EFDA
የኢትዮጵያ ምግብና መድኃኒት ባለሥልጣን
ETHIOPIAN FOOD & DRUG AUTHORITY

EFDA News VOICES

EFDA NEWSLETTER • DECEMBER 2023 •

IN THIS ISSUE

National-Level Food Safety Roadmap

Ethiopia is poised to take a significant stride in ensuring national food safety as it collaborates with the African Union Commission to craft a comprehensive roadmap. Dr. Ashagre Zewdu, a consultant from Addis Ababa University engaged by AU Commission, unveiled this ambitious project during a presentation to exporters on December 11, 2016. The initiative aims to assess the current state of food security on a national scale, with a crucial first step involving the meticulous gathering of data.

Heran Gereba, Director General of Ethiopia Food and Drug Authority

Dr. Ashagre emphasized the foundational importance of data gathering in creating the roadmap. This meticulous process will enable a thorough assessment of various institutions, providing insights into the current state of food security across the nation. The initiative comes at a crucial juncture, recognizing the imperative role of food safety on the agenda of numerous sectors within Ethiopia.

Ms. Heran Gerba, Director General of Ethiopia's Food and Drug, underscored the collaborative nature of the endeavor, emphasizing the need for support from all institutions. She highlighted the importance of offering information to the committees involved in shaping the roadmap, thereby ensuring a comprehensive and well-informed approach.

The crafting of the roadmap involves input from key governmental bodies, including the Ministry of Agriculture, Ministry of Trade and Regional Relations, and the Ministry of Health.

At the national level, the African Union Commission and other pertinent organizations are actively collaborating with the Ethiopian Food and Drug Authority to drive this critical project forward.

IMPORTANT MESSAGE

Ethiopia is poised to take a significant stride in ensuring national food safety as it collaborates with the African Union Commission to craft a comprehensive roadmap.

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:

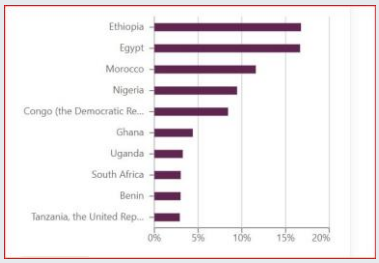
1. Protect the public from unsafe food
2. Safeguard the public from falsified, substandard and ineffective health products
3. Protect the public from tobacco and alcohol related health risks
4. Attain public confidence on food and health product regulation

Strategic Directions

1. Strengthen food safety regulation.
2. Strengthen detection, prevention and response to food adulteration and illegal trade
3. Improve regulation of safety, efficacy, quality and proper use of medicines
4. Strengthen safety, quality and performance regulation of medical devices
5. Improve regulation of safety of cosmetic products
6. Strengthen tobacco and alcohol control system
7. Enhance public ownership
8. Improve efficiency and effectiveness
9. Enhance partnership and collaboration
10. Enhance good governance
11. Improve human resource development and Management
12. Improve evidence-based decision making
13. Strengthen Food and health products regulatory infrastructures
14. Improve quality management system
15. Improve formulation and implementation of legal frameworks

WHO Announces Ethiopia Ranks First in AEFI Report

In a notable development on the global health front, Ethiopia has taken the lead in reporting Adverse Events Following Immunization (AEFI), as confirmed by the World Health Organization (WHO). The announcement comes after Ethiopia held the position of the second-highest reporter of vaccine side effects in Africa until the end of December.



Teshta Shute, Head, Medicine Safety and Post Marketing Surveillance Desk at the Ethiopian Food and Drug Authority, lauded the achievement, emphasizing the collaborative efforts that led to Ethiopia's top-ranking position. Mr. Shute expressed that this accomplishment not only reflects the dedication of numerous stakeholders but also provides an opportunity to bolster the authority's credibility and gain public and stakeholder trust.

Coordination Work to Improve Service Delivery

In a collaborative effort to enhance service delivery in the pharmaceutical, medical device, and cosmetics sectors, key industry players convened for a crucial discussion hosted by the Ethiopian Food and Drug Authority on December 26, 2023. The gathering, led by Ms. Heran Gerba, Director General of the Authority, aimed to address challenges within the area of drugs and medical devices, fostering a united front for improved services. The call for coordinated action underscored the significance of collective efforts in resolving service-related issues and shaping a more robust future for the sector.

Ms. Heran Gerba emphasized the forum's primary goal of discerning the intricacies linked to service delivery in the specified sectors. "The aim is to set a direction for the future, ensuring improved services and addressing the challenges faced by stakeholders," she stated. Highlighting the imperative need for coordinated efforts, Gerba emphasized that collective action by all stakeholders is crucial in resolving issues and elevating service standards.

The Ethiopian Food and Drug Authority proposed the development and implementation of a comprehensive three-year development and investment plan, along with a revision of the existing five-year strategic plan. These strategic initiatives are envisioned to fortify the achieved results and set the groundwork for sustained improvement.

Various topics were deliberated during the meeting, encompassing services provided to importers and distributors of pharmaceuticals and medical equipment, the obstacles encountered by these entities, plans for registering market licenses for these products, and the current state of service delivery.

Stakeholders' Role in Ensuring Food Safety and Supply to Society

In a concerted effort to address the crucial issue of food safety, the Ethiopian Food and Drug Authority organized a forum on December 27, 2023. During this gathering of key stakeholders, including food producers, importers, exporters, and distributors, a unanimous commitment was voiced regarding the shared responsibility of ensuring food safety throughout the entire supply chain.

Ethiopian Food and Drug Authority took a bold step towards enhancing food safety by orchestrating a critical discussion forum on December 27, 2023. The forum, attended by prominent figures in the food industry, highlighted the collective obligation of all stakeholders, including food producers, importers, exporters, and distributors, to uphold the integrity and safety of the nation's food supply.

Ms. Heran Gerba, the Director General of the Ethiopian Food and Drug Authority, emphasized the multifaceted nature of the food sector, stressing that ensuring food safety is a joint responsibility extending from the farm to the consumer's plate. She underscored the potential repercussions of lapses in food safety, citing the risk of both infectious and non-infectious diseases.

"The safety of our food supply is not a singular task; it is a collective responsibility that encompasses everyone involved in the production, import, export, and distribution of food," stated Ms. Heran Gerba during the forum's opening address.

The Ethiopian Food and Drug Authority announced the establishment of a platform designed to facilitate ongoing dialogue among stakeholders, acknowledging the necessity of continuous communication to fulfill shared duties in maintaining food safety. The platform aims to serve as a space for constructive discussions and the exchange of ideas, fostering a collaborative approach to addressing existing gaps in food safety protocols.

Recognizing the importance of working together towards a common goal, the authority urged participants to contribute constructive ideas during the discussions. The call to action emphasized the need for a united front in filling existing gaps in the food safety framework, reinforcing the commitment of all stakeholders to safeguard the well-being of the society through a collective and proactive approach.

Comprehensive Guidelines for Radiopharmaceuticals and Medical Gases Regulation

In a significant move towards bolstering health product control and ensuring product quality, the Authority has unveiled comprehensive guidelines for regulating radiopharmaceuticals and medical gases. The announcement came during a consultative workshop on December 14, 2023, opened by Seyoum Wolde, the Deputy Director General of the Authority's pharmaceutical sector.

The guidelines aim to establish robust institutional control mechanisms, addressing gaps in the oversight of health products and fostering safety and efficacy.

Seyoum Wolde, Deputy Director General of the Authority's pharmaceutical sector

Mr. Seyoum emphasized that the primary objective of these guidelines is to institute institutional control tools, effectively closing existing gaps in health product oversight. The overarching goal is to elevate the quality of radiopharmaceuticals and medical gases, ensuring their safety and efficacy in healthcare practices.

"The guidelines we are introducing are instrumental in our pursuit of achieving the maturity level set by the World Health Organization for regulatory bodies," stated Deputy Director General Mr. Seyoum.

During the consultative workshop, Mr. Seyoum highlighted the collaborative nature of the guidelines' preparation, emphasizing the engagement of stakeholders in the decision-making process. The workshop served as a platform for open dialogue, with participants contributing valuable insights to shape the final recommendations for radiopharmaceuticals and medicinal gases.

Empowering Ethiopian Pharmaceutical Manufacturers through Regulatory Initiatives

December 27, 2023 - The Ethiopian Food and Drug Authority has taken a proactive stance towards advancing its pharmaceutical sector by introducing a range of incentives poised to catalyze growth and innovation. According to Mr. Seyoum Wolde, the Deputy Director General of the authority, these measures aim to strengthen the regulatory framework and propel the local pharmaceutical industry onto a trajectory of self-sufficiency and global competitiveness.

Among the noteworthy incentives unveiled is a groundbreaking initiative allowing foreign manufacturers to produce medicine locally after a decade of market presence following regulatory approval. Mr. Seyoum highlighted this significant development, emphasizing that it opens avenues for foreign investors to play a pivotal role in the evolution of Ethiopia's pharmaceutical landscape.

"The introduction of tax relief, access to industrial parks, a pool of well-trained experts, a robust regulatory body, government procurement support, and an efficient one-window service collectively create an enticing environment for foreign investors looking to contribute to the growth of our pharmaceutical sector," explained Mr. Seyum.

Crucially, the incentive package is expected to drive a substantial increase in the share of the local medicines sector. In a collaborative effort, stakeholders, manufacturers, and medical importers are urged to actively participate in the initiative's implementation to surpass the current 10% coverage of the local medicines market.

Guest

Teshta Shute, Head, Medicine Safety and Post Marketing Surveillance Desk at the Ethiopian Food and Drug Authority.

EFDA Voice: What is Adverse Events Following Immunization (AEFI) and how is it done?

Adverse Event Following Immunization (AEFI) is any untoward medical occurrence which follows administration of an active immunizing agent and which does not necessarily have a causal relationship with the use of a vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease. Evidence regarding vaccine safety generated throughout the vaccine life cycle helps to inform the risk-benefit discussion between immunization providers and potential vaccine recipients or their caregivers. An AEFI can be classified by the following cause specific categories:

Vaccine product-related reaction: an AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product

- **Examples:** vaccination site pain, fever and anaphylaxis

- **Vaccine quality defect-related reaction:** an AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer.
  - **Example:** failure to inactivate polio virus resulting in poliovirus infection
- **Immunization error-related reaction:** an AEFI that is caused by inappropriate usage and, therefore, by its nature is preventable.
  - **Example:** inappropriate administration of live measles vaccine to immunocompromised persons resulting in measles encephalitis or pneumonia.

Immunization triggered stress response/Anxiety related reaction: an AEFI arising from anxiety about the immunization (examples include syncope or hyperventilation).

Coincidental event: an AEFI that is caused by something other than the vaccine product, immunization error, or immunization anxiety but where a temporal association with immunization exists.

- **Example:** meningitis that occurs within days of MMR vaccination that upon investigation is shown to be caused by Streptococcus pneumonia.

Types of AEFI by seriousness

Serious AEFI: an AEFI that meets one or more of the following criteria: life-threatening, results in hospitalization, prolongation of an existing hospitalization, persistent or significant disability/ incapacity, is a congenital anomaly/birth defect, fatal outcome. All serious AEFI should be reported without delay within 24 hours and standard form should be filled and submitted to EFDA within 48 hours.

Minor AEFIs: Most vaccine reactions are minor and subside on their own. Minor vaccine reactions are caused when the recipient's immune system reacts to antigens or the vaccine's components (e.g. aluminium adjuvant, stabilizers or preservatives) contained in the vaccine. Minor AEFIs could be local or systemic. All minor AEFIs must be reported on monthly basis using line list.

The authority established surveillance systems to monitor the safety of vaccines and Monitoring AEFI through the following: -

a. Passive Surveillance

This encompasses all spontaneous AEFI reporting from immunization service providers/hospitals/patients to the first administrative level (district/wereda level) in the surveillance system spontaneously and voluntarily.

b. Active Surveillance

Active (proactive) vaccine safety surveillance is an active system for the detection of adverse events.

continued to page 7

continued from page 6

This is achieved by active follow-up after vaccination. Events can be detected by asking patients directly or by screening patient records. It is best done prospectively. This method aims to monitor certain specific adverse events and seeks to ascertain the number of AEFI entirely through a pre-planned process.

Stimulative Passive Surveillance

This type of surveillance system is useful where AEFI surveillance is new. In order to detect and report cases periodic reminders, education and feedback is important.

AEFI detection, reporting, analysis, investigation, causality assessment and communication.

Based on the results of investigations and causality assessments, the authority may take appropriate actions, such as updating vaccine labels, issuing safety alerts, withdrawing a vaccine from the market, or suspension of the license of MAH. And also provide recommendation for Ministry of Health.

EFDA Voice: What is the role of the Authority and relevant stakeholders in monitoring AEFI?

Vaccine safety monitoring is not a task of one organization. Although EFDA has a mandate to monitor vaccine safety/AEFI in reality it is the responsibility of every organization, health care professionals and citizen to report the safety concerns as soon as possible.

Roles and responsibilities of EFDA

- Responsible for the approval, licensing, and ongoing monitoring of vaccines and also conducts thorough reviews of vaccine safety data during the pre-licensure phase and continue to monitor safety post-licensure.
- Monitor and evaluate implementation of AEFI surveillance in collaboration with stakeholders
- Design and adopt new AEFI monitoring initiatives
- Revise, update, distribute and ensure availability of AEFI monitoring tools
- Strengthen Pharmacovigiliance Advisory Committee and provide secretariat service for causality assessment
- Strengthen AEFI data management system at all levels
- Support regions and strengthening AEFI documentation and reporting system.
- Share AEFI data to relevant stakeholders and global community
- Provide and follow training of personnel involved in AEFI surveillance in collaboration with other stakeholders.
- Analyze AEFI data and providing feedback to stakeholders
- Establish stakeholders' coordination platform
- Carry out risk- benefit analysis of vaccine used in the immunization program
- Take the necessary corrective measures when there is a safety and quality problem of vaccine is observed.
- Communicate AEFI and immunization safety that needs public attention at the National level with MOH.
- Establish /Strengthen efficient communication mechanisms on vaccine safety among stakeholders
- Engage in the planning, training, implementation and monitoring of related activates organized by MOH-EPI

Roles and responsibilities of Stake holders

- Sharing of global good practices on AEFI monitoring system
- Provide technical, financial support for AEFI monitoring activities and collaborate with EFDA in mobilizing resources to strengthen AEFI monitoring system.
- Engage in planning, implementation, monitoring and evaluation AEFI monitoring activities
- Collaborate with EFDA in the continuous development, revision and distribution of tools and guidelines for AEFI monitoring system
- Provide capacity building to strengthen the system on AEFI monitoring and case management in collaboration with EFDA.
- Facilitate and ensure AEFI case management at healthcare facilities.
- Provide support to regions, zones and woredas and health facilities in AEFI monitoring
- Share AEFI reports received from routine immunization, mass campaigns, outbreak response and public with EFDA
- Ensure the implementation of AEFI related recommendations/ decisions reaching up to the lower level
- Conduct laboratory analysis of specimens collected during AEFI investigation in collaboration with EFDA
- Conduct epidemiological studies related to vaccine safety monitoring in collaboration with EFDA
- Collaborate on post marketing clinical trials of vaccines
- Detection, management and recording and document AEFI data and share with the next higher level using the standard reporting tools. Properly document patient medical chart after management of suspected AEFI is very crucial for investigation and research.
- Ensure the availability of AEFI kits at vaccination sites at all times
- Advise vaccine recipients or their parents/care givers about AEFI management and notification
- Keep AEFI monitoring related documents properly such as AEFI line list, copy of reported serious AEFI.
- Collaborate with AEFI case investigation taskforce during investigations process
- Implement feedbacks provided on AEFI monitoring from higher administrative level

EFDA Voice: Our country has recently become the first place /stage in African countries in vaccine safety monitoring/reporting AEFI cases. What has beendone to achieve this result?

Ethiopia established national pharmacovigiliance center in 2002 and joined WHO Program for international drug monitoring (PIDM) on 2008 as the 88th full member. Before August 2023 Ethiopia was 5th from Africa and 37th from world countries in vaccine safety detection, collection and reporting. Currently, as of January 2/2024 we have around 75, 677 individual case safety reports (ICSRs) which are entered in to vigiflow. The ICSRs vigilized and share to global community via Uppsala Monitoring Center (UMC). It the vigilized ICSRs data used to indicate the countries vaccine pharmacovigiliance system monitoring system resilience apart from other criteria. Ethiopian FDA has implemented different strategies to boost the detection, collection and reporting, data entry and vigilization of these cases.

To mention some

- The authority conducted active surveillances

continued to page 8

continued from page 7

- Strengthen its spontaneous report in vaccination campaigns
- Strongly work in collaboration with MoH and other stake holders
- Training health care professionals about vaccine safety monitoring
- Provided face to face training at health facilities
- The country also integrated its surveillance efforts with global vaccine safety networks and organizations, such as the World Health Organization (WHO) and AUDA-NEPAD,3S Project.
- Developed and revised guide lines, SOPs and training materials
- Supportive supervision and feed back
- Closely working during mass vaccination campaign, outbreak response campaign and mass drug administration campaign activities
- Monitoring and evaluation activities
- Implementation of 100 days plan and activity performance
- Zoom meetings and face to face regular meetings
- Designing measureable key performance indicators (KPIs)
- Hiring of national and sub national Vaccine safety monitoring Technical assistants
- Regular communication via different channels email, telegram, phone call, letter and others
- Integrating regional regulatory bodies, pharmacovigiliance centers and other stake holders
- Acknowledgement of health care professionals after reporting safety and quality issues
- Incorporating AEFI activities during woreda based planning, micro planning of EPI activities

EFDA Voice: What is the benefit of the result for our institution and the country?

- It's important to note that reporting of AEFI is an indication of a robust and proactive vaccine safety monitoring system. Continuous monitoring and evaluation are essential to ensure the safety of immunization programs and address any emerging concerns promptly that will build public trust of vaccines then immunization program
- Effective, efficient and transparent regulatory systems are an essential component of overall health systems and contribute to desired public health outcomes. Strong regulatory systems are fundamental to sound public health outcomes, and to the achievement of universal access to health and universal health coverage.
- Being a pioneer in vaccine safety monitoring can enhance the country's global standing. It may lead to increased collaboration with international health organizations, research institutions, and other countries, fostering information exchange and shared best practices.

EFDA Voice: What work is being done to sustain the results?

- Provide regular training sessions, face to face discussion for healthcare professionals on AEFI recognition, documentation, and reporting
- Conducting active and passive surveillance
- Establishing new pharmacovigilance centers in some university hospitals
- Strengthening existing pharmacovigilance centers at university hospitals.
- Integration of AEFI monitoring training with expanded program on immunization (EPI) activities
- Supportive supervision and feedback, serious case investigation and causality assessment,
- Engaging different stakeholders, established stakeholder's forum
- Develop and update guidelines and protocols for AEFI surveillance
- Increase public awareness and engage communities in AEFI surveillance
- Increase collaboration with international organizations and global vaccine safety networks.
- Experience sharing of regulatory authorities to benefit from global expertise and best practices

EFDA Voice: What is being done to improve our status on monitoring and reporting pharmacovigilance in the pharmaceutical sector in Africa?

- Extend the experiences from vaccine surveillance to general pharmacovigilance system
- Engaging different stakeholders, establish stakeholder forum
- Provide regular training sessions, face to face discussion for healthcare professionals on ADE recognition, documentation, and reporting
- Increase collaboration with international organizations such as WHO and the others.
- Experience sharing of regulatory authorities to benefit from global expertise and best practices
- Conducting post marketing surveillance of pharmaceutical products
- Enforcing MAH to assign PV focal point at country level
- Expanding and promotion of means of reporting
  - » Paper based reporting (prepaid yellow form)
  - » Electronic reporting system such as med safety mobile app, web based (www.efda.gov.et), https://primaryreporting.who-umc.org/Et, E-mail: Pharmacovigilance@efda.gov.et
  - » Toll free no 8482

EFDA Voice: Lastly, what do you want to say to the public?

The public should not hesitate to ask their healthcare provider or pharmacist if they have any questions about their medication.

Now a days public medicine/ vaccine safety reporting system in Ethiopia is at infant stage. In order to initiate this reporting system EFDA has planned to advocate and conduct social mobilization at community levels in collaboration with other stakeholders. In this fiscal year we incorporated our plan to train health extension workers at health post levels in collaboration with stake holders so that they reach the community at door-to-door level. By these there may be improved reporting system at community level. In generally, the public adverse event reports contribute to the continuous monitoring and improvement of medication safety. Therefore, the public may use The EFDA toll free number 8482 to report if they notice any unusual or unexpected side effects after taking a medication,

Our ever-lasting motto

"We Protect the Safety of Our People."

EFDA Voice: Thank you so much