

NEWSLETTER

EFDA



VOICE

**EFDA VISION**

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

EFDA MISSION

To protect and promote public health by ensuring the safety, effectiveness, quality and proper use of regulated products through licensing, inspection, registration, laboratory testing, post-marketing surveillance, community participation, and provision of up-to-date regulatory information.

EFDA OBJECTIVE

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

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

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

The World Health Organization (WHO) on 2 October 2025 reported that Ethiopia has been recognized for attaining Maturity Level 3 (ML3) in medicines regulation. This achievement places Ethiopia among only nine countries in Africa to achieve the level in WHO's tiering of national regulatory authorities.

This success showcases the Ethiopian Food and Drug Authority's (EFDA) relentless dedication to protecting public health through its guarantee that imported medicines and vaccines meet international standards of quality, safety, and performance. The accreditation was the outcome of a thorough WHO evaluation using the Global Benchmarking Tool (GBT), which compares regulatory systems against more than 250 benchmarks.

Maturity Level 3 is characterized by WHO as a performing and stable regulation system. In this case, a nation is very much capable of issuing license for medical products,

marketing surveillance, and following up safety events. The higher level is ML4, which is a regulation system that is recognized to constantly improve itself.

Ethiopia is now one among Egypt, Ghana, Nigeria, South Africa, Tanzania, Zimbabwe, Senegal, and Rwanda that have reached this great achievement.

WHO Regional Director for Africa, Dr. Mohamed Yakub Janabi, also hailed Ethiopia's achievement as "a landmark moment not only for the country but for Africa as a whole." He argued that an effective regulatory system builds public trust in the safety and efficacy of medicines, which opens the door to universal health coverage.

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

"Strong regulation saves lives," declared Dr. Yukiko Nakatani, WHO Assistant Director-General for Health Systems, Access and Data. She commended leadership in Ethiopia and its commitment towards protecting its people while working towards improving access to quality medical products at the regional and global levels.

This achievement is not only a national one but also a regional success story. It demonstrates that it is possible for African countries to build good regulatory systems that provide access to quality and safe medical products to all populations through continuous policy reform, visionary management, and digitalisation.

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

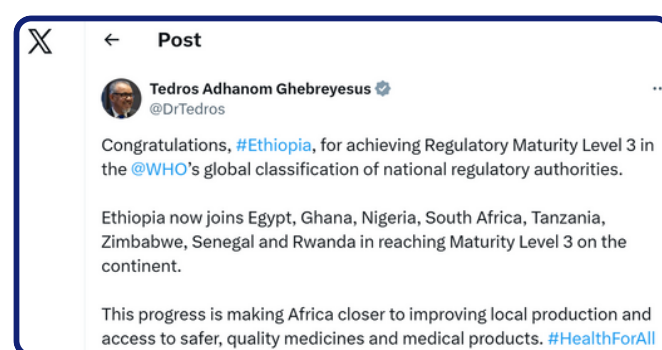
Following WHO's announcement that Ethiopia had achieved Maturity Level 3 in medicines regulation, multiple global institutions were quick to offer congratulations. Africa CDC, AUDA-NEPAD, IGAD, UNICEF, USAID, and the Bill & Melinda Gates Foundation, among others, also celebrated and referred to the milestone as a key milestone towards the strengthening of regulatory systems, public health, and increased access to good-quality and effective medicines across the continent.

WHO Director-General Dr. Tedros Adhanom Ghebreyesus congratulated Ethiopia in an official statement, stating:

"Celebrations, Ethiopia, for reaching Regulatory Maturity Level 3 in WHO's global ranking of national regulatory authorities."

He added that Ethiopia is after Egypt, Ghana, Nigeria, South Africa, Tanzania, Zimbabwe, Senegal, and Rwanda in attaining ML3, stating

that this achievement gets the continent 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 sent his congratulatory messages to Ethiopia when he stated:

"I warmly congratulate Ethiopia on reaching WHO Maturity Level 3 for its medicines regulatory system. This strengthens regulation, guards public health, and takes us closer to our joint vision under Agenda 2063.

Strong and stable regulators are central to Africa's health security and the future of pharmaceutical manufacture."



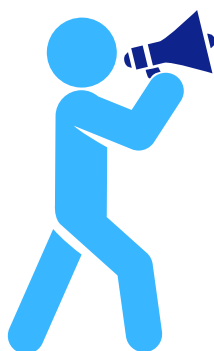
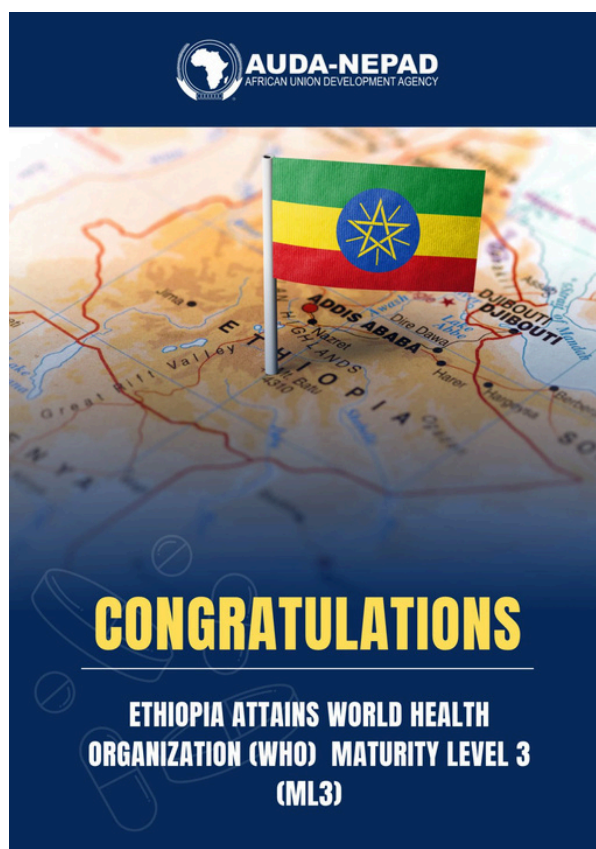
African Union Development Agency (AUDA-NEPAD) also said the same on their official LinkedIn page, congratulating Ethiopia for being the ninth African country to achieve the ML3 status. AUDA-NEPAD mentioned that the EFDA achievement is a demonstration of the highest level of commitment in Ethiopia to ensure that the vaccines and medicines are up to international standards of quality, safety, and efficacy.



AUDA-NEPAD prioritized continental collaboration within its African Medicines Regulatory Harmonization (AMRH) Programme with a focus on building strong, high-performing, and integrated regulatory systems by claiming:

"Together, we are shaping the future of medicines regulation in Africa."

Ethiopia's success marks a significant progress toward improving Africa's regulatory governance, improving public health, and facilitating access to safe, effective, and quality-assured medical products on the continent.



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



Ethiopia is the first in the Horn of Africa to attain the World Health Organization's Medicine Regulation Maturity Level 3 (ML3) level. The accomplishment was disclosed by Health Minister H.E. Dr. Mekdes Daba, who called it a milestone in the nation's public health system.

Dr. Mekdes announced that ML3 success places Ethiopia at the forefront of high-quality, stable, and well-integrated regulatory systems—a new generation of regulatory excellence and safety. She also added that the success goes beyond technical distinction; it is a leap forward to bringing all medicines in Ethiopia up to the highest global standards of quality, safety, and efficacy.

As informed by the Minister, EFDA has proved robust capability to license drugs, regulate drug imports, inspect vaccines, and carry out efficient market monitoring and pharmacovigilance—all according to WHO's global standards.

Dr. Mekdes emphasized that the success of Ethiopia is of continental and regional significance. Being an ML3 country, Ethiopia leads Africa in health product regulation, contributing to the continent towards better regulation of medicines and vaccines. This achievement further contributes to universal health coverage by enabling equitable access to essential medicines and vaccines and positions Ethiopia as the focal point of continental regulatory transformation.

She also averred that the accomplishment is a component of Ethiopia's larger vision of developing robust health systems by bringing about structural transformation, digital innovation, and global partnership. The recognition, she continued, increases public trust, improves national health security, and bolsters Ethiopian leadership globally in health.

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 digitalization were some of the key drivers of Ethiopia's historic attainment of WHO Maturity Level 3 (ML3) in medicines regulation, EFDA Director General, Heran Gerba, said.

At the heart of this transformation is the Electronic Regulatory Information System (eRIS)—a homegrown end-to-end digital system that has revolutionized EFDA's regulatory processes. "Digital systems have taken us this far to ML3," Heran remarked, noting that eRIS integrates essential processes such as licensing, registration, market authorization, inspection, and customs clearance into a single harmonized system. By replacing outdated paper-based systems, 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 regulation, regulatory efficiency, federal and regional coordination, and public trust through transparent decision-making.

It also enables faster information sharing and harmonized systems, positioning Ethiopia as a regional leader in digital health regulation.

Heran also highlighted Ethiopia's single-window electronic clearance system as a central innovation, stating that such technology is a model for other low- and middle-income countries seeking to modernize their regulatory frameworks.

Looking ahead, EFDA is planning to add more features to eRIS to continue to strengthen market surveillance and allow for more robust, evidence-based decision-making. "Digital innovation will remain at the heart of Ethiopia's regulatory excellence and competitiveness agenda," Heran assured.

The Authority held a recognition ceremony for various entities that contributed to achieving Maturity Level 3 in medicine regulation.



The Authority presented recognition awards to Lead Executive Officers (LEOs), Executive Officers (EOs), Regional Regulatory Authorities, Authority branches, individuals and institutions for their contributions in medicines regulation reaching WHO Maturity Level 3.

The ceremony, held on October 18, 2025, was honored with trophy and certificate presentation to the awardees by the Health Minister, Her Excellence Dr. Mekdes Daba, for their exceptional contribution.

At the ceremony, the Authority's Director General, Heran Gerba, was received a special award for her visionary leadership and tireless commitment to this historic milestone.

National Regulatory Bodies Hold Joint Steering Committee Meeting in Jigjiga



The Authority announced preparations were finalized to roll out a pharmaceutical traceability system intended to enhance the quality and safety of medicines. The system employs unique identification codes according to internationally acceptable standards for monitoring and control in the value chain for pharmaceuticals.

On 21 October 2025, the Authority held a consultative meeting with representative of foreign pharmaceutical companies with market authorization and MVC Global, a technology provider, to complete the launch of the new drug distribution and surveillance system.

In her opening remarks, Heran Gerba, the Authority Director General, emphasized that tracking imported medications with unique identification codes would boost supervision and drive regulatory oversight of the pharmaceutical industry supply chain significantly.

She also urged market-authorized producers to prepare for implementing the system, saying that the program is supported by national legislation. The system aims to avert counterfeit and substandard medicines and only permit products to pass on which have been verified to be of quality, safety, and effectiveness.

Besides, she instructed the technology provider, MVC Global, to offer capacity-building training to market-approved producers in order to allow the smooth uptake and operational application of the traceability technology.

The Authority's various officials and regional regulatory heads shared their remarks on the achievement of Maturity Level 3.



Heran Gerba,
Director General of the Authority

The announcement of the results overflowed hearts with great joy and deep feeling. It was more than a time of individual victory — it was a whole-scale celebration of us all coming together on one united vision for national growth. Although we might not all profit directly, we all worked for the greater good of our country. This process has truly stretched out and touched the hearts of many.

I realized that if people have a common vision, great things can be achieved. Words cannot even explain how joyful I was — it was so emotive that many people, including me, wept. I witnessed people striving their best for the country's progress with genuine commitment and enthusiasm in the progress of Ethiopia.

All the Authority leaders and staff relished this good news, and it has become a heart-felt reservoir of hope. Even though the medicine control system of Ethiopia still needs to continue developing, this achievement is a solid ground and sure sign that Ethiopia is moving towards reaching even higher levels in this field.



Bedelu Hailemariam
Oromiya region health bureau , health and health products quality control director.

We are very happy that we have successfully achieved Maturity Level 3. Because the above structure was a work that was carried out with great attention and coordination between the Ministry of Health, EFDA, and the regions, we are very happy to see that this work we have done has been effective.

I would like to congratulate the entire people of our country and our region on this occasion. The results achieved so far are encouraging for all of us, so let's continue the work we have been doing as a result, I believe that all the experiences we have gained in drug control and vaccination services have motivated the staff from top to bottom to continue and be effective, and we will continue to strengthen them.



Burriso Bulasho

Sidama region health bureau , health and health products quality control director.

I am very proud that our country Ethiopia has achieved Maturity Level 3 certification at an international level. This accomplishment attests that 2018 is a year of promise. I am highly happy that barely a day after the inauguration of the Renaissance Dam, which our own resources and experts built within 14 years, our country also achieved Maturity Level 3 status in drug control, ranking 9th on the African continent. This is to indicate that the structure of our nation's Food and Drug Control Authority is firm to its roots. This is due to the fact that it takes a lot of effort to set up a system that will be uniform in the drug control business across the globe. The result achieved in this regard is a huge success for our country, and we have expanded our country's drug control system to this extent. I am very proud and glad that our country has accomplished so much in the field of drug control. It is the result of all that we have accomplished. We were a bit disappointed at the help which we have received from the federal government, but I would like to say I am vastly pleased with progress to date. I would like to take this time to most sincerely thank the Federal Food and Drug Administration. We will keep working night and day to achieve Maturity Level 4.



Abayneh Alemayehu
CEO of the Authority

As a whole, the entire staff and management of the institution had been eagerly awaiting this World Health Organization Maturity Level 3, and we were all very happy to receive it, as it was a good result. It was a matter that we had been working hard on for a long time, and it was a part of our lives in various ways, so our joy was very high. In general, the entire staff in the sector I lead was motivated to do well because we created awareness and made them act with a sense of ownership from the beginning. Now, they are even more motivated. This is because we have seen that if we work day and night and work together, we can do more. The people who came to me, both individually and in groups, expressed their great joy. There is a lot of work ahead of us, especially for the work we are doing in the future, and the motivation to do the work well is very high. This is also visible and clear. It is visible in every employee. Overall, I would like to express that achieving WHO Maturity Level 3 has created a high sense of motivation for us as an institution, as individuals, and as a team.



Atlaw Abate
Medicine quality control laboratory
Executive officer

Above all, congratulations! We have worked hard to achieve WHO Maturity Level 3. I believe that the results we have achieved have been worth it. I am absolutely thrilled that we have been successful. As a country, we have been assured that our drug regulatory system is working well. So we are very happy. So as a country, it has many benefits. It has been expressed in various ways, so I am immensely pleased. Frankly, we have done a lot. There is system work, there is documentation work and specifically upgrading the laboratory level or upgrading the infrastructure, which was not a simple task. Our timeline was very compressed, as you may recall, and our lead auditor informed us that we had an impossible mission made possible, so that gives an idea of how overwhelming a task it was. During that time, there were many unexplained and long-term things we went through. But we succeeded. We've established a world-class laboratory.



Getu Bogale
Dire dawa Branch Head

Personally, I am extremely happy to see the completion of the last audit of Maturity Level 3, which has been attempted by our country and our institution for many years, being accomplished. It was a task which took an immense amount of effort and struggle from top to bottom, including regions, to be accomplished. I am extremely happy to see it accomplished. Because it was a branch office, all employees from top to bottom were giving their best in what we were worried. As a branch, I could observe all the employees were extremely relieved to see this successful and it was great. Becoming Maturity Level 3 is not our intention. As is known, attaining Maturity Level 3 will ensure the general public has access to medicine that have been established to be of good quality, safe, and effective. The work of the regulatory body will also be trustworthy. Additionally, it will ensure international partners believe in our country's regulatory system. In future, one of the tasks is to sustain this Maturity Level 3 by working hard.



Solomon Bishaw
Bahirdar Branch head

As citizens, as the Ethiopian Food and Drug Authority, and more so as Bahir Dar Food and Drug Administration, we are very much happy that Ethiopia has attained Maturity Level 3. It is a great milestone that shows to us that Ethiopia can compete at international level. So, we have seen the joy that we have experienced and the joy that individuals who have observed us are very much contented with us. Since not only the pharma sector was keeping us running, but also the food and administration sectors. With this achievement, we have reached Maturity Level 3 as a country, which brings many benefits, for example, in public health, it allows the public to access quality, safe, and effective medications. Because by developing a robust regulation system, we can eliminate the health problems caused by fake and lower-quality drugs from society. In this way, society will have confidence in the regulatory sector. If we take the importance of regulation into consideration, it will also increase international recognition and cooperation.

Another side, with regard to the economy, is that it will increase the number of local drug producers. That means it will improve our economy. Because it will save us hard currency by decreasing the quantity of imported drugs. It will also open the door for us to earn more hard currency by exporting drugs externally.



Fekadu Nimana
Hawassa Branch head

We are deeply pleased to have contributed, as a branch, to the achievement of Maturity Level 3. I would like to express that all our branch staff are truly delighted with this accomplishment. We also extend our heartfelt appreciation to the regional and federal organizations and reaffirm our commitment to actively play our part in future endeavors.



Semere G/Egziabher
Mekele Branch Head

Maturity Level 3 represents a milestone our country has reached through immense effort and dedication. Personally, I am at a loss for words to describe the joy of being part of this achievement. As a branch office, both the support staff and the management share an indescribable sense of pride and happiness in being connected to this success story.



Juhar Abegaz
kombolcha Branch

The joy felt by our branch staff — from the support team to every member involved — is beyond words, especially knowing we were part of this remarkable success. The entire branch team, along with our partners and stakeholders, share immense pride in this achievement. I would like to take this opportunity to reaffirm our commitment to continue this spirit of collaboration and dedication, striving together to achieve even greater accomplishments for the progress and success of our country.



We encourage you to connect with the Ethiopian Food and Drug Authority (EFDA) through our official social media channels for the most accurate and verified information:

LinkedIn: (<https://www.linkedin.com/company/ethiopian-food-and-drug-authority>) for insights into our regulatory initiatives and professional updates.

Facebook: (<https://www.facebook.com/share/18c8cP82gT/>) to receive current news, events, and information about our community outreach efforts.

Telegram: (<http://t.me/ethiopianfoodanddrugauthority>) for timely updates and important announcements regarding food and drug safety.

Please be advised that any information not disseminated through these official channels has not been verified by EFDA. We emphasize the importance of relying on our official communications to ensure the reliability and integrity of the information you receive. Together, let us promote public health and safety in Ethiopia effectively!