

# Lack of registration is limiting access to essential medicines in Kenya, Tanzania and Uganda, shows new analysis

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The lack of registration of medicines in Kenya, Tanzania and Uganda is limiting access to safe, effective, and affordable essential medicines, according to a new analysis from Newcastle University in the UK and

Makerere University in Uganda, published by the *Journal of the Royal Society of Medicine*.

Before a medicine can be made available in a country, manufacturers must apply to the medicine regulatory agency of the country for a license to sell it and demonstrate the medicine is safe and effective. This is known as market [registration](#).

The researchers compared the essential medicine lists in each country with the medicine products on each country's national drug registers. Their analysis shows that a high proportion of essential medicines are not registered (28% in Kenya, 50% in Tanzania and 40% in Uganda). The lack of registration of essential medicines is a barrier to availability, the researchers say.

Across the three countries, 80–100% of anti-Parkinsonism medicines, 71–90% of antidotes and anti-poisoning medicines, 0–43% of diuretics, 28–41% of antiepileptics, 21–44% of hormonal and endocrine medicines, and 21–30% of anti-infectives were not registered and therefore could not be available.

A significant proportion of essential medicines that are registered have less than three products registered (38%, 45% and 36% for Kenya, Tanzania and Uganda respectively).

"Given that the World Health Organization recommends at least three different manufacturers per medicine to ensure a stable supply, registration of less than three products is insufficient," said Dr. Moses Ocan, a senior lecturer in the department of Pharmacology & Therapeutics at Makerere University College of Health Sciences and co-author of the research.

A sub-analysis of antimicrobials within the research showed that the

high registration of non-essential antibiotics in the three countries is likely to lead to inappropriate use and drive antimicrobial resistance. Dr. Ocan added, "There are thousands of antibiotic medicine products in the market. This is because manufacturers may apply for licenses for the same medicine in different doses and formulations. We found 2,310 products for the 21 most highly registered [antibiotics](#), of which only 46% were essential medicines."

Another of the researchers, Professor Allyson Pollock, Clinical Professor of Public Health at Newcastle University, said, "Over-registration of medicines, particularly non-essential medicines, diverts regulatory resources towards registering non-priority, and sometimes, clinically sub-optimal medicines. The East African Community Medicines Registration Harmonization Project has the potential to improve access to key medicines if registration of essential medicines is prioritized and registration of non-[essential medicines](#) is restricted."

**More information:** Lack of registration is limiting access to essential medicines in Kenya, Tanzania and Uganda, *Journal of the Royal Society of Medicine* (2023). [DOI: 10.1177/01410768231181263](https://doi.org/10.1177/01410768231181263)

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