

Volume 1 Issues 1 & 2
July - December, 2025

INNOVATION



**NATIONAL DRUG
AUTHORITY**

RESEARCH & INNOVATION digest

Volume 1 Issues 1 & 2 July - December,

2025



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EDITORIAL TEAM

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COMMUNICATION FROM THE SECRETARY TO THE AUTHORITY

It's with great honor that I introduce this first edition of the digest from the Research and Innovation Unit under the Directorate of Product Safety. The establishment of this digest marks an important step in strengthening the Authority's ability to integrate research, innovation, and scientific evidence into medicines regulation.

We recognize that effective regulation must be evidence-based and responsive to emerging scientific developments, while remaining sensitive to local contexts.

The Research and Innovation Unit has advanced this agenda through collaboration, strengthened regulatory research frameworks, and initiatives that promote institutional learning. It works to position the Authority as a more knowledge-driven and forward-looking regulator.

This Digest highlights progress in key priority areas, including clinical research regulation, advanced therapies, data systems strengthening, antimicrobial resistance, and research dissemination, demonstrating our commitment to translating research into policy and practice

I commend the Director Product Safety, and staff for their dedication to producing this publication and appreciate the continued support of our partners. I am confident that this Digest will be a valuable platform for knowledge sharing and for strengthening medicines regulation in Uganda and beyond.

David Nahamya
Secretary to the Authority
National Drug Authority



COMMUNICATION FROM THE DIRECTOR PRODUCT SAFETY

It is with great delight that I welcome you to this inaugural publication of the Research and Innovation Unit under the Directorate of Product Safety.

The unit's core function is to strengthen research capacity for making evidence based regulatory decisions. Towards this effort, this financial year 2025/2026, the unit will prepare a quarterly Digest to inform staff about ongoing research and innovation activities as well as the latest scientific developments in the medicine regulatory space.

During quarters 1 & 2, the team has strengthened systems for clinical research, regulation, and innovation through national and regional stakeholder engagements. Our Digest highlights collaborative efforts towards building capacities in advanced therapies, enhancing data systems, Research Ethics Committees, combating antimicrobial resistance (AMR), disseminating research findings, and supporting innovation, among others. These achievements highlight our commitment to ensuring that research and innovation directly strengthen the institutional research capacity for making evidence-based drug regulatory decisions.

We remain grateful for the support of our partners and look forward to continued collaboration in driving Uganda and the region toward safer communities.

Dr. Helen Byomire Ndagije, PhD, FISoP
Director Product Safety
National Drug Authority



RESEARCH HIGHLIGHTS

Key Studies Completed

Among the studies being conducted are;

- **Medication Errors Study:** This was a study conducted among regional referral and general hospitals to assess prevalence of medication errors and knowledge and attitude of health care workers and patients towards medication errors. Data collection and analysis were completed and the study is at report-writing stage.
- **Pharmacists' Availability Study:** A study proposal was completed and received favorable ethical approval. Data collection is ongoing among the study participants, with completion expected by the end of the year.

Articles Published in 2025

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National consumption of antimicrobials intended for use in animal livestock health: a retrospective data analysis of antimicrobial imports to Uganda from 2018 to 2020

Research | [Open access](#) | Published: 04 April 2025
Volume 21, article number 248, (2025) [Cite this article](#)

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Adverse drug reaction reporting with the Med Safety app in Uganda: a cluster-randomised, controlled trial

[Ronald Kiguba](#), PhD ^a ✉ · [Helen B Ndagije](#), PhD ^b · [Norah Mwebaza](#), PhD ^a · [Ronald Ssenyonga](#), PhD ^{c,i} · [Lilian Giibwa](#), MSc ^c · [Gerald Isabirye](#), BSc ^b · [Jonathan Owiny](#), BSc ^b · [Victoria Nambasa](#), MSc ^d · [Ismail Ntale](#), MPH ^b · [Joanitah Atuhaire](#), MSc ^b · [Douglas Mwesigwa](#), MPH ^b · [Julius Mayengo](#), MSc ^b · [David Walusimbi](#), MSc ^d · [Ian Mugisa](#), MSc ^b · [Cordelia Katureebe](#), MMed ^e · [Kendal Harrison](#), BSc ^f · [Prof Charles Karamagi](#), PhD ^g · [Prof Munir Pirmohamed](#), PhD FRCP ^h [Show less](#)



CONFERENCES & MEETING PRESENTATIONS



A cross-section of meeting participants at the Consultative Meeting

A consultative meeting with stakeholders on non-prescription access to antimicrobials

The NDA, in collaboration with the Infectious Diseases Institute CAMO-Net project, convened stakeholders at Piato Restaurant to address non-prescription access to antimicrobials, a key driver of antimicrobial resistance (AMR). Key Issues included public unawareness, unlicensed sellers, and poor healthcare access, which in turn drives treatment failures, the spread of resistant infections, and the loss of vital medicines. Stakeholders called for stronger regulation, community interventions, balanced economic measures, and control of livestock misuse. The core message was that preserving antimicrobial efficacy demands collaboration, regulation, and community engagement to protect Uganda's health and future.





Tackling Antimicrobial Resistance at the Uganda National Drug Authority: An inter-directorate approach

Joanitah Atuhaire^{1,2}, Helen Byomire Ndagije¹, Sheila Ampaire¹, Allan Serwanga¹, Karen I. Barnes²

¹ National Drug Authority, Uganda
² University of Cape Town

Background:

- Antimicrobial resistance has gained momentum recently with Uganda launching its second National Action Plan for tackling antimicrobial resistance (AMR-NAP) in 2024.
- The AMR NAP is headed by the One Health Platform, a collaboration between government ministries, agencies, departments and partners integrating human, animal, and environmental health.

Objective:

- To describe the Uganda National Drug Authority's approach in contributing to the National Action Plan for tackling Antimicrobial Resistance, an important adverse drug event.

Methods:

- This is a qualitative description of the process and progress made by the regulator and partners in addressing focus areas in the Uganda AMR National Action Plan (AMR NAP II).

Results:

- The AMR NAP II is governed by the National One Health Platform (NOHP) which oversees coordination among sectors to align global standards and national priorities for AMR.
- Under this One Health Technical Working Group (OHTWG), the Uganda National Antimicrobial Resistance Subcommittee (UNAMRSC) guides multisectoral efforts for NAP-AMR II implementation.

Intervention:

- NDA established a dedicated taskforce to implement regulator- specific AMR NAP objectives consisting of microbiologists, pharmacists, veterinarians and public health experts drawn from the four technical directorates.

Recent activities



- Members of the AMR Taskforce took part in the annual AMR week where the Hon. Minister of Health (centre) signed the AMR NAP II.

- The taskforce organized a stakeholder meeting to address the concern of over the counter access to antimicrobials on 19th August 2025.

- Collaboration with partners in academia and research to investigate suspected drivers of antimicrobial resistance – a systematic review on antimalarial resistance is currently ongoing with the University of Cape Town.

- Capacity building in collaboration with the Fleming Fund to equip the task force with expertise to tackle AMR.

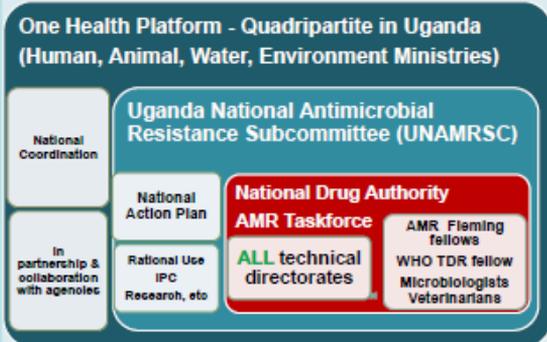
- Support to student AMR clubs in universities in order to embed AMR awareness in pre-service professionals.

Conclusions:

- AMR is a unique pharmacovigilance challenge that demands cohesive efforts from multiple stakeholders.

- Previously, responsibility for AMR was considered implicit and collective, resulting in a lack of clear ownership, segmentation of work and low subsequent follow-up.

- Creation of a dedicated task force has made coordination of AMR easier within NDA departments and provided a clear path to feed into the AMR NAP.



- The Uganda National Drug Authority (NDA) is a member of the UNAMRSC, providing regulatory oversight and technical expertise in antimicrobial use.



Abstract 82 presented at the ISoP Annual Meeting in October 2025.



SCoMRA VII: Advancing Regulatory Harmonisation in Africa



The Official hand over from AMRH Director Symerre Grey-Johnson to H.E. Dr. Delese Mimi Darko, Director-General of the African Medicines Agency (AMA).

The Scientific Conference on Medical Product Regulation in Africa (SCoMRA) VII was held from 11–13 November 2025 in Mombasa under the theme “Regulatory Harmonisation: Unlocking Africa’s Potential in Health Product Manufacturing and Trade.” Jointly organized by AUDA-NEPAD and WHO, the biennial conference brought together over 600 stakeholders from Africa and beyond, including regulators, policymakers, researchers, manufacturers, and development partners, to share best practices, review progress in regulatory harmonisation, and set priorities for Africa’s regulatory future.

The conference featured plenary and breakout sessions across nine thematic areas, including regulatory harmonisation for local manufacturing, trade facilitation under AfCFTA, preparedness for public health emergencies, clinical trials oversight, digitalisation and artificial intelligence in regulation, workforce development, and combating substandard and falsified medical products. NDA participated in selected sessions, contributing to discussions on regulatory harmonisation, emergency preparedness, digital transformation, and clinical trial oversight.

A major highlight of SCoMRA VII was the official operationalization of the African Medicines Agency (AMA), marking a significant milestone toward continent-wide regulatory convergence and strengthened oversight of medical products. Overall, participation in SCoMRA VII provided valuable insights, strengthened regional and global partnerships, and reinforced the importance of harmonized, evidence-based regulatory approaches to support public health, innovation, and trade across Africa.



Advancing the Fight Against Antimicrobial Resistance in Uganda



Members of the NDA AMR task force at the WAAW meeting

Antimicrobial resistance (AMR) remains one of the most pressing global public health challenges, driven largely by the misuse and overuse of antimicrobials in human health, animal production, and agriculture. In Uganda, AMR is recognized as a critical public health and development concern, with national efforts guided by the National Action Plan on AMR aligned to the World Health Organization's Global Action Plan and implemented through a One Health approach that integrates human, animal, and environmental health sectors.

In line with global efforts, Uganda participated in activities marking the Tenth Antimicrobial Resistance Conference held in the context of World Antimicrobial Awareness Week (WAAW), celebrated under the theme "Act Now: Protect Our Present, Secure Our Future." The conference brought together stakeholders from government ministries, regulatory authorities, academia, private and not-for-profit institutions, and development partners to raise awareness, share experiences, and strengthen coordinated action against AMR. The National Drug Authority (NDA) actively

participated in the conference, contributing to discussions on antimicrobial stewardship, regulatory frameworks, and quality assurance across the supply chain. NDA experts, including Dr. Sheila Ampaire and Dr. Brian Sekayomba, emphasized the importance of cross-sector collaboration and maintaining the quality of medicines to ensure the responsible use of antimicrobials in both human and animal health. Conference sessions covered key thematic areas such as public awareness, policy and governance, laboratory surveillance, infection prevention and control, innovation, vaccines, and supply chain management.

Key takeaways from the conference included the need for coordinated One Health action, rational use of antimicrobials, reliable data on antimicrobial use and resistance, strong public awareness campaigns, robust regulatory enforcement, and continued investment in research and innovation. Overall, the conference reinforced the critical role of NDA and its partners in safeguarding the effectiveness of antimicrobials for present and future generations.



RESEARCH ROUNDTABLE DISCUSSIONS

Beginning in June 2025, a series of presenters participated in the NDA Research Round table discussions, one of the ways in which knowledge sharing and continuous professional development is maintained at NDA. Below are synopses of the discussion series.



With Guest Speaker
DEUS KAMYA

PGRstudentQuadramInstitute
Bioscience Norwich, United Kingdom

TOPIC:
**Understanding Bacteriophages:
Biology, Therapeutic Potential,
and Regulatory Considerations**

Bacteriophages are viruses that kill bacteria. Invisible under normal microscopes, they're gaining attention as antibiotic alternatives amidst rising antimicrobial resistance (AMR), which could cause 10 million deaths/year by 2050. They work by attaching, injecting, replicating, and killing the bacteria. Their benefits include, among others, being highly specific, self-replicating, safe, cost-effective, and usable with antibiotics. Some of their challenges are a narrow host range, limited trials, production & storage hurdles. They have been widely used in Georgia & Belgium, restricted in the USA, and with a growing interest in the UK



With Speaker
NASHIRA ASIIMWE

TDRFellow, Inspector of Drugs -
Central region
National Drug Authority

TOPIC:
**Introduction to
Pharmaceutical Systems
and Policies**

A pharmaceutical system, which is part of the broader health system, ensures access to safe, effective, and quality medicines. It includes health products, services, governance, human resources, policies, laws, and regulations. The law is an enforceable rule, a policy, a guiding principle; regulations operationalize laws, and guidelines/ SOPs are non-enforceable. In Uganda, the Ministry of Health and the National Regulatory Agency oversee medicines under the National Medicines Policy and Pharmaceutical Sector Strategic Plan III. Strong policies, governance, and regulations are key to equitable access and improved health outcomes.



With Speaker
RACHEL MUJAWIMANA

BPharm. PGD.MSc
Inspector of Drugs National
Drug Authority

TOPIC:

An overview of the regulations of surgical instruments and appliances

A medical device covers instruments, implants, software, and more. Devices are classified A– D by risk. NDA oversees registration, licensing, import/ export, post- market surveillance, and Good Manufacturing Practice compliance. Clinical trials are mostly exempt for medical devices, except for drug- delivery devices. Some of the challenges faced by the National Drug Authority include Legal gaps, new technologies versus human resources, and counterfeit devices. The National Drug Authority is working towards strengthening regulations, integrating AI/ digital health, and building capacity. The regulation of medical devices ensures safety, innovation, and public health protection.



With Speaker
DR. TOBI NAGEL

Fulbright Scholar USA
Founder and President,
Phages for Global Health

TOPIC:

The fight against AMR: Alternatives to antibiotics

As a continuation from Deus Kamyá's presentation on bacteriophages, both discussions highlighted the urgent need to address antimicrobial resistance (AMR) by advancing safe, effective, and affordable solutions. Key takeaways included Phage therapy potential, already part of the human microbiome, phages have been successfully used to treat resistant infections such as septicemia, UTIs, wounds, burns, and diabetic foot ulcers, regulatory pathways in Europe and the U. S. have mechanisms for limited phage use, but Africa and Asia remain underrepresented in global frameworks, and there is need for Uganda to give a thought to start working toward developing its own guidelines, research and innovation efforts in Uganda include activities like academic symposia, grant- funded studies, and plans for a national phage repository. Collaborative networks are being formed across health, agriculture, food safety, and environmental sectors, and the expected outcomes are reduced reliance on antibiotics, increased awareness of phage therapy, stronger research capacity, and clarified regulatory guidance. Phage therapy offers promise as a cost- effective complement to antibiotics, but more evidence, regulatory clarity, and stakeholder collaboration are needed to fully unlock its potential in Africa.



With Speaker
SHEILA AMPAIRE

BPharm, MPH, and MSc in
Clinical Trials Principal Regulatory
Officer Research Unit

TOPIC:

**Grant applications:
sharing team experiences**

This presentation highlighted the fundamentals of grant funding, explaining what grants are, who awards them, the different types available, and who can apply at both individual and institutional levels. It emphasized the importance of horizon scanning to identify suitable funding opportunities and stressed that successful applications depend on aligning project ideas with funder priorities and eligibility requirements. The talk also highlighted key global health and research funders relevant to healthcare regulation, underscored the need for collaboration and partnerships to strengthen proposals and ensure sustainability, and outlined the grant writing process, including developing a compelling case for support, complying with calls for proposals, and preparing realistic budgets and supporting documents. She further highlighted practical experiences and lessons learned from previous grant applications and project implementation at the National Drug Authority. It reported that grant writing requires early preparation, teamwork, resilience, and consistent engagement with application platforms and collaborators. The talk emphasized that rejection is common and should be expected, but persistence and collaboration significantly increase success. She concluded that excellent project implementation is essential for attracting future funding and encouraged participants to proactively share promising ideas and opportunities so they can be developed into impactful, eligible projects.



With Speaker
**AGNES VANESSA
KEMIGISHA**

BPharm, Mps
Principal Regulatory Officer -
Medicine Unit - DPAR

TOPIC:

**Regulatory intelligence:
A case study of Paracetamol
safety**

The discussions deepened understanding of regulatory intelligence as a critical tool for tracking and applying global regulatory developments to support timely, evidence-based decision-making and strengthen NDA's regulatory preparedness. Key recommendations included establishing an institutional platform to improve information sharing across directorates, reviving the operational-level Technical Committee to enhance cross-directorate collaboration, and investing in regulatory intelligence tools and staff training to interpret better international regulatory actions and their implications for practice in Uganda.



ONGOING GRANT PROJECTS



Partners from UNCST and NDA at the East African Regulatory Information Management System (EARIMS) Grant Inception Meeting

The EARIMS grant project implementation at NDA

The NDA is implementing a two-year collaborative grant project with the Tanzania Medicines and Medical Devices Authority, the Rwanda Food and Drug Authority, the Ethiopia Food and Drug Administration, and the Uganda National Council for Science and Technology, funded by the Gates Foundation. The grant inception was in October 2024, and it is expected to end in September 2026.

The grant project is titled “East African Regulatory Information Management System Enhancement Collaboration.” Its primary objective is to strengthen data systems among partners, focusing on improving system efficiencies, tracking key performance indicators, and supporting data-driven regulatory decision-making.

The project aims to enhance data systems for three regulatory functions: Market Authorization, Clinical Trials, and Good Manufacturing Practices.

Consortium for Developing Regulatory Capacity of Clinical Trials Using Gene Therapy Products and Strengthening Pharmacovigilance in the Conduct of Clinical Trials in East Africa.

A consortium has been established to build regional capacity for the regulation and conduct of clinical trials involving gene therapy products in East Africa. This initiative acknowledges the rapid advancements in gene-based medicine and the necessity for robust regulatory and clinical oversight to ensure safety, efficacy, and ethical compliance.

The consortium's focus areas include developing frameworks to guide the oversight of clinical trials using gene therapy products, strengthening regulatory agencies by enhancing their capacity to supervise clinical research involving these advanced therapies, and building the skills of researchers and clinicians to effectively use and manage gene therapy in clinical settings.

By fostering collaboration between regulators, researchers, and clinicians, the consortium aims to position East Africa at the forefront of safe, innovative medical research while ensuring patient safety through strong pharmacovigilance practices.



Participants at the Infarmed training as part of the Capacity 2023 project

Supporting Research Ethics Committees for efficient functionality and national accreditation to Review Clinical Trials in Uganda and Ethiopia

A regional initiative is underway to enhance the efficiency and credibility of Research Ethics Committees (RECs) in Uganda and Ethiopia. The program focuses on building strong, accredited systems that can effectively oversee clinical trials and safeguard research integrity. Key priorities include supporting the accreditation of RECs in Ethiopia, equipping committees with the skills and knowledge needed to review and monitor clinical trials, linking national RECs to the Pan African Clinical Trials Registry to promote transparency and accountability, and expanding the use of digital technologies for the submission and review of trial protocols. This initiative is set to improve ethical standards, streamline clinical trial oversight, and foster trust in biomedical research across the region

Strengthening Clinical Trial Regulatory and Ethical Review Oversight in East Africa

A new program, advancing the regulatory and ethical review of clinical trials in Ethiopia and Uganda, with a focus on strengthening collaboration and leadership across key institutions. The initiative seeks to enhance the capacity of National Regulatory Authorities (NRAs), National Ethics Committees (NECs), and Institutional Review Boards (IRBs) to effectively review, approve, and oversee clinical trials, strengthen collaboration between ethics and regulatory bodies by fostering closer ties and improved communication among NECs, NRAs, IRBs, and other stakeholders, and build regional research leadership by working with the Eastern Africa Consortium for Clinical Research (EACCR). By bridging regulatory and ethical oversight, this effort aims to ensure safer, more transparent, and higher-quality clinical research across the region.



INNOVATION

TRAINING OPPORTUNITIES

Research Communication Course

This is an online course where participants learn a structured approach to translating complex scientific evidence into clear, persuasive, and actionable messages tailored for diverse audiences, from policymakers and frontline health workers to community stakeholders. Guided by communication experts, the training blends practical tools with proven strategies grounded in Aristotle's timeless principles of persuasion: evidence (head), storytelling (heart), and credibility (trust). Access:

https://tdrmooc.org/courses/course-v1:TDR+COM700en+2025_Pilot/about

LEARNING

Resources available

NDA has access to online journals and databases for scientific literature:

<https://portal.research4life.org/>

NDA resource center:

<https://www.nda.or.ug/e-resources-database/#1606200591942-ea5afa08-ff5e>