THE NATIONAL DRUG AND HEALTH PRODUCTS AUTHORITY BILL, 2025, NO. 19 2025

ISER Submission to the Uganda Human Rights Commission

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About the Initiative for Social and Economic Rights (ISER)

The Initiative for Social and Economic Rights (ISER) is a Non-Governmental Organization, established in 2012, seeks to promote the effective understanding, monitoring, implementation, accountability, and full realization of Economic and Social Rights (ESRs). ISER holistically works on social economic rights. It simultaneously runs four programs in its day- to- day operations: the right to health; the right to education, Business and Human Rights, Economic Inclusion and Fiscal Policy. It uses community engagement, research to support system reform, evidence-based advocacy, and strategic litigation to realise these rights. ISER is an ardent advocate for the adoption and use of a human rights-based approach to healthcare service delivery and has actively engaged in advocacy for the right to health especially for vulnerable groups including the poor, and Persons with Disabilities (PWDs). ISER's right to health program focuses on realizing the right to health and universal health coverage with a particular focus on vulnerable groups.

Introduction

The initiative for Social and Economic Rights (ISER) appreciates the opportunity to provide input into the proposed National Drug and Health Products Bill, 2025. We acknowledge that this third reading stage of the Bill presents a critical moment to align it with Uganda's constitutional and international human rights obligations, including the right to health under Article 45 of the Constitution, the International Convention on Economic Social and Cultural Rights (ICESCR), General Comment 14, and the World Health Organisation medicine and health products recognised norms, standards, and guidelines.

This submission does not attempt to cover all health and human rights concerns pertaining to the Bill. The Omission of an issue should not be construed as insignificant or unworthy of consideration.

The right of everyone to the enjoyment of the highest attainable standard of physical and mental health continues to be directly undermined by the ongoing cumulative effects of underfunding, fiscal austerity, cuts to public health care services. Thus, a well-designed and fit-for-purpose regulatory law must guarantee availability, accessibility, affordability, acceptability, quality (AAAQ), and safety of medicines and health products for all, especially marginalised groups.

Positive aspects of the Bill

ISER notes that the Bill is a significant improvement to the 1993 post-colonial law as recognises technological, scientific, regulatory, and ethical advancement in the sector. seeks to align the evolving mandate and function of the National Drug Authority with contemporary World Health Organisations guidelines and overall sector developments, particularly, in respect to sector regulation and human right-based principles. Some of the positive aspects of the Bill include; repeal of the 1993 National Drug Policy and Authority Act; regulation of pharmacies in health units, the distribution of drugs, release of vaccines; expansion of the scope of the Authority to regulate medical devices, cosmetic products that contain, hydroquinone, health products, and nutritional supplementary.

Human rights concerns and proposed recommendations

The Bill comes at an especially difficult time for Uganda's health sector. It is characterised by recurrent stockouts of essential medicines, catastrophic out-of-pocket expenditures, declining external donor support, proliferation of substandard and falsified products, weak regulatory capacity, and increased reliance on traditional and complementary medicines. These economic and public health pressures disproportionately affect poor and disadvantaged segments of society whose access to safe, affordable, and culturally acceptable medicines and health products is already compromised. At the same time, the health sector is rapidly inclined to digital health technologies, AI-enabled medical devices, emerging vaccines, and global supply disruptions.

In this context, the proposed Bill provides a unique opportunity to modernise Uganda's regulatory framework, align it with global standards, enhance public accountability, and strengthen the foundation needed for Uganda to participate meaningfully in international regulatory harmonisation initiatives while boosting local pharmaceutical production. However, this opportunity can only be realised if the Bill is carefully revised to centre human rights principles, particularly affordability, accessibility, availability, quality, safety, and non-discrimination.

What the Bill reads (Clause)	Why it matters for rights and people	Recommendation to strengthen the Bill
Clause 2. Adverse reactions	The current definition is narrow as it limits its scope to drugs and nutritional supplements while leaving out cosmetic product despite the Bill's explicit intention to regulate them.	Expand the definition to cover cosmetic products particularly those with active pharmaceutical, chemical or biological ingredients, to ensure full protection under the law.
21(8) harsh criminal penalties for non-regulatory compliance. The provision imposes steep fines of up to 60,000,000 (corporation), 10,000,000 (individuals) or ten years imprisonment.	This blanket criminalisation depicts a colonial punitive regulatory system that disregarded traditional knowledge systems, especially traditional medicine as unscientific, rather than as complementary to biomedicine. Instead of protecting the public, harsh penalties risk suppressing innovation, and pushing small scale producers under-ground, thereby reducing access to affordable traditional medicines and instead maintain Uganda's external dependence appetite high for medical products.	Introduce a non-punitive administrative enforcement measure like warning letters and corrective action plans.
21 (1) and (2) criminalise any manufacture, import, export, supply, dispensation, or distribution of any drug including herbal or complementary medicine unless first registered, notified, or listed by NDA	Uganda's population increasingly relies on traditional medicine due to frequent drug stock-outs at public health facilities[1], affordability barriers, cultural acceptability, and accessibility among others. overly rigid, costly, and bureaucratic procedures will criminalise cultural health practices that pre-	Limit mandatory registration to products placed on the commercial market, not household-level or community-prepared herbal products. Develop community-based safety standards with the Ministry of Health's Department of Traditional & Complementary Medicine.

[1] Initiative for Social and Economic Rights. Community Voices: The Looming threat of drug stock-outs in Uganda's public health facilities, available at: https://url-shortener.me/2E4L accessed 08 December 2025.

	date biomedicine, push practitioners underground and undermine WHO and Astana Declaration recommendations. See: Declaration of Astana at https://url-shortener.me/2E3C. Thus, hash penalties and bureaucratic registration procedures may effectively close	
Clause 26- importation of drugs for donation	Clause 25 already requires all imported drugs/medicines regardless of their end users to meet safety, efficacy, and quality standards. Creating a separate clause for *"donated medicines"* implies these products are fundamentally different or require a different approval pathway. Clause 26 also reinforces harmful historical patterns around aid-dependent supply chains (Uganda as a dumping site for near-to-expire drugs and medicines)	Delete the whole clause as it is outdated, redundant, and inconsistent with contemporary regional and international regulatory frameworks.
Clause 29 (4) a drug shop only in an area that is not sufficiently served by pharmacies.	The clause is vague and subject to abuse by enforcement officers and opens doors to regulatory uncertainties, discriminatory enforcements, and economic interferences. The provision further undermines the right to access medicines since drug shops are often the first-line of contact for poor and disadvantaged consumers	Amend the provision and clearly define *'sufficiently served'*. The criteria must be objective, realistic, and measurable.

	due to their low over-the counter pricing.	
Clause 103- destruction of products not fit for purpose. (over reliance on court processes)	Legal bottleneck Requiring the Authority to apply for a court order before destruction ignores Uganda's chronic judicial administrative delays and case backlogs, and limited technical capacity are persistent.	Adopt a two-tier destruction mechanism. i) one that allows the Authority to immediately destroy any product that poses imminent threat to public health without requiring order authorisation. However, to avoid systemic abuse, the Authority must require a written report by a government analyst, accompanied by photographic evidence and the affected person be notified of their right to seek judicial compensation in the event the destruction erroneous. ii) Maintain judicial oversight for cases that do not pose immediate public threat and panic.
Clause 56 – 60 mandatory registrations, notification and listing of medical devices.	The Bill treats all devices equally; from complex imaging equipment to basic walking devices for persons with disabilities. This rigid approach risks reversing the gains in Uganda's biomedical engineering and innovation ecosystem; making it financially impossible for small-scale innovators to manufacture simple devices. This approach limits equitable access to essential assistive technologies for Persons with disabilities (PWDs), older persons, and rural health facilities.	Adopt risk-based regulatory framework and allow notification for low-risk assistive medical devices.

Clause 112- required fee payment on access to information request	Article 41 of the 1995 Constitution and the Access to Information Act guarantee right to access information. Imposing a fee as a prerequisite to accessing publicly available information restricts public's ability to access information and disproportionately locks out the poor and disadvantaged from exercising their constitutional guarantee. The phrase *'reasonable times'* is vague and creates a loophole in implementation. It also opens window for the Authority to restrict or limit access to information.	Delete the phrase '..at a prescribed fee' Proposed The register shall be available online and in physical form, free of charge, and updated in real time to promote transparency, public safety, and the right to access health information."

Conclusion

The National Drug and Health Products Authority Bill, 2025 represents a historic opportunity for Parliament to modernise Uganda's regulatory ecosystem and equitably advance the right to health for all. However, without the proposed amendments, the Bill risks entrenching inequities, undermining traditional knowledge systems, restricting access to essential medicines, enabling regulatory abuse, and compromising the safety of millions of Ugandans.

ISER therefore urges the Parliamentary Committee on Health to:

- Embed explicit human rights obligations within the Bill, ensuring that affordability, accessibility, availability, acceptability, and quality (AAAQ) guide all regulatory decisions.
- Strengthen transparency and accountability mechanisms, including free public access to the medicines register, risk-based regulatory frameworks, and clear limits on ministerial control.
- Protect vulnerable populations by eliminating punitive approaches that criminalise poverty, traditional medicine, or community-based health practices.