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ETHIOPIAN FOOD & DRUG AUTHORITY

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MEDICINE INFORMATION BULLETIN

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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.

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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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Scientific Information

WHO Recommends Injectable Lenacapavir for HIV Prevention

Lenacapavir (LEN) is a long-acting injectable antiretroviral drug for HIV prevention that could reshape the HIV global response. It is the first Pre-exposure Prophylaxis (PrEP) option approved for a biannual dosing schedule. The World Health Organization (WHO) has issued global guidance recommending LEN as an additional PrEP option, complementing both daily oral PrEP and long-acting cabotegravir. LEN could be a transformative step forward in protecting people at risk of HIV, particularly those who face challenges with daily adherence, stigma, or access to healthcare.

In September 2025, Gilead Sciences, the originator company, entered into a voluntary licensing agreement to enable the production of affordable, quality-assured generic versions of LEN for more than 120 low- and middle-income countries by 2027. This comes less than two years after regulatory approval of Gilead's product in high-income countries, ensuring that LEN, like dolutegravir, will be within reach for millions who need it most in low-income settings.

LEN is a first-in-class HIV-1 capsid inhibitor that targets the viral capsid protein (p24) rather than the viral enzymes. By binding to the interface between capsid subunits, it interferes with multiple essential stages of the viral lifecycle, making it effective against drug-resistant strains. Two clinical trials have demonstrated good efficacy, about 100% efficacy, in preventing HIV infection with minimal side effects with high adherence compared with oral PrEP. These trials provide unequivocal evidence that LEN offers virtually complete protection against HIV infection when used as PrEP.

LEN is given as a 927 mg subcutaneous injection every six months. Patients must be confirmed HIV-negative before the first and each subsequent dose. The injection is administered by a trained health professional under aseptic conditions. Because the drug persists in the body for a long time, missed or delayed doses may increase the risk of HIV infection and resistance, making timely administration essential.
The benefit of LEN compared with other PrEP options is that, unlike daily oral PrEP, LEN requires only two injections per year, reducing the burden of daily pill-taking and potentially improving adherence. Compared with long-acting cabotegravir, which is administered every two months, LEN offers fewer clinic visits while maintaining comparable high efficacy (>99%) across diverse populations. Its prolonged dosing interval and discrete administration may also reduce stigma associated with daily medication use.

LEN is generally safe and well-tolerated including adolescent and young adults. It also safe and effective during pregnancy and breasting feeding based on the PURPOSE clinical trials. The most commonly reported adverse events are mild to moderate injection-site reactions (pain, redness, swelling) and transient systemic symptoms such as nausea, headache, or fatigue. Serious adverse events, including hypersensitivity reactions or injection-site abscesses, are rare.

WHO. It provides a convenient alternative alongside daily oral PrEP and the long-acting injectable cabotegravir.

References

1. World Health Organization. WHO recommends injectable LEN for HIV prevention. WHO; 2025. Available from: https://www.who.int/news/item/14-07-2025-who-recommends-injectable-lenacapavir-for-hiv-prevention World Health Organization
2. Das SR, Eshleman SH, Akello CA, Mgodi N, Billioux BJ, Wawer MJ, et al. Twice-yearly lenacapavir or daily emtricitabine–tenofovir alafenamide for HIV prevention (PURPOSE-1 trial). N Engl J Med. 2025;392(5):401–13. doi:10.1056/NEJMoa2407001
3. Landovitz RJ, Delany-Moretlwe S, Marrazzo JM, Schechter M, Beyrer C, Ogbuagu O, et al. Twice-yearly lenacapavir for HIV prevention in men and gender-diverse persons (PURPOSE-2 trial). N Engl J Med. 2025;392(7):689–702. doi:10.1056/NEJMoa2411858

A Step Forward in Paracetamol Overdose Regimen

Acetaminophen (paracetamol) overdose is a leading cause of drug-induced liver injury worldwide. Since the 1970s, intravenous N-acetylcysteine (NAC) has been the standard antidote to prevent hepatotoxicity, traditionally given a 3-bag infusion over 21 hours with a total dose of 300 mg/kg. This protocol is also recommended in the Ethiopian guidelines for poison information and control center. However, the U.S. FDA has recently suggested a lower dose of 200 mg/kg of NAC for the management of paracetamol overdose.

The 3-bag regimen is effective but prone to medication errors, treatment interruptions, and frequent non-allergic anaphylactic reactions (NAARs), which can limit its tolerability in clinical practice.

To address these limitations, simplified 2-bag regimens were developed to maintain efficacy while reducing errors and adverse reactions. Growing evidence supports these regimens, and the U.S. FDA has now approved a 2-bag regimen for patients weighing more than 40 kg.

The most studied 2-bag regimen involves a 20-hour infusion: 200 mg/kg of NAC over the first 4 hours, followed by 100 mg/kg over the next 16 hours. Research shows it offers a comparable protection against hepatotoxicity while significantly reducing the incidence of adverse events and a notable decrease in medication errors with the 2-bag regimen compared to the 3-bag protocol. Improved tolerability has also been noted in paediatric populations. Large multi-center studies report reduced hypersensitivity reactions and shorter delays in treatment. Shorter regimens, such as a 12-hour regimen (100 mg/kg over 2 hours followed by 200 mg/kg over 10 hours), show promising for low-risk patients, although more data are needed.

With the recent FDA approval of the 2-bag regimen for patients over 40 kg, clinicians are encouraged to continue using the traditional 3-bag protocol for those weighing 40 kg or less due to insufficient safety data on simplified regimen in smaller or special populations. In cases of significant overdose or early severe hepatotoxicity, the 3-bag regimen may still be appropriate despite the higher risk of NAARs.

Overall, the 2-bag NAC regimen is a simpler, safer alternative that can reduce errors and streamline care. While questions remain regarding optimal duration and use in specific groups, this approach represents meaningful progress and has strong potential to improve acetaminophen overdose management in Ethiopian clinical settings.

References

1. Alrashed M, Alyousef A, Badreldin HA, Bin Saleh K, Al Harbi S, Albekairy AM, et al. Comparison of three-bag method acetylcysteine versus two-bag method acetylcysteine for the treatment of acetaminophen toxicity: an updated systematic review and meta-analysis. Diseases. 2024;12(12):332. doi:10.3390/diseases12120332.
2. Glass KA, Stoecker ZR, LeRoy J, Palmer CL, Stipek J, Boley S. Investigating a novel two-bag N-acetylcysteine regimen for acetaminophen toxicity. J Med Toxicol. 2024;20:381-8. doi:10.1007/s13181-024-01010-3.
3. Tamur S, Alyahya B, Alsani F, Bahauddin AA, Aljaid M, Al-Malki S, et al. Two versus three infusion regimens of N-acetylcysteine for acetaminophen overdose. Pediatr Rep. 2024;16:232-42. doi:10.3390/pediatric16010020.
4. Thomas MC, Edwards CJ, Dunlap A. Practice patterns for N-acetylcysteine dosing for acetaminophen toxicity in the United States. Innov Pharm. 2025;15(4):10.24926/iip.v15i4.6459.
5. Nakatsu L, et al. Comparison of two-bag and three-bag acetylcysteine regimens in the treatment of paracetamol poisoning: a systematic review and meta-analysis. Clin Toxicol (Phila). 2025;63(3):155-165.
6. PR Newswire. FDA approves Acetadote sNDA. News release. December 9, 2024. Accessed December 10, 2024. https://www.prnewswire.com/news-releases/fda-approves-acetadote-snda-302326652.html
1. McGovern G. IV form of NAC receives FDA sNDA to prevent, lessen liver injury after ingesting toxic quantities of acetaminophen. Pharmacy Times. 2024 Dec 10. Available from: https://www.pharmacytimes.com/view/iv-form-of-nac-receives-fda-snda-to-prevent-lessen-liver-injury-after-ingesting-toxic-quantities-of-acetaminophen
2. Rumack BH. Acetylcysteine treatment of acetaminophen overdose: foundational and clinical development. Livers. 2025;5(2):20. doi:10.3390/livers5020020.
3. Isbister G, Chiew A, Buckley N, Downes M, Page C, Isoardi K. A non-inferiority randomised controlled trial of a shorter acetylcysteine regimen for paracetamol overdose: the SARPO trial. J Hepatol. 2025;83:881-7. doi:10.1016/j.jhep.2025.07.038.

4. Thomas MC, Edwards CJ, Dunlap A. Practice patterns for N-acetylcysteine dosing for acetaminophen toxicity in the United States. Innov Pharm. 2025;15(4):10.24926/iip.v15i4.6459.
5. Nakatsu L, et al. Comparison of two-bag and three-bag acetylcysteine regimens in the treatment of paracetamol poisoning: a systematic review and meta-analysis. Clin Toxicol (Phila). 2025;63(3):155-165.
6. PR Newswire. FDA approves Acetadote sNDA. News release. December 9, 2024. Accessed December 10, 2024. https://www.prnewswire.com/news-releases/fda-approves-acetadote-snda-302326652.html
7. McGovern G. IV form of NAC receives FDA sNDA to prevent, lessen liver injury after ingesting toxic quantities of acetaminophen. Pharmacy Times. 2024 Dec 10. Available from: https://www.pharmacytimes.com/view/iv-form-of-nac-receives-fda-snda-to-prevent-lessen-liver-injury-after-ingesting-toxic-quantities-of-acetaminophen
8. Rumack BH. Acetylcysteine treatment of acetaminophen overdose: foundational and clinical development. Livers. 2025;5(2):20. doi:10.3390/livers5020020.
9. Isbister G, Chiew A, Buckley N, Downes M, Page C, Isoardi K. A non-inferiority randomised controlled trial of a shorter acetylcysteine regimen for paracetamol overdose: the SARPO trial. J Hepatol. 2025;83:881-7. doi:10.1016/j.jhep.2025.07.038.
10. Cole JB, Oakland CL, Lee SC, Considine KA, Rudis MI, Swanson AL, et al. Is two better than three? A systematic review of two-bag intravenous N-acetylcysteine regimens for facetaminophen poisoning. West J Emerg Med. 2023 Nov;24(6):1131-42. doi:10.5811/westjem.62005.
11. Sudanagunta S, Camarena-Michel A, Pennington S, Leonard J, Hoyte C, Wang GS. Comparison of two-bag versus three-bag N-acetylcysteine regimens for pediatric acetaminophen toxicity. Ann Pharmacother. 2023 Jan;57(1):36-43. doi:10.1177/10600280221097700. Epub 2022 May 19.
12. Wong A, Isbister G, McNulty R, Isoardi K, Harris K, Chiew A, et al. Efficacy of a two-bag acetylcysteine regimen to treat paracetamol overdose (2NAC study). EClinicalMedicine. 2020;20: 100288.
13. .Federal Democratic Republic of Ethiopia, Ministry of Health. Guideline for Poison Information and Control Center. Addis Ababa: Emergency and Critical Care Directorate; 2017 May.

FDA Approved a New Non-Opioid Analgesic for Moderate-to-Severe Acute Pain Management.

On January 30, 2025, the U.S. FDA approved suzetrigine, the first non-opioid drug specifically indicated for moderate to severe acute pain in adults. This is the first new class of analgesic in over two decades and reflects the FDA's ongoing efforts to curb the opioid crisis by promoting safer pain management alternatives.

Suzetrigine works by selectively blocking the NaV1.8 sodium channel, a key mediator of pain signal transmission from peripheral nerves to the brain. By locking this channel in a closed state, it prevents sodium influx and interrupts pain transmission—without affecting the brain's opioid pathways, which significantly reduces the risk of addiction and common opioid-related side effects.

The effectiveness of Suzetrigine was demonstrated in two randomized, double-blind clinical trials involving abdominoplasty and bunionectomy patients. In both cases, suzetrigine significantly reduced pain compared to placebo. Though it is not approved for chronic pain, trials have shown some benefit in treating diabetic peripheral neuropathy compared to standard treatments. However, it does not completely replace opioids in cases of severe, intractable pain.

Suzetrigine is available as a 50 mg tablet and must be swallowed whole. The initial dose is 100 mg on an empty stomach, followed 12 hours later by 50 mg every 12 hours. Maintenance doses can be taken with or without food. It should not be taken with grapefruit, strong CYP3A inhibitors, or by patients with severe liver impairment. Women taking certain hormonal contraceptives should use alternative or additional non-hormonal methods during treatment and for 28 days after discontinuation.

Common side effects include itching (2.1%), muscle spasms (1.3%), elevated creatine phosphokinase (1.1%), and rash (1.1%).

Source:

1. FDA. FDA Approves Novel Non-Opioid Treatment for Moderate to Severe Acute Pain. Accessed Feb 02, 2025.
2. Osteen JD, Immani S, Tapley TL, et al. Pharmacology and Mechanism of Action of Suzetrigine, a Potent and Selective NaV1.8 Pain Signal Inhibitor for the Treatment of Moderate to Severe Pain. Pain Ther. 2025;14(2):655–674.
3. APHA. Pharmacy Library. Premier educational resource for pharmacy education. Vol 31, issue 5.
4. Evaluation of e cacy and safety of VX-548 for acute pain after an abdominoplasty. ClinicalTrials.gov. Updated August 27, 2024. Accessed February 21, 2025.
5. Evaluation of e cacy and safety of VX-548 for acute pain after a bunionectomy. ClinicalTrials.gov. Updated December 16, 2024. Accessed February 21, 2025.
6.Carrie Macmillan. FDA A. February 21, 2025.

Current Updates

The WHO Global Benchmarking Tool (GBT): A Game Changer and a Common Language for Measuring and Strengthening of Regulatory System.

The WHO Global Benchmarking Tool (GBT) is a standardized framework developed by World Health Organization (WHO) to assesses and strengthen the national regulatory systems for medical products, including medicines, vaccines, and medical devices. WHO began assessing regulatory systems in 1997 using a set of different, fragmented tools to measure regulatory capacity focusing on regulatory program for vaccines. Since that time, several revisions have been introduced and employed to assess regulatory systems.

The 67th World Health Assembly adopted WHA 67.20 resolution in May 2014, titled "Regulatory System Strengthening for Medical Products." It serves as a foundational global policy framework for improving national regulatory systems for medicines, vaccines, diagnostics, and medical devices. Consequently, the development of a unified, single and standardized tool called GBT introduced in 2018. The GBT replaced all tools previously used by WHO, representing the first truly "globally accepted" tool for benchmarking regulatory systems.
The tool and benchmarking methodology enable WHO and regulatory authorities to: identify areas of strength and areas for improvement; build on strengths and address gaps by formulating an institutional development plan (IDP); prioritize investments in IDP implementation; and monitor progress.

The GBT evaluates the overall regulatory framework and its core functions, namely: National Regulatory System (RS), Registration and Marketing authorization (MA), Vigilance (VL), Market Surveillance and Control (MC), Licensing of establishments (LI), Regulatory Inspections (RI), Laboratory testing (LT), Clinical Trials Oversight (CT). Each function has a series of indicators and sub-indicators that determine the extent to which the national regulatory authorities met the requirements. The tool covers more than 268 sub indicators and each sub-indicators are rated on a five-level scale as implemented, partially implemented, ongoing implementation, implemented and not applicable.
Based on the overall indicator ratings, the regulatory system is assigned one of the four maturity levels for the overall strength and functionality of the regulatory system as follows:

ML1: Some elements of a regulatory system exist – correspond to "No formal regulatory system in place".
ML2: Evolving system that partially performs essential regulatory functions
ML3: Stable, well-functioning, and integrated regulatory system
ML4: Advanced regulatory system with continuous improvement and innovation.
Reaching Maturity Level 3 under WHO GBT is a significant milestone for any national regulatory authority. It signifies a stable, functional, and integrated regulatory system capable of protecting public health in a sustainable manner by ensuring the safety, efficacy and quality of medical products. The benefits extend far beyond national borders, fostering public trust, stronger health systems, regional cooperation, economic implications, and global recognition.
References
1.WHO, Manual for benchmarking and Formulation of institutional development plans, 2023

Regulatory Tips

EFDA: Sustaining WHO Maturity level 3 (ML3) and next actions in realizing its vision

The World Health Organization (WHO) has recently recognized Ethiopia Food and Dug Authority (EFDA) for achieving Maturity Level 3 (ML3) in 8 (eight) different regulatory functions by end of September 2025. The functions evaluated in WHO maturity benchmarking include: the National regulatory system (RS), Registration and Marketing Authorization (MA), vigilance (safety monitoring), market surveillance and control (MC), licensing of establishments (LI), Regulatory inspection (RI), laboratory testing (LT) and clinical trials oversight (CT).

The WHO benchmarking of regulatory systems referred to in Resolution World Health assembly (WHA) 67.20 implies a structured and documented process by which Member States (MSs) can identify and address gaps with the goal of reaching a level of regulatory oversight commensurate with a stable, well-functioning and integrated regulatory system.

The use of the WHO global benchmarking tool (GBT) is the primary means by which WHO assesses regulatory systems for the regulation of medical products. The tool and benchmarking methodology enable WHO and regulatory authorities to identify areas of strength as well as areas for improvement; facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address identified gaps; to aid in the prioritization of investments in IDP implementation; and to help monitor progress.

The recent attainment of WHO Maturity Level 3 in medical product regulation marks a significant foundation for EFDA, positioning it for further success and propelling the authority closer and well aligned to its vision of becoming “a Center of excellence in food and health products regulation in Africa”. This achievement demonstrates Ethiopia's commitment to protecting public health, strengthening its national health system, and playing a leading role in setting regional regulatory standards.

As EFDA continues to build on this momentum, the Authority will continue actively working towards attaining vaccine Lot release (LR), one of EFDA’s immediate priorities. Establishing vaccine lot release capabilities is a vital function that ensures only safe, effective, and quality-assured vaccines are released into the national immunization program. This step will further boost public trust and strengthen the country’s ability to respond to vaccine-preventable diseases.

With ongoing capacity development, international partnerships, and policy reforms, the Authority is well on its way to realizing its vision.

The use of Paracetamol during Pregnancy remains unchanged: Regulatory Authorities

Paracetamol (acetaminophen) is the safest medicine recommended for the treatment of pain and fever during pregnancy. However, in recent years concerns have raised about potential neurodevelopmental risks, although evidence is inconclusive. Studies suggest that prenatal paracetamol exposure during pregnancy may be associated with neurodevelopmental conditions such as attention-deficit/hyperactivity disorder (ADHD) and autism spectrum disorder. However, regulatory bodies consensus and studies highlight key methodological limitations of the studies:

·Correlation is not causation: The studies only show a statistical association, not that paracetamol causes these conditions.

·Confounded findings: The underlying reasons for taking paracetamol (e.g., viral infection, high fever, inflammation, or chronic pain) are themselves known risk factors for adverse neurodevelopmental outcomes. Thus, the findings could be confounded by those factors that contribute to disorders. For instance, a study published in 2022 by Ahlqvist et al., found no evidence of a causal relationship between maternal paracetamol use during pregnancy and a child's risk of autism, ADHD, or intellectual disability in sibling control analyses. The associations observed in other models may have been attributable to confounding.
·Lack of high-quality data: Many studies rely on retrospective self-reporting, subject to recall bias, and lack precise information on dosage, frequency, and timing of paracetamol use.

Recently, in support of this, regulatory authorities globally, including the UK Medicines and Healthcare products Regulatory Agency (MHRA), the European Medicines Agency (EMA), and the US FDA, consistently reaffirm that the available evidence does not justify changes in clinical practice as strong evidence between paracetamol and neurodevelopmental disorders is lacking. As such, they continue to recommend paracetamol as the safest and most effective analgesic and antipyretic during pregnancy by balancing risk-benefit. Unless high-grade fever is treated with paracetamol, maternal fever can increase the risk of miscarriage, preterm birth, and congenital anomalies.

While untreated pain may contribute to maternal hypertension and psychological stress, adversely affecting fetal outcomes. Thus, balancing risk-benefit is the most important thing considered to use paracetamol during pregnancy. In line with this, regulatory authorities recommended that all pregnant mothers should follow the universal principle for all medications during pregnancy that take the medication at the lowest effective dose, for the shortest duration possible, and only when medically indicated.

In conclusion, paracetamol remains globally endorsed as the preferred treatment for pain and fever in pregnancy despite the controversies continue. In general, medication use during pregnancy should be avoided if not necessary. If paracetamol need for pregnant women, it should be taken in consultation with health professionals.

References

1. Medicines and Healthcare products Regulatory Agency (MHRA). Paracetamol and pregnancy: reminder that taking paracetamol during pregnancy remains safe. Drug Safety Update. London: GOV.UK; 2025. Available from: https://www.gov.uk/drug-safety-update/paracetamol-and-pregnancy-reminder-that-taking-paracetamol-during-pregnancy-remains-safe
2. European Medicines Agency (EMA). Use of paracetamol during pregnancy unchanged in the EU. Amsterdam: EMA; 2025. Available from: https://www.ema.europa.eu/en/news/use-paracetamol-during-pregnancy-unchanged-eu
3. MHRA. MHRA confirms taking paracetamol during pregnancy remains safe and there is no evidence it causes autism in children. London: GOV.UK; 2025. Available from: https://www.gov.uk/government/news/mhra-confirms-taking-paracetamol-during-pregnancy-remains-safe-and-there-is-no-evidence-it-causes-autism-in-children
2. Ahlqvist VH, Liu X, Sjölander A, Chang Z, Larsson H, Almqvist C, et al. Association of prenatal exposure to acetaminophen with risk of autism spectrum disorder, attention-deficit/hyperactivity disorder, and intellectual disability. JAMA. 2022;327(19):1812-20.
3. Acetaminophen in pregnancy and attention-deficit and hyperactivity disorder and autism spectrum disorder. Obstet Gynecol. 2025;145(5):916-8. Available from:https://journals.lww.com/greenjournal/fulltext/2025/05000/acetaminophen_in_pregnancy_and_attention_deficit.16.aspx

News

The World Health Organization Announces Ethiopia's Landmark Achievement in Medicines Regulation

The World Health Organization (WHO) announced on October 2, 2025, that Ethiopia has been recognized for reaching Maturity Level 3 (ML3) in medicines regulation. This achievement places Ethiopia among only nine African countries that have attained this status in WHO's classification of national regulatory authorities.

This milestone reflects the Ethiopian Food and Drug Authority's (EFDA) strong commitment to protecting public health by ensuring that medicines and imported vaccines meet international standards of quality, safety, and effectiveness. The designation follows a thorough WHO assessment using the Global Benchmarking Tool (GBT), which evaluates regulatory systems based on more than 250 indicators.

According to WHO, Maturity Level 3 signifies a stable and well-functioning regulatory system. At this level, a country can effectively authorize medical products, conduct market surveillance, and monitor safety events. The highest level, ML4, represents an advanced regulatory system that emphasizes continuous improvement.

Ethiopia now joins Egypt, Ghana, Nigeria, South Africa, Tanzania, Zimbabwe, Senegal, and Rwanda in reaching this important milestone.
WHO Regional Director for Africa, Dr. Mohamed Yakub Janabi, praised Ethiopia's achievement, describing it as "a landmark moment not only for the country but for Africa as a whole." He emphasized that a strong regulatory system builds public trust in the safety and effectiveness of medicines, laying the foundation for universal health coverage.

The benchmarking assessment, completed in September 2025, was supported by the WHO Regional Office for Africa and the WHO Country Office in Addis Ababa.

"Effective regulation saves lives," stated Dr. Yukiko Nakatani, WHO Assistant Director-General for Health Systems, Access and Data. She commended Ethiopia's leadership and commitment to protecting its people while helping to improve access to quality medical products both regionally and globally.

This achievement is not only a national success but also a model for the region. It demonstrates that with sustained policy reform, strong leadership, and digital transformation, African countries can build robust regulatory systems to ensure all communities have access to safe and high-quality medical products.

News

Global Organizations Applaud Ethiopia's Achievement of WHO Maturity Level 3

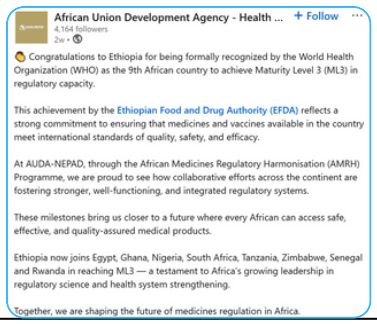
Following WHO's announcement of Ethiopia's attainment of Maturity Level 3 in medicines regulation, several global organizations extended their congratulations. The Africa CDC, AUDA-NEPAD, IGAD, UNICEF, USAID, and the Bill & Melinda Gates Foundation, among others, celebrated the achievement, describing it as a significant milestone toward strengthening regulatory structures, protecting public health, and improving access to quality and effective medicines across the continent.

WHO Director-General, Dr. Tedros Adhanom Ghebreyesus, applauded Ethiopia in an official post, stating:
"Congratulations, Ethiopia, for achieving Regulatory Maturity Level 3 in WHO's global classification of national regulatory authorities."

He noted that Ethiopia now joins Egypt, Ghana, Nigeria, South Africa, Tanzania, Zimbabwe, Senegal, and Rwanda in attaining ML3, adding that this achievement takes Africa a step closer to greater local production and access to quality-assured, safe medicines and medical commodities.

Dr. Jean Kaseya, Director-General of the Africa Centres for Disease Control and Prevention (Africa CDC), also congratulated Ethiopia, stating:
"I warmly congratulate Ethiopia on reaching WHO Maturity Level 3 for its medicines regulatory system. This strengthens regulation, safeguards public health, and advances us in our shared vision under Agenda 2063. Strong and stable regulators are essential to Africa's health security and the future of pharmaceutical manufacturing."

The African Union Development Agency (AUDA-NEPAD) echoed similar sentiments on its official LinkedIn page, congratulating Ethiopia on becoming the ninth African country to achieve ML3 status. AUDA-NEPAD highlighted that the achievement by EFDA demonstrates Ethiopia's strong commitment to ensuring that medicines and vaccines meet international standards of quality, safety, and efficacy.



Within its African Medicines Regulatory Harmonization (AMRH) Programme, AUDA-NEPAD underscored the importance of continental collaboration in building strong, high-performing, and integrated regulatory systems, stating:
"Together, we are shaping the future of medicines regulation in Africa."
Ethiopia's accomplishment marks a significant stride toward improving Africa's regulatory governance, strengthening public health, and ensuring access to safe, effective, and quality-assured medical products across the continent.

News

Ethiopia Becomes the First Country in the Horn of Africa to Attain WHO Maturity Level 3

Ethiopia has become the first country in the Horn of Africa to achieve the World Health Organization's Maturity Level 3 (ML3) in medicine regulation. The Minister of Health, H.E. Dr. Mekdes Daba, announced the achievement, describing it as a turning point in the nation's public health system.

Dr. Mekdes stated that the attainment of ML3 places Ethiopia among countries with high-quality, stable, and well-integrated regulatory systems—ushering in a new era of regulatory excellence and safety. She added that the accomplishment goes beyond technical recognition; it represents a transformative leap toward ensuring that all medicines in Ethiopia meet the highest international standards of quality, safety, and efficacy.

According to the Minister, EFDA has demonstrated strong capacity to license medicines, regulate pharmaceutical imports, monitor vaccines, and conduct effective market surveillance and pharmacovigilance—all aligned with WHO's international standards.

Dr. Mekdes emphasized that Ethiopia's success holds both regional and continental significance. With ML3 status, Ethiopia becomes a leader in health product regulation in Africa, contributing to the continent's progress toward enhanced medicine and vaccine regulation. This achievement also supports universal health coverage by ensuring equitable access to essential medicines and vaccines and positions Ethiopia at the forefront of continental regulatory reform.

She further noted that the success aligns with Ethiopia's broader vision of building sustainable health systems through structural reform, digital innovation, and global collaboration. The recognition, she said, enhances public trust, strengthens national health security, and reinforces Ethiopia's leadership in global health.

News

Government Commitment, Legal Reforms, and Digital Solutions Behind Ethiopia's WHO ML3 Success, Says EFDA Director General Heran Gerba

Government commitment, strong leadership, legal reforms, and digital transformation were key drivers of Ethiopia's historic attainment of WHO Maturity Level 3 (ML3) in medicines regulation, said EFDA Director General, Heran Gerba.

At the heart of this transformation is the Electronic Regulatory Information System (eRIS)—an in-house developed comprehensive digital platform that has revolutionized EFDA's regulatory operations. "Digital systems have brought us this far to ML3," Heran stated, noting that eRIS integrates major processes such as licensing, registration, market authorization, inspection, and customs clearance into a single harmonized system. By replacing outdated paper-based procedures, EFDA has reduced delays, improved transparency, and enabled real-time tracking of medicines and medical devices.

With over 31,000 active users and tens of thousands of registered food, medicine, and medical device products, eRIS has strengthened digital oversight, enhanced regulatory efficiency, improved coordination between federal and regional bodies, and fostered public trust through transparent decision-making. It also supports faster information sharing and unified systems, positioning Ethiopia as a regional leader in digital health regulation.

Heran also highlighted Ethiopia's single-window electronic clearance system as another significant innovation, noting that such technologies serve as a model for other low- and middle-income countries seeking to modernize their regulatory systems.

Looking ahead, EFDA plans to expand eRIS with new functionalities to further strengthen market surveillance and support more robust, evidence-based decision-making. "Digital innovation will remain at the forefront of Ethiopia's regulatory excellence and competitiveness agenda," Heran affirmed.