

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.

OBJECTIVE

The objective of the Authority is to protect the public health by regulating food, medicine and medical devices, blood and blood products, traditional, complementary or alternative medicine, cosmetics, tobacco, quality control service provider, bioequivalence centers and other products and services entrusted to the Authority to regulate.



Contents

- Editorial
- Scientific information
- Current updates
- Regulatory Tips
- News

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Editorial

This is the first issue of the bulletin for the year 2025. 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.

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Thank you for helping us make our bulletin better!



Scientific Information

A self-administered Subcutaneous Depot Medroxyprogesterone Acetate has been introduced

Subcutaneous depot medroxyprogesterone acetate (DMPA-SC) is a progestin-only injectable contraceptive (104 mg/0.65 mL) administered every 12–14 weeks under the skin, subcutaneously. It is approved by the U.S. Food and Drug Administration (USFDA) and recommended by the world health organization for contraception and endometriosis pain management. Several studies consistently demonstrate that self-administered DMPA-SC is safe, effective, and associated with significantly higher continuation rates compared to healthcare provider-administered. Meanwhile DMPA-SC offers equivalent efficacy, safety, and adverse effect profiles compared to provider-administered DMPA, including generally mild injection site reactions, however it does require proper training to ensure correct self-administration and adherence to dosing schedules. Additionally, some users may encounter challenges related to storage, handling, or self-confidence in administering injections.

Self-administered DMPA-SC is included in the 7th edition of the Ethiopian essential medicine list. Additionally, the Ministry of Health (MOH) of Ethiopia has included in family planning guideline as one of the family planning products since 2024. This offers women greater control over their reproductive health, and can address logistical barriers to accessing healthcare.

- The MOH plans to pilot it in selected health facilities. In parallel, it is essential to create public awareness about the availability of DMPA-SC, self-administration technique, and its potential benefit in reducing costs, and frequent visit of health facilities. In conclusion, self-administered DMPA-SC could be a promising family health product for expanding access to contraceptives and autonomy of women.
- Sources
- 1. World Health Organization (WHO). WHO guideline on self-care interventions for health and well-being: sexual and reproductive health and rights. Geneva: WHO; 2022.
- 2. Centers for Disease Control and Prevention (CDC). U.S. Selected Practice Recommendations for Contraceptive Use, 2021. MMWR Recomm Rep. 2021;70(4):1–46.
- 3. Kennedy CE, Yeh PT, Gaffield ML, Brady M, Narasimhan M. Self-administration of injectable contraception: a systematic review and meta-analysis. *BMJ Glob Health*. 2019;4(2):e001350.
- 4. Burke HM, Chen M, Buluzi M, Fuchs R, Wevill S, Venkatasubramanian L, et al. Effect of self-administration versus provider-administered injection of subcutaneous depot medroxyprogesterone acetate on continuation rates in Malawi: a randomised controlled trial. *Lancet Glob Health*. 2018;6(5):e568–78.

New combination of medicine to treat parasitic worm infections

Soil-transmitted helminth infections (STH) are among the most common infections worldwide and according to estimates by the World Health Organization (WHO) they affect 1.5 billion people, approximately a quarter of the world's population. For lymphatic filariasis, the WHO estimated in 2023 that 657 million people in 39 countries were living in areas at risk, with 25 million men affected by hydrocele (scrotal swelling) and 15 million people with lymphoedema (swelling in body tissues).

Ivermectin / Albendazole is indicated for use in adults, adolescents and children 5 years or older, for the treatment of STH, caused by different types of intestinal parasitic worms, which are spread through soil contaminated by human faeces in areas with poor sanitation. Among the worms responsible for these diseases are hookworms (*Ancylostoma duodenale*, *Necator americanus*), roundworms (*Ascaris lumbricoides*), whipworms (*Trichuris trichiura*) and a roundworm called *Strongyloides stercoralis*.

Ivermectin/Albendazole is also indicated for the treatment of microfilaraemia (the presence of worm larvae in the blood) in patients with lymphatic filariasis (LF). The LF is a neglected tropical disease commonly known as elephantiasis, which impairs the lymphatic system and can lead to the abnormal enlargement of body parts, causing pain, severe disability and social stigma. Ivermectin/Albendazole is indicated for the treatment of cases of lymphatic filariasis caused by *Wuchereria bancrofti*, a parasite

which is responsible for 90% of cases worldwide.

Ivermectin /Albendazole is combination of two active substances: ivermectin and albendazole. Ivermectin is an antiparasitic agent used to treat a variety of infections, both in people and animals. Albendazole is also a broad spectrum antiparasitic used to treat several intestinal parasite infections.

When co-administered, ivermectin and albendazole act in synergy. Ivermectin targets the parasite's nervous and muscular systems, causing paralysis, while albendazole disrupts the parasite's metabolism and energy production. This dual approach immobilises and kills the parasite and improves effectiveness of the treatment.

The development of Ivermectin /Albendazole holds a high public health value as it will bring concrete advantages to the effectiveness of mass administration programmes in countries where these diseases are endemic. It will help reduce the risk of incorrect dosage, improve adherence, and reduce manufacturing and transport costs. Ultimately, this will allow more people to be treated.

The safety and efficacy of Ivermectin/Albendazole is mainly based on the results of a phase II/III randomised clinical trial including 1223 patients, which compared a single dose of the fixed dose combination (FDC) with a single dose of 400 mg of albendazole alone, as well as a 3-day FDC regimen with a single dose of 400 mg albendazole given alone for treatment of certain worms (e.g., whipworm, hookworm and roundworm).

The study demonstrated the superiority for both the FDC single dose and the 3-day FDC regimen in all subgroups for patients infected

with whipworm (except for co-infected patients treated with the FDC single dose). For hookworm infections the trial showed superiority for the 3-day FDC regimen compared to the albendazole-alone single-dose regimen. The efficacy of the treatment in filariasis is inferred based on the results of a study conducted in Mali and published in 2010.

The most common side effects with Ivermectin/Albendazole are headache, abdominal pain and elevated liver enzymes.

Source: EMA Website

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Factsheet

ANTIMICROBIAL RESISTANCE

STOPPING THE RISE OF SUPERBUGS
Antimicrobial resistance (AMR) is one of the biggest challenges we face in public health today. It threatens our ability to treat infections and can make common procedures much riskier. Understanding AMR is crucial for everyone, and here's a look at what it is, why it's a problem, its main drivers, and how we can prevent it.

HOW DO ANTIMICROBIALS WORK?
Antimicrobials work by entering harmful organisms and blocking their important functions. This can either kill the microbes or prevent them from multiplying. However, as we use these drugs, some microbes develop ways to resist them. This resistance can happen through several methods.

MAIN DRIVERS OF AMR
While AMR can be a natural evolutionary process, certain actions have accelerated it. The primary driver is the overuse of antimicrobials in both humans and animals. In many cases, antibiotics are prescribed for viral infections or not taken as directed, allowing resistance to develop.

WHAT ARE ANTIMICROBIALS?
Antimicrobials are substances that kill microbes or stop their growth. These include antibiotics, which target bacteria, as well as antiviral, antifungal, and antiparasitic agents. The use of antimicrobials goes back thousands of years, but modern antimicrobials began in the early 1900s with breakthrough like penicillin. They have changed the way we handle infections and have become essential in medicine.

THE CONSEQUENCES OF AMR
AMR leads to treatments becoming less effective, making infections harder to treat. Diseases that were once easy to manage can now require more expensive or prolonged treatment. Some might even become untreatable.

PREVENTING AMR
1. **Basic Awareness:** Education is vital. Understanding AMR helps everyone make informed choices.
2. **Strengthen Research:** More research is needed to track AMR and develop new treatments and vaccines.
3. **Reduce Infections:** Improve sanitation and hygiene, especially in healthcare settings. This includes promoting handwashing and safe food and water practices.
4. **Optimise Use:** Use antimicrobials wisely in both humans and animals. Implement stewardship programs to ensure appropriate usage.
5. **Invest in Solutions:** Increase funding for new medicines and diagnostics to ensure we have effective tools to fight infection.

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Conquering the Global Antimicrobial Use Report

Antimicrobial resistance (AMR) is a global health crisis driven by inappropriate antibiotic use and limited access to quality antimicrobials in low- and middle-income countries (LMICs). To tackle AMR the World Health Organization (WHO) launched the Global Antimicrobial Resistance and Use Surveillance System (GLASS) in 2015. This initiative aims to standardize the global collection, analysis, and sharing of data related to AMU. It promotes surveillance data to ensure rational antimicrobials use and equitable access, targeting 70% of global antibiotic use from WHO's AWARe Access group and robust national AMU surveillance by 2030. The key findings and implications of the 2022 GLASS-AMU report are summarized below:

Key Findings

• **Antibiotic Consumption:** Global use totaled 16.6 billion defined daily doses (DDDs), with a median of 18.3 DDDs/1,000 inhabitants/day (range: 6.3–67.7). South-East Asia, Eastern Mediterranean regions reported higher use; low-income countries showed lower use, indicating access gaps. Ethiopia's antibiotic use (10 DDD/1,000 inhabitants/day) is below the global median (18.3 DDD, range: 6.3–67.7), indicating limited access rather than optimal prescribing.

• **AWARe Classification:** The report indicated that disproportionate use of Watch antibiotics and underutilization of recommended Access first-line treatments. Access antibiotics comprised 52.7% of use, missing WHO's 60% (2023) and 70% (2030) targets. Watch antibiotics (45.3%) were overused, especially in LMICs, while Reserve antibiotic access was limited in resource-constrained settings. Ethiopia's Access

AMR Crisis: Insights from the 2022 GLASS-

antibiotic use was approximately 60%, meeting WHO's 2023 target (60%) but falling short of the 2030 goal (70%). Meanwhile Watch antibiotics (e.g., azithromycin, ciprofloxacin) comprised a significant portion (~38%), indicating overuse risks. Reserve antibiotic use was negligible, reflecting lack of access for those antibiotics.

• **WHO Essential Medicines List (EML):** essential antibiotics as listed in the EML accounted for 89% of use, but non-EML Watch and Reserve antibiotics were prevalent, suggesting misalignment with national EMLs.

• **Use Patterns:** Oral antibiotics, primarily amoxicillin and amoxicillin-clavulanate, accounted for 94.2% of overall consumption. High use of Watch group antibiotics (e.g., azithromycin) and parenteral antibiotics in some countries suggests overuse, while low use of recommended antibiotics (e.g., nitrofurantoin, cefazolin) points to access or guideline challenges. Notably, nitrofurantoin was underutilized in 25% of countries, and cefazolin was absent in nine countries.

To effectively combat AMR, the 2022 GLASS-AMU Report emphasizes several critical strategies. Expanding participation in the GLASS-AMU, particularly in LMICs, is essential to achieve the 2030 target. Promoting antimicrobial stewardship is equally vital, which involves increasing the use of Access antibiotics while reducing inappropriate prescribing of Watch antibiotics through enhanced education and adherence to evidence-based guidelines. Additionally, improving access to Reserve antibiotics for treating multidrug-resistant infections and addressing barriers to essential antibiotics, such as nitrofurantoin and cefazolin, is crucial to ensure effective treatment options are

available. In line with these recommendations, Ethiopia should adopt AWARe-guided prescribing in hospitals to prioritize Access antibiotics and minimize inappropriate Watch antibiotic use. Strengthening supply chains for Reserve antibiotics and scaling up multisectoral stewardship programs will optimize antibiotic use across healthcare facilities.

Source: World Health Organization. Global antimicrobial resistance and use surveillance system (GLASS) report 2022. World Health Organization; <https://www.who.int/publications/i/item/9789240062702>

The Future Center of Excellence Hub in Africa

About the center

The first quality control center for food, medicine, and medical devices in our nation will feature 257 quality inspection rooms, 400 spaces for parking, and a contemporary sewage disposal

The center will greatly benefit Ethiopia and East Africa and contribute to the Authority's goal of making Africa a center of excellence by realizing the vision set forth in the ten-year strategic plan.

The benefits of the center

- Self-sufficient and model center of Excellence that can serve as food and medicines quality assurance related research, training and testing services provider the country and the region (Africa)
- Motivated international investment flow in to the country
- Strong collaborative network among neighboring countries and meeting the future African medicine Agency (AMA) laboratory testing need.

The center's construction is nearing completion.

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our Social media



Current Updates

Mpox as a global and national threat

Mpox, formerly known as monkeypox, is a viral zoonotic disease caused by the mpox virus from the Orthopoxvirus genus. There are two types of the virus that causes mpox, clade I and clade II. Both types spread the same way and can be prevented using the same methods. It causes more severe symptoms, especially among children, pregnant women, and immunocompromised individuals. It represents a significant global and national public health challenge. In Ethiopia, proactive public health measures are being taken to monitor and contain the disease.

Transmission

Mpox spreads through close or intimate contact (e.g., face-to-face, skin-to-skin, mouth-to-mouth), respiratory droplets, or prolonged proximity or contact with contaminated objects (e.g.; clothing, bedding, or surfaces), bites or scratches from infected animals (especially rodents or primates). It can also transmit from pregnant woman to newborns during birth via contaminated objects in healthcare settings.

Symptoms

Symptoms usually begin 5–21 days after exposure and the illness lasts 2–4 weeks. Initial symptoms include fever, headache, muscle aches, and swollen lymph nodes. The disease could progress to a rash or skin lesions, which go through various stages (macules, papules, vesicles, pustules, scabs).

Preventions

· **Personal Hygiene:** Wash hands frequently with soap and water or use hand sanitizer to reduce the risk of transmission.

· **Avoiding Close Contact:** Avoiding close contact with infected individuals and animals. Refrain from face-to-face, skin-to-skin, or mouth-to-mouth contact, and avoid prolonged close contact, especially in healthcare settings or large gatherings where Mpox patients may be present.

· **Cleaning Contaminated Objects:** Regularly disinfect surfaces and objects that may have been touched by an infected person to prevent transmission.

· **Safe Handling of Animals:** Avoid bites, scratches, or contact with infected animals during activities like hunting, skinning, or cooking, and use protective measures when handling animal products.

· **Healthcare Precautions:** Healthcare workers should follow strict protocols to avoid exposure to Mpox patients

· **Getting vaccinated:** if you are at high risk or have been exposed to the virus.

Supportive therapy

· **Pain Management:** Use of over-the-counter medications like paracetamol or ibuprofen to relieve fever, headache, and muscle pain, ensuring appropriate dosing and monitoring for side effects.

· Hydration and Nutrition:

Encourage adequate fluid intake and a balanced diet to support the immune system and maintain strength during the 2–4-week recovery period.

· **Skin Care:** Keep lesions clean and dry to prevent secondary bacterial infections. Apply antiseptic ointments or dressings as advised, and avoid scratching to reduce scarring or complications.

· **Isolation:** Patients should isolate at home or in a healthcare facility until all lesions have crusted over, scabs have fallen off, and new skin has formed, typically 2–4 weeks, to prevent transmission.

Sources

· **World Health Organization (WHO). (2023).** Mpox (monkeypox).

Available at: <https://www.who.int/news-room/fact-sheets/detail/mpox>

· **Centers for Disease Control and Prevention (CDC). (2023).** Mpox: Symptoms, Transmission, Prevention, and Treatment.

Available at: <https://www.cdc.gov/poxvirus/mpox/index.html>

· **Ethiopian Public Health Institute (EPHI). (2023).** Mpox National Preparedness and Response Guidelines.[Note: Access may be restricted to internal or official sources. Check EPHI website or contact EPHI.]



Regulatory Tips

Common mistakes in medicine registration application submissions potentially leading to return or rejection in EFDA

Medicine registration is a process of ensuring quality, safety and efficacy of medicines through rigorous regulatory evaluation of dossiers for the purpose of marketing authorization of products to the Ethiopian healthcare market. The registration and marketing authorization process comprises good manufacturing practice (GMP) site inspection, dossier assessment and quality analysis of samples.

According to the Food and Medicine Administration Proclamation No. 1112/2019, Article 20 (1), “Any medicine and medical device shall not be manufactured, imported, exported, stored, distributed, transported, sold, hold, used, or transfer to any other person without registration and marketing authorization”. Applicants are required to get marketing authorization certificates of their products before marketing in Ethiopia.

According to Medicine Marketing Authorization Directive No. 963/2023, applicants may apply for marketing authorization and follow-up registration status through a local agent (i.e., legally authorized scientific/Representative Office, licensed medicine importer, or medicine regulatory consultancy offices). These local agents are responsible for submitting required documents as per the existing laws and guidelines via the EFDA's electronic regulatory information system (eRIS), processing

registration fees, and handling all correspondence with the Ethiopian Food and Drug Authority (EFDA).

The EFDA emphasizes that local agents must have strong technical competency, regulatory experience, and a thorough understanding of laws, guidelines and submission procedures. This is essential for effective policy implementation and meeting registration timelines. Unfortunately, applicants often make minor to major mistakes during submission, which can lead to the application being returned or rejected before scientific assessment begins—significantly delaying the registration timeline. Common mistakes made by local agents during application submission include:

1. Submission in Incorrect pathway: EFDA offers distinct submission pathways dedicated according to the product nature, risk profile, applicant profile and other criteria outlined as per the registration guidelines such as; Regular pathway, conditional approval pathway, SRA pathway, WHO prequalification pathway and low risk products registration pathway. Applicants are therefore required to understand the various pathways, their product type, risk category and eligibility to the pathways and use the right pathway to submit applications
2. Incorrect payment amount;

3. Registration service charges are outlined in the Rate of Service Fees for Food, Medicine, Health Professional and Health Institutions Registration and Licensing Council of Ministers Regulation No. 370/2015 and applicants are required to pay the right service fee amount for the service and upload the appropriate receipts in to the eRIS system during application. The system is recently updated in a way that one receipt is used only for one application submission. Therefore, agents need to understand that, it is not allowed to pay various payments in one receipt for multiple applications.

1. Filling incorrect information in the eRIS system; Agents commonly fill wrong information to very critical sections of eRIS which will appear in the final marketing authorization certificate and then will return for certificate amendment request usually after the feedback from the marketing authorization holder. Common mistakes include but not limited to missing “statement of similarity”, wrong “recommended storage condition”, manufacturing site address which sometimes exchanged with corporate address, etc
2. Submitting incomplete application; It is observed that sometimes applications with missing

sections in CTD, displacement of sections, blank attachments, etc. are also submitted. These incomplete submissions are commonly captured in the pre-screening stage and returned to the applicants, which may end up with significant waste of both the applicant and the authority time.

3. Fraud documents;

Submission of fraudulent documents purposefully to cheat or influence the decision of the authority in anyway will lead to rejection and potentially for other administrative measures both on applicant and local agents.

Overview of the new Community Pharmacy Standard in Ethiopia

The key benefits of standards include establishing a common language for measurement, reducing unethical practices, ensuring consistent service delivery, and enhancing consumer trust and confidence in services and products. In line with this, Ethiopia has issued a compulsory standard for community pharmacy services to ensure public safety and well-being. The pharmacy and drug shop requirements ensure the safety, efficacy, and quality of medicines and protecting public health. The requirements ensure that every community pharmacy, from urban centers to rural communities, adheres to a unified standard of operation, maintaining uniform excellence in pharmacy services across Ethiopia, regardless of location or establishment date. The Compulsory Ethiopian Standard for pharmacies (CES 363:2024) and drug shops (CES 362:2024) were developed under the coordination of the Institute of Ethiopian Standards (IES) with technical input from EFDA, Regional Regulatory Bodies and the TC 88, then endorsed by the National Standards Council. The requirements of CES 363:2024 and CES 362:2024 are legally binding and community pharmacies

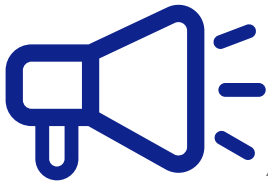
The standard is applicable to community pharmacies operating independently as private pharmacies and drug shops, Kenema pharmacies, Red Cross pharmacies, and Public Model pharmacies. In contrast, Hospital-based pharmacies within healthcare facilities are not covered under the standard.

The standard contains general and specific requirements and designed around the “4P”s - Practices, Professionals, Premises and products. The standard is developed based on global best practices and existing local experiences, incorporating the expanded roles of community pharmacies, including their public health functions. In summary, some of key importance of developing pharmacy and drug shop requirements are:

- Protect public health by ensuring the safety, quality, and efficacy of medicines
- Increase consumer trust and confidence in pharmacy services, and professionals
- Guarantee equitable and continuous timely access to medicines and pharmacy services to the public
- Enhance uniform and consistent regulatory operations across the country
- Improve regulatory maturity to ensure competition in the regulatory arena
- Minimize unethical and malpractices in pharmacy services including dispensing and compounding activities
- Promote rational use of medicines, containment of antimicrobial resistance, and minimize the infiltration of substandard and falsified medicines
- Ensure consistent service delivery in community

pharmacies throughout the country.





News

EFDA Achieves Major Milestones in Medicine Registration and Dossier Assessment

The Ethiopian Food and Drug Authority (EFDA) has announced two significant achievements in its ongoing efforts to improve access to essential and life-saving medicines across the country. Over the past nine months, the Authority successfully registered and granted market authorization for 421 new medicines, marking a major milestone in expanding the availability of safe and effective treatments. All approved products underwent rigorous regulatory reviews to ensure compliance with national standards for safety, efficacy, and quality.

In parallel, EFDA assessed more than 1,300 medicine dossiers during the same period as part of its nationwide backlog clearance campaign, a transformative initiative aimed at accelerating access to crucial medications. This campaign is a key component of EFDA's broader reform agenda, guided by Proclamation No. 1112/2019, which seeks to strengthen regulatory systems and ensure timely delivery of health interventions.

A cornerstone of this success has been EFDA's strategic collaboration with leading academic institutions, including Addis Ababa University and Jimma University. These partnerships led to the training and mobilization of over 74 dossier assessors, primarily drawn from public universities.

Their contribution has not only expedited medicine registration timelines but also enhanced national regulatory capacity and ownership.

This dual achievement has already had a significant impact, enabling faster access to treatments for serious public health challenges, including cancer and multidrug-resistant tuberculosis. EFDA's coordinated efforts reflect its unwavering commitment to public health and its determination to ensure that all Ethiopians benefit from prompt access to quality-assured medicines.

Through effective partnerships, local capacity building, and streamlined regulatory processes, EFDA is not only addressing the country's immediate health needs but also establishing a new benchmark for medicine regulation in the region.

EFDA Revises GMP Validity Period to Strengthen Regulatory Oversight

The Ethiopian Food and Drug Authority (EFDA), in accordance with its mandate under Proclamation No. 1112/2019, has introduced a revised regulatory directive aimed at enhancing oversight of pharmaceutical manufacturers and aligning with international standards. The Authority has officially replaced the previous Good Manufacturing Practice (GMP) Inspection

Procedure Directive No. 999/2024 with the newly issued Directive No. 1055/2025.

A key change in the new directive is the reduction of the GMP validity period from five years to three years, effectively increasing the frequency of re-inspections. This adjustment is designed to strengthen regulatory surveillance, improve the quality of pharmaceutical products, and ensure continuous compliance with GMP requirements.

As part of the implementation of this directive, EFDA is calling on all foreign pharmaceutical manufacturers to update their current Good Manufacturing Practice (cGMP) certificates and associated documentation to reflect the new validity period. Under Directive No. 1055/2025, the validity of fees paid for both GMP inspections and GMP waivers is now limited to three years from the date of receipt by the Authority.

Furthermore, pharmaceutical manufacturers who were previously issued a five-year cGMP compliance certificate based on physical inspection are now required to reapply for GMP inspection in line with the revised three-year validity period.

The EFDA urges all relevant stakeholders to comply with the updated requirements to ensure efficient application processing and avoid delays related to re-inspection timelines. The Authority

will soon issue individual notifications to applicants with affected certificates, instructing them to reapply under the new regulatory framework.

Through this updated directive, EFDA reinforces its commitment to strengthening regulatory systems and safeguarding public health by ensuring that all medicines produced for the Ethiopian market consistently meet the highest standards of quality, safety, and efficacy

EFDA Approved 421 New Medicines to Strengthen National Healthcare Access

EFDA has confirmed the importation of medicines and pharmaceutical inputs worth over 249 billion birr during the same period. This includes 245.8 billion birr worth of finished medicines, 2.4 billion birr in pharmaceutical raw materials, and 50.8 million birr in medicines procured through the New Procurement System (NPS). These imports play a critical role in meeting the country's healthcare demands and were approved following rigorous regulatory assessments.

In a related development, the Authority has taken decisive enforcement actions against more than 400 pharmaceutical businesses found in violation of regulatory requirements. Offenses included the sale of unregistered medicines, dispensing without valid licenses, and the illegal diversion of government-supplied drugs into the private sector. As a result, EFDA issued 227 warnings, 105 suspensions, 32 license cancellations, and 66 operational bans. The Authority reaffirmed its commitment to strict regulatory enforcement and ongoing inspections to ensure a safe, legal, and reliable pharmaceutical supply chain across Ethiopia.

EFDA
Ethiopian Food & Drug Authority

Streamline Your Medical and Food Product Approvals with EFDA's eRIS Platform!

- i-License**
Allows importers, exporters, wholesalers and manufacturers to apply for the certificate of competency and EFDA staff to manage these applications online.
- i-Register**
Allows importers to apply for and receive medicine registration certificate to import medicines online and EFDA staff to manage these applications online.
- i-Import**
Allows importers to apply for and receive permits to import medicines, medical devices and food online and EFDA staff to manage these applications online.
- i-Clearance**
Allows importers to apply for and receive port release applications of medicines, medical devices and food online and EFDA staff to manage these applications online.
- i-Inspect**
Allows EFDA to inspect importers, exporters, wholesalers, and manufacturers online using ODK collect as a supporting application.