



ZAMBIA MEDICINES  
REGULATORY  
AUTHORITY

# ZAMRA NEWSLETTER

THIRD QUARTER - 2025



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**President Hakainde Hichilema** (right) addressing ZAMRA exhibitors during the 97th Agricultural and Commercial Show in Lusaka.

## President Hichilema nods ZAMRA

Lusaka, 2nd Aug 2025

His Excellency President Hakainde Hichilema, on the 2nd of August 2025, commended ZAMRA for its good works in Medicines and Allied Substances regulation. He also reminded ZAMRA to focus on the

one-health approach in the regulation of medicines for both human and veterinary use. He further emphasized the need to continue providing services in a timely manner.

The president said this when he visited the ZAMRA stand during the 97th Agricultural and Commercial Show in Lusaka, held under the theme "Adapting to climate change."

# Building National Medicines Regulatory Authorities ( NRAs ) capacity on global best practices in medicine safety surveillance for the health workforce

authorization granted by the WHO for Covid-19 vaccines, limited safety profile, and the need for reliance mechanisms by African National Regulatory Authorities (NRAs).

As key stakeholders in Medicine Safety and Health Care Delivery, Mr Uno took Pharmacists and Pharmaceutical Scientists through health care fundamentals, including;

- The role of Pharmacists and Pharmaceutical Scientists in Health Care Delivery
- An overview of the AU-3S Programme and solutions following the roll-out of Covid-19 vaccines
- Approach to Signal Management by the Joint Signal Management (JSM) Group
- Safety Recommendations and decision-making by Member States

At the same workshop, Mr. José António Goncalves shared on the "Repair and maintenance of biomedical equipment and development of renewable energy. Devices are designed to interact with biological systems and help healthcare professionals provide accurate and effective care." The ISWA-2025 took place from the 9th -10th of September in Lusaka, Zambia.



**Mr. Kenneth Onu, AUDA-NEPAD Head of AU-3S programme.**

On Tuesday, 9th of September 2025, AUDA-NEPAD conducted a capacity building workshop for pharmacists and pharmaceutical scientists in Zambia. The workshop, which was moderated by the Zambia Medicines Regulatory Authority (ZAMRA) Director-General Mr. Makomani Siyanga predominantly aimed at showcasing the African Union Smart Safety Surveillance (AU-3S) programme, and to help participants appreciate their role in its success.

The meeting took place on the sidelines of the first ever Industrial Skills Week for Africa (ISWA-2025) organized by AUDA-NEPAD, in collaboration with the Zambian Ministry of Technology and Science, Private Sector organisations, the International Labour Organisation (ILO), the United Nations Industrial Development Organisation (UNIDO) and other partners.

AUDA-NEPAD Head of the AU-3S programme, Mr. Kenneth Onu highlighted how the organisation leveraged AU-3S in Africa to monitor roll out of Covid-19 vaccines during the pandemic. This was in response to Africa's fragile healthcare system, emergency use

# ZAMRA strengthens capacity in the regulation of biosimilars

The Zambia Medicines Regulatory Authority (ZAMRA) successfully conducted a five-day training workshop for its assessors from 22nd to the 26th of September 2025, focusing on the regulation of biological products and biosimilars.

For decades, biologic medicines have transformed the treatment of cancer, autoimmune disorders, and rare diseases, with biosimilars further reshaping healthcare globally by expanding access to quality, safe, and effective therapies for both human and animal health.

As these products become increasingly complex, ensuring they meet rigorous international regulatory standards is vital.

The workshop, which was facilitated by Mr. Charlton Tatenda - Dossier Assessment Specialist from the Botswana Medicines Regulatory Authority (BOMRA), provided participants with technical expertise to, among other things:

- Enhance regulatory oversight of biological products
- Shorten registration timelines
- Improve access to life-saving medicines for the Zambian public

Through such initiatives, ZAMRA reaffirms its commitment to safeguarding public health while promoting innovation in Medicines and Allied regulation.



# ZAMRA engages stakeholders on quality assurance in supply chain

Lusaka, 3rd July 2025

On 3rd July, 2025, the Zambia Medicines Regulatory Authority (ZAMRA) engaged stakeholders in the pharmaceutical supply chain to formulate a sampling plan of medicines and allied substances.

The meeting was aimed at selecting products of focus in the continuous quality monitoring in 2026 under the Post Marketing Surveillance (PMS).

PMS is a vital regulatory function that monitors the quality of medicines and allied substances at all levels of the supply chain, throughout their shelf-life.

This is important in ensuring that medicines and allied substances used by the public consistently meet the standard of quality, safety and efficacy (or performance).

Opening the meeting, ZAMRA Director-General, Mr. Makomani Siyanga, highlighted the importance of stakeholders in the fight against substandard and falsified medical products.

He highlighted the significance of coordination among stakeholders who include supply chain actors, health professionals and the general public.

Stakeholders came from the Ministry of Health, Ministry of Livestock and Fisheries, Zambia Medicines and Medical Supplies Agency (ZAMMSA), Churches Health Association of Zambia (CHAZ), Zambia Pharmaceutical Business Forum (ZPBF), Global Health Supply Chain Program - Procurement and Supply Management (GHSC-PSM), and the Hospital Pharmacists Association of Zambia (HOPAZ). Others were Veterinary Association of Zambia (VAZ) and the Pharmaceutical Society of Zambia (PSZ).

Products earmarked for sampling include medicines for human and animal health, and allied substances such as medical devices among others.

Strengthened vigilance and market surveillance and control are key in safeguarding public health from unsafe substandard and falsified medicines and allied substances.



# ZAMRA launches the Single Point of Contact (SPOC) network against substandard and falsified medical products and illegal medicines on the zambian market.

Lusaka, 11th Sep 2025

Substandard and falsified medical products have continued posing a health threat, exposing patients, communities, and governments to increased disease burden and social-economic challenges worsened by out-of-pocket spending by patients and their families.

These products also continue contributing to the rise in Antimicrobial Resistance (AMR), with 155,000 children dying annually due to falsified anti-malaria drugs, and a similar number dying from acute pneumonia after treatment with substandard and falsified antimicrobials.

To curb the above problem, the Zambia Medicines Regulatory Authority (ZAMRA) and its partners, on the 11th of September 2025 established a Single Point Of Contact (SPOC) Network aimed at providing a platform for real-time collaboration between law enforcement agencies, civil society as well as the public in the prevention, detection and response to proliferation of substandard, falsified and illegal medical products in Zambia.

In his officiating remarks, ZAMRA Director-General Mr. Makomani Siyanga said Zambia recognizes the risk the production, trafficking and use of substandard and falsified medical products poses on human and animal health and is optimistic that the SPOC will aid in curbing this problem.

“This network will allow for swift evaluation of incoming reports, enforcement, national and international collaboration, as well as public communication on consequences of consuming substandard, falsified and illegal medical products.” He assured.

The SPOC Network includes, the Ministry of Health, the Ministry of Livestock and fisheries, the Ministry of Justice, the Zambia Medicines and Medical Supplies Agency, the Zambia National Airports Corporation, the Zambia Revenue Authority, the Zambia Police and the Drug Enforcement Commission, to mention but a few. The launch took place at Mulungushi International Conference Center in Lusaka, Zambia.



## Eight people arrested in Kafue district, Lusaka province for operating unregistered pharmacies



Section 14(1) of the Medicines and Allied Substances Act number 3 of 2013 of the laws of Zambia, prohibits the operation of all unregistered pharmacies.

On Sunday, 7th September 2025, eight people of Kafue District, Lusaka Province were arrested for operating unregistered pharmacies contrary to section 14 (1) of the Medicines and Allied substances Act No. 3 of 2013 of the laws of Zambia.

This followed an operation that was conducted by the Zambia Medicines Regulatory Authority (ZAMRA) in collaboration with the Zambia Police Service. The activity aimed at curbing the increasing illegal trade in medicines and allied substances on the Zambian market.

The outlets were mapped during the sensitization program which was conducted prior to the operation.

Failure in adhering to set standards with regards to the sale of Medicines and Allied substances results in offenders being prosecuted.

## Zambia reinforces blood regulation with support from the PEI bloodtrain



Lusaka, 27th Aug 2025

Blood is a lifesaving and irreplaceable resource, with no synthetic substitute, and is classified by the World Health Organization (WHO) as an essential medicine. Therefore, ensuring its quality, safety, and efficacy is a critical priority for public health. This far, Zambia has made remarkable strides in strengthening the regulation of blood and blood products.

However, to assess progress and chart the way forward in reinforcing Zambia's blood regulatory systems, the Zambia Medicines Regulatory Authority (ZAMRA), on the 27th of August 2025, convened a high-level stakeholder review meeting at Protea Hotel, in Lusaka. This was in collaboration with the Zambia National Blood Transfusion Service (ZNBTS), the Ministry of Health, and with support from the Paul Ehrlich Institut (PEI) BloodTrain.

During the meeting, ZAMRA Director-General, Dr. Makomani Siyanga reaffirmed resolve to fully implement regulations and guidelines that will safeguard patients across the country and thanked the PEI BloodTrain for its unwavering technical support in Zambia's blood regulatory strengthening journey right from inception.

Meanwhile, ZNBTS Medical Director, Dr. Joseph Mulenga, through his Assistant Director, Mr. David Chama highlighted the increased demand for blood in Zambia due to specialised health needs, and said this resulted in the scaling up of collection to at least 2% of the population.

Head of the BloodTrain Dr. Jens Reinhardt expressed happiness at the strong collaboration of Zambian institutions in the blood transfusion chain.

Zambia currently serves as the vice chairperson of the African Blood Regulators-Technical Committee (ABR-TC), under AUDA-NEPAD, demonstrating its commitment to the strengthening of blood regulatory systems across the continent.

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# Enhancing Africa's vigilance systems for Medical products

This milestone demonstrates Africa's collective commitment to harnessing digital surveillance technologies for medical products to build resilient and future-ready systems that protect African lives, and Zambia is among wave 3 countries.

AUDA-NEPAD, under the AU-3S Programme, from the 25th to the 27th of August 2025 convened a 3-day hands-on Vigilance Technology Onboarding Workshop in Lusaka, Zambia for Wave 2 countries (DRC, Egypt, Mozambique, Rwanda, Senegal, Tanzania, and Uganda).

With technical support from the United Kingdom Medicines and Healthcare products Regulatory Agency (UK MHRA) and the Gates Foundation, AUDA-NEPAD brought together 15 pharmacovigilance and technology experts to fast-track Africa's safety surveillance systems business.

The host and Director-General of the Zambia Medicines Regulatory Authority (ZAMRA) Mr. Makomani Siyanga applauded UADA-NEPAD and partners for helping National Regulatory Authorities across Africa to ensure only quality reports are submitted.



"Every Individual Case Safety Reports (ICSRs) submitted must meet minimum standard of quality in guaranteeing safety of African population in the use of medical products," he said.

Key technology challenges identified during the 3-day workshop include:

- Gaps in real-world evidence and structured data before product launches in Africa
- Underreporting of adverse events despite significant investments
- Fragmented, siloed legacy systems with limited interoperability
- Shortage of advanced analytics capacity for signal detection and safety communication
- Resource constraints in monitoring medicines and vaccines.
- Country-specific insights into digital vigilance gaps
- Hands-on training in data migration, systems integration, and safety informatics
- Peer learning and cross-country knowledge exchange
- Action plans leveraging data pipelines, dashboards, and structured reporting standards
- Kick-off of a Wave 2 campaign targeting high-quality safety reports into SafetyConnect (AfriVigilance Lite)

Core outcomes achieved during the Technology Onboarding Workshop include:



## ZAMRA Public Relations officers trained in leadership and effective communication.

The Zambia Institute of Public Relations and Communication (ZIPRC) in conjunction with the Petersen Communication Limited, from the 22nd to the 26th of September convened a training for Public Relations and Communication officers from Zambia, in Mombasa Kenya.

The training was aimed at ensuring participants take a critical role in helping their institutions to look beyond profitability, and to align their services and activities to sustainability.

This was in response to the urgent need for effective communication and stakeholder participation in averting and mitigating development challenges, that include effects of climate change.

The training was also a platform for equipping participants from different institutions, with skills in Artificial Intelligence (AI) and aiding them leverage new technology while maintaining professionalism and authenticity.

The training gave insights on;

- Leadership communication
- The Environmental, Social and Governance framework
- Artificial intelligence

Through this initiative, ZIPRC members were awarded 40 Continuous Professional Development (CPD) points, as part of the 60 CPD points needed for practitioners to renew their licenses.

ZAMRA was represented by its Senior Public Relations Officer Mr. Ludovic Mwape and Public Relations Officer Mrs. Lister Mutukwa, respectively.

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# Provincial stakeholder meetings and activities



## Southern

Meetings with veterinary stakeholders and partners in Southern province, from the 11th to the 15th of August 2025.

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## Central

Meetings with veterinary stakeholders and partners in Central province, from the 14th to the 19th of September 2025.

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## Lusaka

Exhibition at the Zambia Agriculture and Commercial Show (ZACS) in Lusaka, from the 30th of July to the 4th of August 2025.

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## Copperbelt

Exhibition at the 59th Zambia International Trade Fair (ZITF) in Ndola, on the Copperbelt, from the 2nd to the 7th of July 2025.

# Media Programmes

Fifteen media programmes on the ZAMRA mandate



**RADIO PROGRAMMES:** Radio Pheonix (1) • Radio Ichengelo (1) • Radio Chimwemwe (1) • Radio Maranatha (1) • Radio Christian Voice (5) • ZNBC Radio 2 (2) • Sky FM (1)



**TELEVISION PROGRAMMES:** ZNBC TV1 (2) | PRIME TV (1)

# Highlights

**ZAMRA's laboratory officer Julius Mubipe at work. The National Drug Quality Control Laboratory is key to human and animal health protection.**

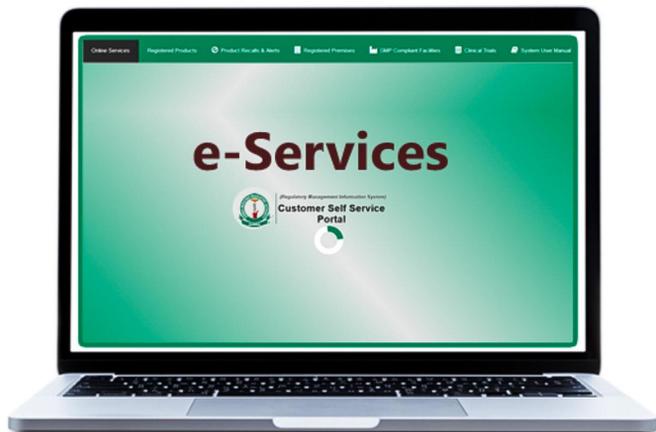


**ZAMRA Director-General Mr. Makomani Siyanga moderating the AUDA-NEPAD organised training of Pharmacists and Pharmaceutical scientists during the ISWA-2025 at the Mulungushi International Conference Center in Lusaka.**

**Marketing authorisation assessors diligently reviewing applications. Their work enables the Authority to ensure only quality, safe and efficacious medical products are registered on the Zambian market.**



**ZAMRA officer Florence Tirani making a presentation at the Blood regulation stakeholder meeting at Protea Hotel in Lusaka.**



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