ZAMBIA MEDICINES REGULATORY AUTHORITY

ZAMRA NEWSLETTER

FOURTH QUARTER - 2025

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ZAMRA engages stakeholders on the draft **Medicines and Allied Substances Bill, 2025**

The Zambia Medicines Regulatory Authority (ZAMRA), on the 9th of October 2025 began the process aimed at aligning the Medicines and Allied Substances Act, No. 3 of 2013 to the African Union (AU) Model Law on Medical Products Regulation endorsed by African heads of States and government at the AU Summit held in Addis Ababa, Ethiopia in January 2016.

"The proposed provisions in the Bill, once enacted, will result in strengthening the legislative framework for purposes of attaining World Health Organisation (WHO) maturity level 3 (ML3) status, a global recognition of regulatory excellence, which is one of ZAMRA's highest strategic priorities."

Mr Siyanga also reiterated the critical role stakeholders play in protecting human and animal health, saying their recommendations are a vital requirement in the legislative process.

The stakeholder engagement took place at M'kango Cresta Golfview Hotel, Lusaka, from 9th to 10th October 2025.

AFRICAN MEDICINES AGENCY (AMA) HOSTS ZAMRA DELEGATION

ZAMRA is pleased to be the first National Medicines Regulatory Authority to officially pay a courtesy call on the African Medicines Agency (AMA) since its operationalization, reaffirming Zambia's commitment to regulatory harmonization and strengthened medicines regulation across Africa.

On Friday, 12th December 2025, the Director-General of the Zambia Medicines Regulatory Authority (ZAMRA), Mr. Makomani Siyanga, led a delegation to pay a courtesy call on Her Excellency, Dr. Delese Mimi Darko, the inaugural Director-General of the African Medicines Agency (AMA), at the AMA Headquarters in Kigali, Rwanda.

During the engagement, Mr. Siyanga informed Dr. Darko of the successful study visit to the Rwanda Food and Drug Administration (Rwanda FDA) by ZAMRA, aimed at drawing lessons to accelerate the Authority's journey towards attaining World Health Organisation (WHO) Maturity Level 3 (ML3).
Rwanda attained ML3 on 6th December 2024, a recognition of a stable and well-functioning national medicines regulatory system, conferred by the World Health Organisation, following a rigorous assessment using their Global Benchmarking Tool (GBT).

The ZAMRA Director-General expressed gratitude to the Ministry of Health (MOH) for its leadership and support and the WHO Country Office for sponsoring the study visit. He also acknowledged the Rwanda Cooperation Initiative (RCI) and the Rwanda FDA for their invaluable cooperation. Mr Siyanga further noted that the next phase will focus on implementing Institutional Development Plans (IDPs) in preparation for the formal benchmarking next year.

In her remarks, Dr. Darko outlined AMA's key continental priorities, which include strengthening the capacities of national medicines regulatory authorities, promoting local pharmaceutical manufacturing, and encouraging African Union (AU) Member States to ratify the African Medicines Agency Treaty. She emphasized that widespread ratification is critical to building confidence and ensuring that continental regulatory recommendations are effectively adopted and implemented at the national level.

WHO strengthens ZAMRA's effort to attain **Maturity Level 3 (ML3)**

Monday, 27th October 2025, was another momentous day, as the Zambia Medicines Regulatory Authority (ZAMRA) proudly welcomed a distinguished team from the World Health Organisation (WHO) Regulatory System Strengthening (RSS) programme.

Their visit marked the beginning of a pivotal self-assisted assessment using the WHO Global Benchmarking Tool (GBT), which ran from 27th to 31st October 2025. This collaboration is a significant step in ZAMRA's journey towards achieving WHO Maturity Level 3 recognition, a testament to our commitment to becoming a stable and reliable national regulatory authority.

The assessment is a crucial step as it demonstrates our pledge to:

1. Ensure quality, safety, and efficacy of medicines and allied substances in Zambia.
2. Open opportunities for the local pharmaceutical Manufacturing sector to a global market.
3. Inspire confidence in ZAMRA to provide oversight on complex regulatory requirements in the manufacturing of biologicals such as vaccines.

ZAMRA deeply values the support from WHO HQ, AFRO and Country Office in strengthening the Authority's regulatory systems for the health and well-being of all Zambians.

Enhancing capacity in oversight of sterile products

Zambia Medicines Regulatory Authority (ZAMRA) assessors completed two weeks of intensive training on the evaluation of sterile pharmaceutical products, which are classified as high-risk due to their direct impact on patient safety. Sterile products, such as injectable medicines, intravenous fluids, eye solutions, and certain surgical implants, are among the highest-risk medicines because they are delivered directly into the body.

Speaking during the closing session, ZAMRA Director-General, Mr Siyanga, expressed appreciation to the facilitator, Mr Nathaniel Nkrumah, for his expertise in delivering the training.

"The knowledge and skills imparted during this programme are critical to strengthening regulatory performance," said Mr Siyanga.

He added that such training programmes and partnerships with other regulatory authorities will continue to promote regulatory harmonisation, enhance dossier evaluation efficiency, and align with international best practices.

In his remarks, Mr Nkrumah highlighted that many African regulatory authorities face similar challenges in the regulation of sterile formulations. He emphasised the need for stronger inter-agency collaboration and knowledge sharing, commending ZAMRA for its active participation in regional initiatives that promote excellence in dossier evaluation.

The training, which commenced on 29th September and concluded on 10th October, marks another milestone in ZAMRA's ongoing efforts to strengthen regulatory systems and safeguard public health.

Local Pharmaceutical Manufacturers trained in product dossier preparation

In its continued effort to strengthen regulatory compliance, enhance efficiency in the approval of marketing authorisations, and ensure timely access to quality medicines and allied substances, the Zambia Medicines Regulatory Authority (ZAMRA) conducted a three-day training for local pharmaceutical manufacturers in product dossier preparation from 8th to 10th September 2025.

Speaking on behalf of the Director-General At the closing session, Mr Lyoko Nyambe, Director of Marketing Authorisation, expressed confidence that the participants were now better equipped to prepare comprehensive dossiers that align with regulatory standards, and that this would reduce the back-and-forth in the registration process, ultimately shortening turnaround time.

The workshop took place at the Mulungushi International Conference Centre in Lusaka

ZAMRA trains inspectors In pharmaceutical analysis of medicines using the GPHF-MINI® Test Kits

From 13th to 17th October 2025, ZAMRA conducted training for its staff in the field screening of medicines to ascertain their quality and to detect substandard and falsified medicines on the market using the GPHF-Minilabs®.

Field screening of medicines is crucial for ensuring public health, as it enables the real-time detection and removal of substandard and falsified medicines from the supply chain.

These tests, which can be visual, physical, or chemical, help regulatory authorities and partners identify poor-quality drugs in the field, thereby protecting patients from ineffective or harmful treatments.

Minilabs are a mobile laboratory technology used to perform basic quality screening of medicines, helping to identify and prevent the circulation of substandard and falsified (counterfeit) medicines.

This is especially important in low- and middle-income countries, where resources may be limited.

They decentralise drug quality testing, allowing for more rapid screening at points of entry and during post-marketing surveillance, without the need for a full-service quality control laboratory.

The staff trained are involved in Good Distribution Practices and were drawn from all regional and sub-regional offices of the Authority. Also trained were staff from the Churches Health Association of Zambia (CHAZ) to help them, as pharmaceutical supply chain actors, to effectively take responsibility and embrace practices that prevent the penetration of substandard and falsified medical products.

The training took place at Churches Health Association of Zambia (CHAZ) Office Complex.

ZAMRA National Drug Quality Control Laboratory (NDQCL) receives **technical support from WHO**

On Wednesday, October 22nd, 2025, the Authority, led by Director-General Mr. Makomani Siyanga, warmly welcomed the Technical Officer for Market Surveillance and Control under the Regulation and Safety Unit of the World Health Organisation (WHO), Ms Natércia Maria Guverra Simões.

Ms. Simões was in Zambia for a period of two days to provide technical assistance and follow up on the preparation of the National Drug Quality Control Laboratory of the Zambia Medicines Regulatory Authority (ZAMRA) is progressing towards attaining WHO Prequalification. Collaboration with WHO aims to enhance the laboratory's capabilities in assuring the quality, safety, and efficacy of medicines in Zambia.

We appreciate WHO's support in strengthening Zambia's regulatory systems for better public health outcomes.

ZAMRA disposes of 60,042 kg of forfeited medicines and allied substances

In its quest to ensure only quality, safe, and efficacious pharmaceutical products, the Zambia Medicines Regulatory Authority (ZAMRA) conducted, on 10th October 2025, the disposal of medicines and allied substances weighing sixty thousand forty-two kilograms (60,042 kg) belonging to Safina Pharmaceuticals Limited, which had been forfeited to the state.

The court forfeited all the seized medicines and allied substances to the state and ordered their disposal by ZAMRA in the presence of Senior Clerk of Court.

Awareness campaign in **Northern Province**

In the fourth quarter, ZAMRA extended its 2025 provincial awareness campaign to Kasama in Northern Province. The programme started with courtesy calls to our partners in ensuring quality, safe, and efficacious medicines and allied substances on the Zambian market. Offices visited included the Kasama Municipal Council, Police Headquarters, the Drug Enforcement Commission, the Zambia Revenue Authority, and the Competition and Consumer Protection Commission.

On 15th November 2025, the Authority held a stakeholder meeting in Kasama aimed at sharing information on regulatory processes, providing updates on the regulation of cosmetics, pharmacovigilance, and the Service Delivery Charter, and helping clients understand how to navigate the Integrated Regulatory Information Management System (IRIMS)

The ZAMRA team, which comprised Public Relations and ICT officers from the Headquarters in Lusaka, as well as inspectors from the Kasama office, also took advantage of this platform to obtain feedback from participants regarding our service delivery and encouraged them to remain compliant with established regulatory guidelines and requirements, including the payment of annual returns.

At the engagement, the Drug Enforcement Commission gave a presentation on money laundering and cautioned pharmaceutical players against engaging in such activities to safeguard their businesses.

The meeting, which attracted 35 participants from pharmaceutical businesses and ZAMRA partners, took place at Urban Hotel in Kasama, Northern

Strengthening health systems through collaboration

On 20 November 2025, we had the honour of hosting delegates from the 3rd Regional Advisory Committee (RAC) of the World Bank–financed Health Emergency Preparedness, Response and Resilience (HEPRR) Project at the Zambia Medicines Regulatory Authority (ZAMRA) Headquarters.

The delegation comprised representatives from Ethiopia, Burundi, the Democratic Republic of Congo (DRC), Rwanda, Kenya, São Tomé and Príncipe, Malawi, Mozambique, and Zambia. During the visit, they toured key departments of the Authority, including the National Drug Quality

The interactive engagement provided an excellent platform for knowledge sharing and peer learning, aimed at strengthening health system resilience and emergency preparedness across the region.

Collaboration with partners such as the HEPRR Programme, the Intergovernmental Authority on Development (IGAD), the East, Central and Southern Africa Health Community (ECSA-HC), the Ministry of Health, the World Bank, and participating Member States remains critical to safeguarding public health and advancing regional health security.

Creating awareness In Muchinga Province

In November 2025, the Authority also carried out awareness activities in Muchinga Province, including a visit and exhibition at Nakonde Urban Health Centre.

The engagement was exceptionally productive and was made even more rewarding by the warm reception and support received from the facility's management and staff.

During the outreach, ZAMRA staff distributed Information, Education and Communication (IEC) materials to members of the public as well as to the health facility.

The materials are an essential tool in strengthening knowledge, improving compliance, and empowering communities to take an active role in safeguarding their health.
It is imperative to note that health workers and health institutions remain at the core of ensuring the protection of both human and animal health. Their commitment, expertise, and close interaction with communities position them as indispensable partners in promoting public health and advancing the shared mandate of safety and wellbeing.

ZAMRA extends its gratitude to Nakonde Urban Health Centre and looks forward to continued collaboration for the benefit of the community. This activity took place on the 18th of November 2025.

"The strongest safeguard is not the fear of inspections, but the confidence to do the right thing. Prevention starts with understanding."

City sensitisation in Kalingalinga, Mtendere, Chazanga, and Ng'ombe Compounds.

During its sensitisation campaign in the capital city, ZAMRA targeted, among other groups, children. This was done with the aim of raising a generation that is aware of its responsibility in medicine safety and nurturing a cadre of future pharmaceutical businesswomen and businessmen who fully appreciate the importance of compliance.

A team of ZAMRA officers from the Licensing, Surveillance and Enforcement Directorate, together with the Public Relations Unit, shared information, including:

1. The ZAMRA mandate and key functions.
2. How to register a pharmaceutical business.
3. How to get import or export permits from ZAMRA.
4. Substandard and falsified medicines.
5. Antimicrobial resistance.
6. Annual returns.
7. Misuse and abuse of substandard and allied substances.

ZAMRA takes part in the International Anti-Corruption Day

ZAMRA was among the institutions that took part in the commemoration of the International Anti-Corruption Day, which took place on 9th December 2025, at the Mulungushi International Conference Centre.

Prior to the event, the Authority participated in the exhibition, which was held at the University Teaching Hospitals (UTH), where different entities showcased their services and demonstrated how they are ensuring zero corruption in their service delivery. The 2025 commemoration was officiated by H.E President Hakainde Hichilema under the theme, **"Uniting with youths against Corruption: Shaping tomorrow's Integrity."**

The ZAMRA team was led by Chairperson of the Integrity Committee and Laboratory Services Director Mr Bonaventure Chilinde.

Mission Nampudwe, Shibuyuini, Nangoma and Mumbwa.

A trip taken by the Licensing, Surveillance and Enforcement (LSE) team together with the Public Relations Office on the 10th and 11th of December 2025 to educate pharmaceutical dealers on the need to register their facilities.

We shared guidelines and requirements for registering a pharmacy, health shop, and Agro-veterinary shop.

We appreciate the people of Nampundwe, Shibuyunji, Nangoma, and Mumbwa for the cooperation and reception.

A big thank you also to Nampundwe Police, Shibuyunji Council and Mumbwa Police for the support. Partnership is key.

ZAMRA strengthens regulatory capacity towards WHO **Maturity Level 3**

Friday, 19th December 2025, marked the successful conclusion of a week-long training programme for ZAMRA inspectors in Good Manufacturing Practice (GMP), which ran from Monday, 15th December 2025, at Mkango Golfview Hotel in Lusaka.

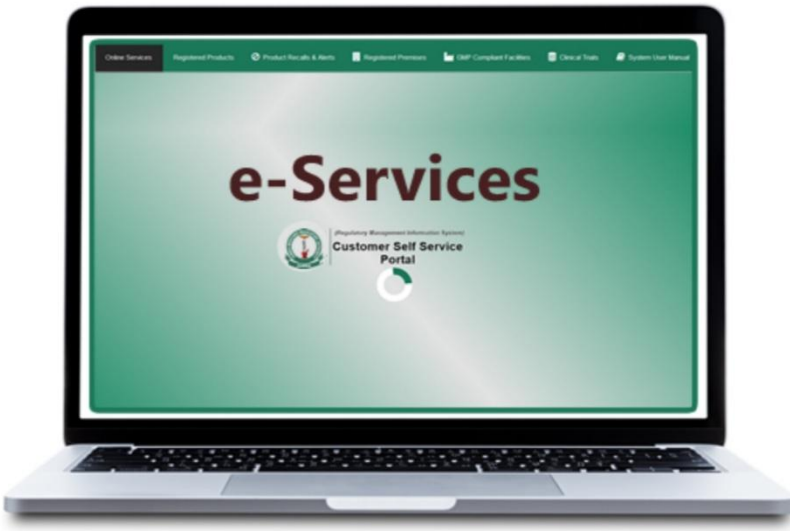
The training was facilitated by AUDA-NEPAD Consultant Mr Washington Dengu and focused on strengthening inspectors' technical competence, professionalism, and alignment with international regulatory best practices.

During the certification ceremony, ZAMRA Director-General Mr Makomani, applauded the facilitator for dedicating time to equip the inspectors with the critical skills necessary for effective GMP inspections.

He expressed optimism that the training would translate into improved performance and quality input from GMP inspectors in the execution of their regulatory duties.

Mr Dengu, on the other hand, encouraged ZAMRA to institutionalise the WHO GBT processes, tools, expectations, and requirements as part of its regulatory framework, in order to fully align its activities with global best practices as the Authority continues its journey towards achieving WHO Maturity Level 3 (ML3).

Service delivery charter



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