AUGUST , 2024

EFDA
የኢትዮጵያ ምግብና መድኃኒት ባለሥልጣን
ETHIOPIAN FOOD & DRUG AUTHORITY

www.efda.gov.et

MEDICINE INFORMATION BULLETIN

A QUARTERLY BULLETIN PUBLISHED BY ETHIOPIAN FOOD AND DRUG AUTHORITY

VISION

To be a center of excellence in food and health products regulation in Africa.

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.

Contents

contact us
contactefda@efda.gov.et

Editorial

This is the first issue of the bulletin for the year 2024. Several topics having current importance are hereby brought to our readers. We certainly hope that the information covered under this bulletin useful particularly to health professionals and the public in general.

Tell us what you think!

Your thoughts and suggestions are important to us. To help us improve our bulletin and better serve your interests, we would greatly appreciate your feedback. Please take a moment to share your comments, ideas, or any topics you'd like us to cover in future editions.

Send your feedback to via
E-mail: contactefda@efda.gov.et
Telegram: https://t.me/edib2024

Thank you for helping us make our bulletin better!

Scientific Information

New antibiotic authorized to fight infections caused by multidrug-resistant bacteria

Infections due to Gram-negative bacteria that are resistant to many currently available antibiotics are a serious public health problem since patients have limited or sometimes no treatment options. Infections due to unprecedented drug resistance problems, scientists have been searching for new antibiotic medicines.

The European Medicine Agency (EMA) has recommended granting a marketing authorization in the European Union (EU) for aztreonam-avibactam, indicated for the treatment of complicated intra- abdominal and urinary tract infections, hospital-acquired pneumonia and infections caused by certain types of bacteria (aerobic Gram-negative) where treatment options are limited.

Aztreonam-avibactam is a fixed- dose combination of two active substances, aztreonam and avibactam. Aztreonam is an antibiotic that belongs to the group 'beta-lactams'. It works by attaching to proteins on the surface of the bacteria. This prevents the bacteria from building their cell walls, which kills them. Avibactam blocks the action of many of the bacterial enzymes called beta-lactamases. These enzymes enable bacteria to break down beta-lactam antibiotics, such as aztreonam, making them resistant to theantibiotic's action. By blocking these enenzymes, avabibactam restores the activity of aztreonam against aztreonam- resistant bacteria. Aztreonam- avibactam is administered by intravenous infusion. EMA's human medicines committee (CHMP) considered that the benefits of aztreonam-avibactam outweigh its risks for patients with infections caused by Gram-negative bacteria when they have few or no therapeutic options to fight the disease. Aztreonam has been shown tobe effective at treating a range of serious infections. Microbiology data indicate that aztreonam in combination with avibactam is effective in infections caused by many multidrug-resistant aerobic Gram-negative pathogens and the combination could therefore address an unmet medical need.

Aztreonam-avibactam was evaluated under EMA's accelerated assessment mechanism because it is considered to be of major public health interest. MA's recommendation is based on the safety and efficacy data already available for each active substance and the results of two phase III randomized studies submitted by the applicant. The studies were not designed to demonstrate efficacy but do provide safety and complementary data for the combination. This is in line with EMA's guideline that allows for a flexible approach in the development of new antibiotics for human use targeting multidrug- resistant pathogens for which new treatments are needed.

The most frequent side effects in patients treated with Aztreonam-avibactam were a decrease in the number of red blood cells, elevated levels of liver transaminase and diarrhoea. This is in line with the documented safety information available for each individual substance.

Source:Ema.europa.eu/medicines/human/

Niapelfas antipsychotic is onboard

What is Niapelf?

Niapelf is an antipsychotic medicine used for the maintenance treatment of schizophrenia in adults whose disease has already been stabilised on treatment with paliperidone or risperidone. Niapelf contains the active substance paliperidone.

How is Niapelf used?

Niapelf is available as a prolonged-release suspension for injection in prefilled syringes. Treatment with Niapelf starts with two injections, given one week apart, followed by monthly maintenance injections. For more information about using Niapelf, see the package leaflet or contact your doctor or pharmacist.

How does Niapelf works?

The active substance in Niapelf, paliperidone, is an active metabolite of risperidone. In the brain, paliperidone attaches to several different receptors on nerve cells. This disrupts signals transmitted between brain cells by neurotransmitters, chemicals that allow nerve cells to communicate with each other. Paliperidone acts mainly by blocking receptors for the neurotransmitters dopamine and 5-hydroxytryptamine (also called serotonin). By blocking these receptors, paliperidone helps to normalise the activity of the brain and reduce symptoms of the disease.

Niapelf is contraindicated to hypersensitivity to the active substance to risperidone or to any of the excipients. Paliperidone should not be used to manage acutely agitated or severely psychotic states when immediate symptom control is warranted. Furthermore, the adverse drug reactions (ADRs) most frequently reported are insomnia, headache, anxiety, upper respiratory tract infection, injection site reaction, parkinsonism, weight increased, akathisia, agitation, sedation/ somnolence, nausea, constipation, dizziness, musculoskeletal pain, tachycardia, tremor, abdominal pain, vomiting, diarrhoea, fatigue, and

The Ethiopian Food and Drug authority has approved a new malaria vaccine

Malaria is a leading cause of morbidity and mortality worldwide and is one of the most important public health issues in Ethiopia. Furthermore, around 75% of the landmass in Ethiopia is estimated to be malarious, and 68% of the total population in the area is at risk of malaria.

Children are particularly vulnerable; nearly half a million African children die from malaria every year. According to a report from the Ethiopian Ministry of Health, malaria is the top ten leading causes of morbidity. Plasmodium falciparum is malaria species which accounts for 60%-70% of malaria cases, with the rest caused by P. vivax.

The World Health Organization (WHO) has recommended a new vaccine, R21/Matrix-M, for the prevention of malaria in childrenand prequalified for use by October 2023. The R21 vaccine is the second malaria vaccine recommended by WHO, following the RTS,S/AS01 vaccine,which received a WHO recommendation in 2021. Both vaccines are shown to be safe and effective in preventing malaria in children and, when implemented broadly, are expected to have high public health impact.

The new vaccine, (R21/Matrix-M™), demonstrated promising efficacy which accounts around 75% especially in younger age groups, and correlated with specific antibody responses. Considering the recommendation given by WHO and rigorousevaluation of the safety, efficacy and quality profileof the R21 vaccine, the EFDA approved and granted Market Authorization for use in Ethiopia.

EFDA OBJECTIVES

To protect and promote public health through realization of the following objectives:

- Protect the public from unsafe food
- Safeguard the public from falsified, substandard and ineffective health products
- Protect the public from tobacco and alcohol related health risks
- Attain public confidence on food and health product regulation

STRATEGIC DIRECTIONS

- Strengthen food safety regulation.
- Strengthen detection, prevention and response to food adulteration and illegal trade
- Improve regulation of safety, effi cacy, quality and proper use of medicines
- Strengthen safety, quality and performance regulation of medical devices
- Improve regulation of safety of cosmetic products
- Strengthen tobacco and alcohol control system
- Enhance public ownership
- Improve efficiency and effectiveness
- Enhance partnership and collaboration
- Enhance good governance
- Improve human resource development and Management
- Improve evidence-based decision making
- Strengthen Food and health products regulatory infrastructures
- Improve quality management system
- Improve formulation and implementation of legal framework.

Optimizing prophylactic antibiotic use among surgery patients in Ethiopian hospitals

An abstract taken from Journal of Infection and Public Health Volume 16, Supplement 1, December 2023, Pages 82- 89 (Getachew Alemkere , Hailu Tadeg, Workineh Getahun , Wendosen Shewarega , Asrat Agal, Mohan P. Joshi , Niranjan Konduri)

Background: Since 2018, the Ethiopian Ministry of Health (MOH) has been working to institutionalize antimicrobial stewardship (AMS) programs across the country. The objective of this paper was to evaluate the effect of a quality improvement intervention to optimize the use of antimicrobials for surgical prophylaxis.

Methods

Basic AMS interventions were introduced in five hospitals from January to May 2023. The AMS committees and multidisciplinary teams working at the surgical wards were trained and provided on-site support to implement surgical antibiotic prophylaxis (SAP) interventions. A before-after comparison was made for 206 medical records at baseline and 213 during the intervention phase. Qualitative data were gathered through discussions during experience-sharing workshops to supplement the quantitative results.

Results

There were improvements in the presurgery dose of the prophylactic antibiotic and its timing: the doses within the recommended range increased from
11.2 % to 61.0 % ($p < 0.001$) and the optimal timing increased from 68 % to 82.6 % ($p < 0.001$). The hospitals also demonstrated some non significant improvement in the duration of prophylactic antibiotic use (from 35 % to 44.6 % [$p = 0.106$]), with change in practice hampered by practitioners' resistance to early discontinuation for fear of infection due to perceived weaknesses in infection prevention and control practices. No availability of the recommended antibiotic of choice for surgical prophylaxis was another major challenge in addressing all the elements of SAP. The intervention demonstrated a significant antibiotic- related average cost saving, 51.8 Ethiopian Birr (1 USdollar) per patient($p = 0.028$).

Conclusion

Short-term investments with basic AMS interventions can help to improve SAP use in surgical wards. However, comprehensive success requires complementing AMS interventions with concurrent attention to proper supply chain and infection prevention and control.

EFDA laboratory accreditation

ANAB
ANSI National Accreditation Board

CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Medicine Quality Control Directorate (MQCD) of the Ethiopian Food and Drug Authority (EFDA)

Kirkos Sub-City, Kebele 02/03, House Number 03, African Avenue (Bole Road) Street, PO Box 5681 Addis, Ababa, Ethiopia

Fulfills the requirements of

ISO/IEC 17025:2017

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document. The current scope of accreditation can be verified at www.anab.org.

ANAB
ANSI National Accreditation Board

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Medicine Quality Control Directorate (MQCD) of the Ethiopian Food and Drug Authority (EFDA)

Kirkos Sub-City, Kebele 02/03, House Number 03, African Avenue (Bole Road) Street PO Box 5681, Addis Ababa, Ethiopia

Seyoum/Wolde +251118592203/ +251115524122
cwolde@efda.gov.et www.efda.gov.et

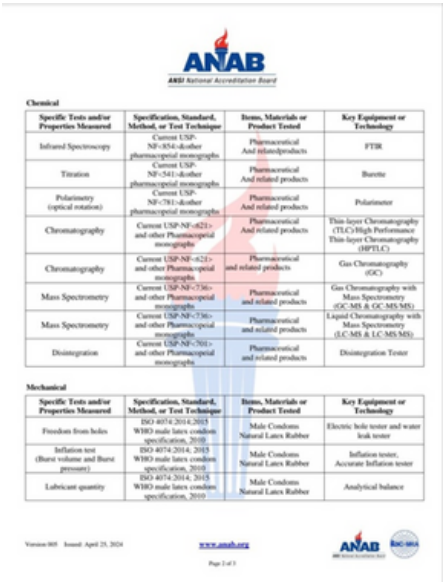
TESTING

Valid to: June 4, 2025 Certificate Number: AT-2680

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Chromatograph y HPLC	Current USP-NF<621> and other pharmacopeial monographs	Pharmaceutical and related products	HPLC
Spectrophotometry	Current USP-NF<851> and other pharmacopeial monographs	Pharmaceutical and related products	UV/VIS Spectrophotometer
pH	Current USP-NF<791> and pharmacopeial monographs	Pharmaceutical and related products	pH Meter
Dissolution	Current USP-NF<711> and other pharmacopeial monographs	Pharmaceutical and related products	Spectrophotometer, HPLC, Dissolution System, Analytical Balances
LOD	Current USP-NF<731> and pharmacopeial monographs	Pharmaceutical and related products	Ovens, Analytical Balances
KF	Current USP-NF<921> and pharmacopeial monographs	Pharmaceutical and related products	Titrators, Analytical Balances
Uniformity of Dosage Units	Current USP-NF<905> and pharmacopeial monographs	Pharmaceutical and related products	Spectrophotometer, HPLC, Analytical Balances
Conductivity	Current USP-NF<645>& other pharmacopeial monographs	Water	Conductivity Meter

Version 005 Issued: April 25, 2024 www.anab.org Page 1 of 3



ANAB
ANSI National Accreditation Board

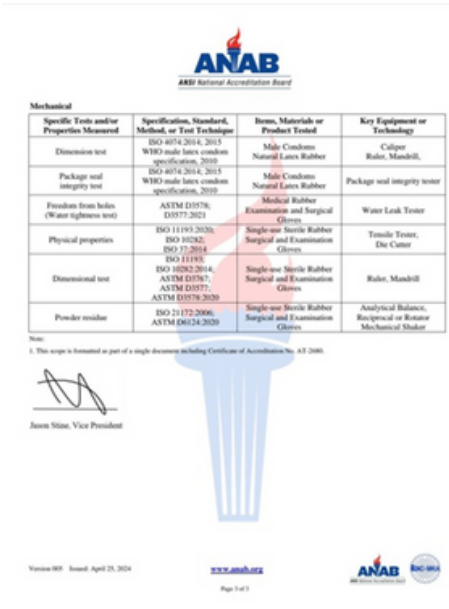
Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Infrared Spectroscopy	Current USP-NF<854>&other pharmacopeial monographs	Pharmaceutical And relatedproducts	FTIR
Titration	Current USP-NF<541>&other pharmacopeial monographs	Pharmaceutical And related products	Burette
Polarimetry (optical rotation)	Current USP-NF<781>&other pharmacopeial monographs	Pharmaceutical And related products	Polarimeter
Chromatography	Current USP-NF<621> and other Pharmacopeial monographs	Pharmaceutical And related products	Thin-layer Chromatography (TLC)/High Performance Thin-layer Chromatography (HPTLC)
Chromatography	Current USP-NF<621> and other Pharmacopeial monographs	Pharmaceutical and related products	Gas Chromatography (GC)
Mass Spectrometry	Current USP-NF<736> and other Pharmacopeial monographs	Pharmaceutical and related products	Gas Chromatography with Mass Spectrometry (GC-MS & GC-MS/MS)
Mass Spectrometry	Current USP-NF<736> and other Pharmacopeial monographs	Pharmaceutical and related products	Liquid Chromatography with Mass Spectrometry (LC-MS & LC-MS/MS)
Disintegration	Current USP-NF<701> and other Pharmacopeial monographs	Pharmaceutical and related products	Disintegration Tester

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Freedom from holes	ISO 4074:2014:2015 WHO male latex condom specification, 2010	Male Condoms Natural Latex Rubber	Electric hole tester and water leak tester
Inflation test (Burst volume and Burst pressure)	ISO 4074:2014, 2015 WHO male latex condom specification, 2010	Male Condoms Natural Latex Rubber	Inflation tester, Accurate Inflation tester
Lubricant quantity	ISO 4074:2014, 2015 WHO male latex condom specification, 2010	Male Condoms Natural Latex Rubber	Analytical balance

Version 005 Issued: April 25, 2024 www.anab.org Page 2 of 3



ANAB
ANSI National Accreditation Board

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Dimension test	ISO 4074:2014, 2015 WHO male latex condom specification, 2010	Male Condoms Natural Latex Rubber	Caliper Ruler, Mandrill,
Package seal integrity test	ISO 4074:2014, 2015 WHO male latex condom specification, 2010	Male Condoms Natural Latex Rubber	Package seal integrity tester
Freedom from holes (Water tightness test)	ASTM D3578; D3577:2021	Medical Rubber Examination and Surgical Gloves	Water Leak Tester
Physical properties	ISO 11193:2020; ISO 10282; ISO 37:2014	Single-use Sterile Rubber Surgical and Examination Gloves	Tensile Tester, Die Cutter
Dimensional test	ISO 11193; ISO 10282:2014; ASTM D3767; ASTM D3577; ASTM D3578:2020	Single-use Sterile Rubber Surgical and Examination Gloves	Ruler, Mandrill
Powder residue	ISO 21172:2006; ASTM D6124:2020	Single-use Sterile Rubber Surgical and Examination Gloves	Analytical Balance, Reciprocal or Rotator Mechanical Shaker

Note:
1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2680.

Jason Stine, Vice President

Version 005 Issued: April 25, 2024 www.anab.org Page 3 of 3

Current Updates

“Antimicrobial resistance (AMR) is Invisible, I am not”

The World AMR Awareness Week 2024 Campaign slogan for sharing real-life stories to encourage global action against antimicrobial resistance is "Antimicrobial resistance is invisible, but its victims are not." It emphasizes that while AMR itself is invisible, its consequences are not. This highlights the importance of raising awareness about AMR. Similar to COVID-19, drug-resistant infections have no borders and no single country or individual can fight AMR alone. Therefore, every nation needs to address the burden of AMR.

Understanding the consequences of AMR

Ethiopia has developed the third strategic plan for the period of 2021 – 2025 in one health approach to prevent and contain antimicrobial resistance, and to address this multifaceted problem. Its vision is to protect human, animal and plant populations and the environment from the health, socioeconomic and environmental consequences of AMR in Ethiopia. The mission is to reduce the negative impacts of antimicrobial resistance through the generation and utilization of evidence, awareness and education on the prudent use of anti-microbial and the promotion of sectoral, national and global alliance and collaboration.

The goal of the strategic plan is to ensure continuity of successful prevention, control and treatment of infectious diseases in the human, animal, plant and environment sectors through evidence-based prevention and containment of AMR following multi-sector collaboration through a one health approach.

The scope of the strategic plan covers improving awareness and understanding on AMR, preventing and controlling infections, strengthening the knowledge and evidence on antimicrobial resistance through surveillance and research, ensuring the prudent use of antimicrobials and the governance of antimicrobial resistance prevention and containment in human, animal and plant health care, food and feed production and the environment sectors at the national, regional and facility levels.

The national strategic plan responds to these requisites through the one health approach under the following five strategic objectives.

1.Improve awareness and understanding of antimicrobial resistance through effective behavior change communication, education and training. 2. Strengthen the knowledge and evidence on antimicrobial use and resistance through surveillance and research.

3.Enhance infection prevention and control through effective environmental health, infection prevention and bio-risk measures in human, animal and plant health.

4.Optimize the use of antimicrobials in human, animal and plant health care.

5.Strengthen and establish partnerships, alliances, governance and resource mobilization at all levels.

Regulatory Tips

EFDA is reforming and standardizing its regulatory system

Why regulation is important?

Simply, regulators are important to oversee the compliance of performance vis-à-vis the global or national standards. The mere existence of the national regulatory authorities (NRAs) is to effectively protecting the public health by assuring the safety, efficacy, quality and rational use of medicines, and other regulated by organizing itself under various functions and implementing Good Regulatory practices (GRP) .The WHO states the ultimate aim of GRP is to serve and protect public health and patients’ interests, with respect for all applicable ethical principles. GRP has nine principles:

1.Legality: Regulatory systems and the decisions that flow from them must have a sound legal basis

2.Consistency: Regulatory oversight of medical products should be consistent with existing government policies and legislation and be applied in a consistent and predictable manner.

3. .Independence: Institutions responsible for regulation of medical products should be independent

4. Impartiality: All regulated parties should be treated equitably, fairly and free from bias

5.Proportionality: Regulatory oversight and regulatory decisions should be proportional to the risk and to the regulator’s capacity to implement and enforce the decisions.

6.Flexibility: Regulatory oversight should be flexible in order to respond to a changing environment and unforeseen circumstances.

7. Clarity: Regulatory requirements should be accessible to and understood by users

8.Efficiency: Regulatory systems should achieve the intended results within the required time and at reasonable effort and cost

9. Transparency: Regulatory systems should be transparent; requirements and decisions should be made known, and input should be sought on regulatory proposals. While traditional governance and

EFMACA was a huge organization that brought challenge in effectively regulating all the products, premises, practices and professionals (4Ps)activities and gave birth for the current product focused regulatory authority named as Ethiopian Food and Drug Authority (EFDA). The basis for the establishment of EFDA was proclamation No 1263/2021 followed by Regulation No 531/2023.

EFDA at a glance

The EFDA is an autonomous regulatory body responsible for protecting and promoting public health by ensuring the compliance to the safety, effectiveness and quality profile of regulated products. The regulated products include food, medicine, medical devices, cosmetics, tobacco etc. EFDA also controls establishments associated in the production, importation, exportation, and distribution of these regulated products. The authority is led by a Director General three Deputy Director Generals. The EFDA is responsible for registration and marketing authorizations, Regulatory inspection and establishments licensing, quality control laboratory testing clinical trials, oversight Pharmacovigilancence, surveillance and market control and takes administrative measures against non-compliance. Currently the Authority has seven branches and 18 Ports of Entry (POE) across the country and works with regional and city administration regulatory bodies.

Achievements accomplished

The EFDA has got many notable achievements that need to be sustainedand enhanced serving as a springboard for future reform, some of these includes.

1.Well-defined legal and regulatory framework: the availability of science based laws, standards, guidelines and procedures.

2. Digitization of its regulatory systems

This helps to harness the technology advantage that save time, costs,, human errors and easy of doing bussince.

3. Obtaining and Maintaining Certifications and expansion food, medicine and medical device quality control laboratories and regulatory inspection functions.

3. Effort to attain maturity level 3 recognition from WHO: assessed and in a good track for achieving ML3.

4.Evidence generation and utilization:

various assessments have been made and evidences generated whereby the authority basis on studies to provide informed decisions.

5. Capacity building

The efforts could be categorized under three pillars

·System and Process: different system improvement initiatives are underway.

·Human Resources: efforts which help all experts are of highly competent to their respective positions that help both the customer and the public at large.

· Construction of premises: Construction of state of the art laboratory and office premises that will be serving as center of excellence is ongoing.

6. Maximizing results through utilization of principles such as:

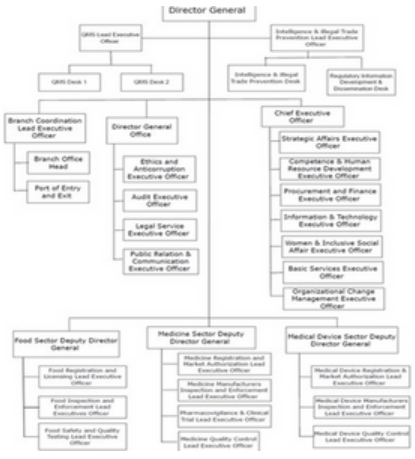
·Trust based

·Preventative approach, and

·Risk based principles. Details of this will be discussed in our next issue

These are among the many important achievements, still much is expected and efforts are underway for further success. EFDA is moving forward investing in different areas and with full commitment of the management and all employees paving the way to its destination of tomorrow, “Regulatory Excellence”.

The current organizational structure is presented below:



EFDA Values

· **Public First:** all possible efforts are to ensure the best interest of the public at large not for satisfying the interest of some groups or segments of the public and get contribution from the public in the notion of ensuring the health of the public is ensuring my health.

· **Integrity and respect:** being ethical, professional, objective, honesty and adhering to moral values.

· **Continuous improvement:** be able to be responsive and adapt policies, systems and processes.

·**Accountability:** taking full responsibility for our actions and outcomes.

· **Quality:** strive to deliver the best services to the customers with utmost professionalism and with no compromise on safety and quality of products.

· **Commitment:** uphold highest standards of conduct and commitments while acting in the best interest of the public.

· **Transparency:** operate in a fully transparent manner and communicate openly and timely with the public and relevant stakeholders.

· **Excellence:** demonstrate the highest standards of performance consistent with international standards and best practices; and achieve excellence in regulatory operations and public services through promoting research, innovation, continual learning and openness to change.

· **Teamwork:** having a united sense of purpose that all members believe to achieve the mission, support one another, work cooperatively and respect one another’s views.

News

EFDA Achieves Key Milestones in Medicine Regulation for 2016

During the 2016 budget year, the Ethiopian Food and Drug Authority (EFDA) achieved significant milestones in regulating medicines. The Authority successfully registered and granted market authorization for 776 new medicines. Additionally, it conducted pre-license inspections of 448 pharmaceutical import and distribution facilities, as well as small- scale manufacturing organizations, all of which met the necessary requirements.

Furthermore, 595 drug importers and distributors received new certificates of competence following inspections. The EFDA also performed risk-based auditing inspections on 12 domestic manufacturing facilities and 59 small-scale pharmaceutical manufacturing organizations. Moreover, 1,181 drug importers and distributors underwent risk-based audits to ensure compliance with regulations. The Authority also completed Good Manufacturing Practice inspections at 60 foreign pharmaceutical industries.

In the same period, medicines and medical devices worth More than 92 billion birr were imported into Ethiopia after passing essential quality control measures. Additionally, drugs and medical devices valued at 126.7 million birr were prevented from being imported and distributed due to non-compliance with relevant regulations.

These accomplishments underscore the EFDA's commitment to ensuring the safety, quality, and regulatory compliance of medicines and pharmaceutical products in Ethiopia.

Community Pharmacy Standards: a milestone to improve the future pharmacy services

The Ethiopian Food and Drug Authority (EFDA) and the Institute of Ethiopian Standards (IES) have announced the approval of a new national community pharmacy standard, developed in collaboration with regional regulatory bodies and relevant stakeholders. Community pharmacies have been regulated by regional regulatory bodies. Due to the absence of national standards, the regulatory environment of community pharmacies and the services rendered face overarching challenges.

The discrepancies in the regulatory environment create variations in the maturity of the regulatory system. To address this issue, the authority has initiated a national and uniform community pharmacy standard. The standards were approved by the Institute of Ethiopia Standards after consultations with various stakeholders.

The new standard aims to create harmonized and consistent regulatory activities across regional regulatory bodies, ensure consistency in the provision of pharmacy services across the country, promote rational use of medicines and prevent illegal infiltration of medicines into the market, ensure ethical practices in dispensing and compounding activities, increase regulatory maturity so as to ensure competition in the regulatory arena, and ensure a more equitable distribution of community pharmacy services across the country.

Furthermore, to facilitate the smooth implementation of the standards, the Authority has developed and distributed a comprehensive implementation guideline and provided training to regional regulatory bodies for its implementation.

Ethiopian Food and Drug Authority Alerts Public to Falsified Breast Cancer Medication

The Ethiopian Food and Drug Authority (EFDA) has issued a critical warning regarding a falsified version of the breast cancer medication, Herseptin 440 mg, which has been notified by the original manufacturer and other regulatory bodies of other countries.

Despite the legitimate registration of the company listed to distribute it's the productupon registration in Ethiopia, the EFDA has notified that there are falsified Herseptin
440 mg circulating in other countries. The fake medication features fraudulent identification details, including a false ID number (C05830083) and an incorrect batch number (H5170).

Manufactured in the United States, Herseptin is typically available in powder form for injection. However, this falsified variantis not authorized for import into Ethiopia and does not meet the required safety standards.

The EFDA stresses the importance of purchasing medical products only from authorized suppliers to ensure their authenticity and safety. They have urged the public, along with pharmaceutical importers, distributors, retailers, and healthcare providers, to exercise caution and verify the legitimacy of medical products before use.

In response to this issue,the EFDA has alerted relevant stakeholders and the public to be cautious and take actions against those involved in the illegal distribution of this medication. It also has intensified market surveillance efforts to safeguard public health.