied on data from well-established regulatory bodies.

Abayneh highlighted the on-going collaboration between the Gates Foundation and the Authority on various initiatives and stressed the importance of utilizing the allocated funds for their intended purposes. He also emphasized the need for timely submission of both technical and financial reports as required.

Seble Shambel, the Lead Executive Officer of the Authority's Drug Registration and Marketing Authorization Division, stated that the project aims to strengthen national regulatory

pathways to ensure the availability of safe, high-quality, and effective medicines in Ethiopia. She added that the project will reduce the workload and improve efficiency by significantly shortening the approval timelines for essential medicines.

Seble further explained that, with the financial support of the Gates Foundation, the Authority will review at least 200 applications submitted through the reliance pathway over the course of this one-year project. In addition, the project will focus on capacity building for dossier assessors, experience-sharing, and collaborative discussions to establish systems that support further collaboration in the reliance system.

It was also noted that the EFDA recently revised its reliance guidelines as part of system strengthening, following the WHO benchmarking for maturity level 3.

# SPECIAL EDITION

## Basics of Quality Management System in Service Organizations

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### 1. Introduction

Quality management system is a systematic approach to ensuring that services, and processes consistently meet or exceed customer expectations. At its core, quality management is about striving for excellence in every aspect of an organization's operations. By implementing robust quality management practices, organizations can enhance customer satisfaction, drive operational efficiency, and maintain a competitive edge in the service arena.

#### 1.1 Principles of Quality Management System:

Quality management system principles are a set of fundamental beliefs, norms, rules and values that are accepted as true and can be used as a basis for quality management. The seven quality management principles are:

- **Customer Focus:** Understanding and meeting customer needs and expectations is paramount to quality management.
- **Leadership Involvement:** Engaging leadership in setting the vision, values, and goals of quality management within the organization.
- **Employee Involvement:** Empowering employees to contribute their knowledge, skills, and creativity to improving quality.
- **Process Approach:** Managing activities and resources as interconnected processes to achieve desired outcomes efficiently.
- **Continuous Improvement:** Embracing a culture of continuous improvement to enhance processes, products, and services over time.
- **Evidence-Based Decision Making:** Using data and analysis to make informed decisions and drive improvement initiatives.
- **Relationship management:** Cultivate effective relationships with stakeholders, including customers and suppliers.

Encompassing all actors who influence or are influenced by the activities of the organisation.

#### 1.2 Key Benefits of Quality Management System:

Implementing a Quality Management System (QMS) offers numerous benefits. Here are the main advantages:

- **Enhanced Customer Satisfaction:** By consistently delivering high-quality services that meet or exceed customer expectations.
- **Improved Operational Efficiency:** By optimizing processes, reducing waste, and minimizing defects, organizations can streamline operations and reduce costs.
- **Regulatory Compliance:** Meeting quality standards and regulatory requirements is essential for organizations operating in regulated industries.
- **Risk Management:** Identifying and mitigating risks associated with quality issues can prevent costly recalls, lawsuits, and damage to reputation.

Quality management system is a fundamental aspect of organizational success, driving improvements in services, processes, and customer satisfaction. By embracing quality management principles and practices, organizations can achieve excellence and sustain long-term growth and success.

#### 2. The Requirements of ISO 9001 and Its Implementation

ISO 9001 is the international standard for quality management systems, providing a framework for organizations to establish, implement, maintain, and continually improve their quality management processes.

##### 2.1 Requirements of ISO 9001:

- **Context of the Organization:** Understanding the internal and external factors that influence the organization and its ability to achieve its quality objectives.

- **Leadership:** Demonstrating leadership commitment to quality and establishing a quality policy and objectives aligned with the organization's strategic direction.
- **Planning:** Planning and implementing processes to address risks and opportunities, establish quality objectives, and allocate resources effectively.
- **Support:** Providing the necessary resources, infrastructure, and competence to support the operation and effectiveness of the quality management system.
- **Operation:** Implementing and controlling processes to meet customer requirements and deliver consistent products and services.
- **Performance Evaluation:** Monitoring, measuring, analyzing, and evaluating the performance of the quality management system and processes.
- **Improvement:** Taking corrective and preventive actions to address non-conformities, enhance customer satisfaction, and continually improve the effectiveness of the quality management system.

### 2.1 Implementation of ISO 9001:

- **Gap Analysis:** Assessing the organization's current processes and practices against the requirements of ISO 9001 to identify areas for improvement.
- **Documentation:** Developing documentation, including a quality manual, procedures, work instructions, and records, to support the implementation of ISO 9001.
- **Training and Awareness:** Providing training and awareness programs to ensure that employees understand their roles and responsibilities within the quality management system.
- **Implementation:** Implementing the processes and procedures outlined in the quality management system and ensuring compliance with ISO 9001 requirements.
- **Monitoring and Measurement:** Establishing processes for monitoring, measuring, and analyzing key performance indicators (KPIs) to evaluate the effectiveness of the quality management system.
- **Internal Audit:** Conducting internal audits to verify compliance with ISO 9001 requirements and identify opportunities for improvement.

- **Management Review:** Conducting regular management reviews to assess the performance of the quality management system, identify areas for improvement, and make necessary changes.

### 3. Exploring the Benefits of ISO certification

ISO certification signifies that an organization has implemented and maintained a quality management system that meets international standards. While the process may require initial investment and effort, the long-term advantages make it a worthwhile endeavor for organizations seeking to achieve excellence in quality management. ISO certification offers numerous benefits as follows:

**Enhanced Credibility and Reputation:** ISO certification signals to customers, and stakeholders that an organization is committed to quality and continuous improvement. It enhances credibility and instills confidence in the organization's services and operations.

**Improved Operational Efficiency:** Implementing ISO standards encourages organizations to streamline processes, reduce waste, and optimize resources. This leads to improved efficiency, lower costs, and higher productivity.

**Greater Customer Satisfaction:** ISO certification demonstrates a commitment to meeting customer requirements and delivering consistent quality services. This can lead to increased customer satisfaction, trust, and reputation.

**Risk Management and Compliance:** ISO standards help organizations identify, assess and mitigate risks associated with quality issues, compliance to global standards, and operational disruptions. By adhering to ISO requirements, organizations can ensure compliances, and minimize risks and liabilities.

### 4. Understanding the ISO 9000 Series and Sector-Specific Standards

The ISO 9000 series is a set of international standards developed by the International Organization for Standardization (ISO) that provide guidelines and frameworks for quality management systems. The ISO 9000 series

consists of several standards, with ISO 9001 being the most widely recognized and implemented standard.

**ISO 9001:** ISO 9001 is the cornerstone of the ISO 9000 series and provides requirements for establishing, implementing, maintaining, and continually improving a quality management system. It focuses on customer satisfaction, process optimization, and compliance with statutory and regulatory requirements. ISO 9001 certification demonstrates an organization's commitment to quality and its ability to consistently meet customer requirements. In addition to ISO 9001, there are sector-specific standards that address the unique challenges and requirements of particular industries and sectors. These sector-specific standards build upon the principles of ISO 9001 and provide additional requirements and guidance tailored to the specific needs of each industry.

## 5. Conclusion

A Quality Management System in service organizations ensures consistent service delivery by optimizing processes and operations. It focuses on customer satisfaction through continuous improvement. ISO standards are internationally recognized guidelines and frameworks for quality management systems. Among these, the ISO 9001 standard is a fundamental framework that provides comprehensive guidelines for establishing and improving quality management systems. By adhering to the requirements of ISO 9001 and implementing effective quality management practices, organizations can enhance customer satisfaction, drive operational efficiency, and achieve sustainable success.



**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!**

# GATS | ETHIOPIA 2024

## GATS Objectives

The Global Adult Tobacco Survey (GATS) is a global standard for systematically monitoring adult tobacco use (smoking, smokeless, and heated tobacco products) and tracking key tobacco control indicators.

GATS is a nationally representative survey, using a consistent and standard protocol across countries including Ethiopia. GATS enhances countries' capacity to design, implement and evaluate tobacco control programs. It will also assist countries to fulfill their obligations under the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) to generate comparable data within and across countries. WHO developed MPOWER, a technical package of selected demand reduction measures contained in the WHO FCTC that include:



## GATS Methodology

GATS uses a global standardized methodology. It includes information on respondents' background characteristics, tobacco use (smoking, smokeless, and heated tobacco products), electronic cigarette use, cessation, secondhand smoke, economics, media, and knowledge, attitudes, and perceptions towards tobacco use. In Ethiopia, GATS was conducted in 2024 as a household survey of persons 15 years of age or older by the Ethiopia Public Health Institute with collaborative engagement of Ethiopian Food and Drug Authority; Ethiopian Statistical Service; and WHO Ethiopia. A multi-stage, geographically clustered sample design was used to produce nationally representative data. A total of 12,209 households were sampled and one individual was randomly selected from each participating household to complete the survey. Survey information was collected electronically by using handheld devices. There were a total of 11,876 completed individual interviews with an overall response rate of 97.4%.

## GATS Highlights

### TOBACCO AND ELECTRONIC CIGARETTE USE

- 4.6% overall (2.4 million adults), 8.8% of men, and 0.5% of women currently used tobacco.
- 4.0% overall (2.1 million adults), 7.7% of men, and 0.4% of women currently smoked tobacco.
- 1.0% overall (0.5 million adults), 1.8% of men, and 0.2% of women currently used smokeless tobacco.
- <0.1% overall (<0.1 million adults), <0.1% of men, and 0.0% of women currently used electronic cigarettes.

### CESSATION

- 55.4% of current smokers planned to or were thinking about quitting smoking.
- 49.2% of smokers who visited a healthcare provider in the past 12 months were advised to quit smoking.

### SECONDHAND SMOKE

- 19.8% of adults who worked indoors (2.1 million adults) were exposed to tobacco smoke in enclosed areas at their workplace.
- 14.0% of adults (7.3 million adults) were exposed to tobacco smoke inside their homes.
- 20.2% of adults (2.4 million adults) were exposed to tobacco smoke when visiting restaurants.

### ECONOMICS

- The average (mean) amount spent on 20 manufactured cigarettes was 174.1 Ethiopian Birr.
- The average (mean) monthly expenditure on manufactured cigarettes was 2341.5 Ethiopian Birr.

### MEDIA

- 15.8% of adults noticed anti-cigarette smoking information on the television or radio.
- 5.1% of adults noticed any tobacco products (smoked and/or smokeless) advertising or promotions in stores where tobacco products are sold.
- 9.2% of adults noticed any tobacco products (smoked and/or smokeless) advertisements, promotions, or sporting event sponsorship.
- 18.4% of current smokers thought about quitting because of warning labels.

### KNOWLEDGE, ATTITUDES & PERCEPTIONS

- 87.9% of adults believed smoking causes serious illness.
- 80.9% of adults believed breathing other peoples' smoke causes serious illness in non-smokers.