

East African countries should prioritise their essential medicines for drug registration

By Allyson M Pollock, Moses Ocan & Petra Sevcikova

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The World Health Organisation (WHO) introduced an [essential medicine list](#) in 1977. The aim was to help countries prioritise which medicines to make available for public use. Every two years the WHO publishes a model list which countries use to develop national lists of essential medicines.



Antimicrobial resistance is a real threat.

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Most low- and middle-income countries have adopted and adapted the WHO model list concept and developed their own essential medicine lists in line with their disease and treatment priorities. These lists of a few hundred medicines make it easier for governments to choose what to procure from the many thousands of medicines on the market.

The lists are developed alongside standard treatment guidelines to help healthcare professionals prescribe the right medicines in the right doses for the right length of time. Therefore, essential medicine lists are an important tool for ensuring that the right medicines are available and are used in the right way.

But the lists are only part of the system. Medicines on the list also have to be registered for use in a country and the pharmaceutical industry has to apply to register its products. After approval by regulatory authorities, they are listed on national drug registers. But there appear to be mismatches between lists of essential medicines and lists of registered medicine products in some countries. One [study in Uganda](#) showed that almost half (49%) of essential medicines weren't registered for use in the country.

Looking to fill a gap in information about these mismatches, we conducted a [study](#) in Kenya, Uganda and Tanzania. We compared the antimicrobial products on national drug registers with those on the three countries' essential medicine lists.

We chose antimicrobials because antimicrobial resistance is a global problem. It develops when disease-causing organisms adapt to survive treatment with antimicrobial medicines, and as a result those medicines no longer work. Resistance is fuelled by inappropriate use of medicines: when the wrong medicine, dose or treatment length is used for a particular condition.

For these medicines, then, it's particularly important to be guided by lists that narrow down the thousands of existing products. And the right medicines must be made available through registration. If they are not available, people might die for want of treatment.

Comparing lists

We wanted to establish the extent to which medicines prioritised for use on the essential medicine lists are registered for use in Kenya, Tanzania and Uganda.

We found many antimicrobials on the essential medicine list of each country that were not registered for use. In Kenya, 33 of 160 (20.6%) of antimicrobial medicines on the essential list were not registered. For Uganda and Tanzania the proportions were 50 out of 187 (26.7%) and 52 out of 182 (28.6%) respectively. The medicines weren't registered because no manufacturer had successfully applied for a licence to market them.

Of equal concern is that we found hundreds of antimicrobial products on the register of each country which were not on the essential medicine lists. In Kenya only 36% of the 2,105 registered antimicrobial products corresponded to antimicrobials on the essential medicine list. In Uganda only 49% of the 1,563 registered antimicrobial products were essential medicine products and in Tanzania, only 47% of the 1,327 registered antimicrobial products were essential medicine products. Over half of all registered antimicrobial products, therefore, are non-essential.

In 2017 the WHO introduced a new classification system within the Essential Medicine Lists to help tackle antimicrobial resistance: the [AWaRe classification](#). It classifies antibiotics into three categories: Access, Watch and Reserve.

Access antibiotics are the treatments of choice for common infections and must be readily available. They are at low risk of causing antimicrobial resistance. *Watch* antibiotics come with a higher risk of causing resistance and should only be used in selected circumstances. *Reserve* antibiotics are last-resort options, only to be used once all other antibiotics have failed. These categories are used in health systems to decide where antibiotics should be available, for example in very basic healthcare centres or in hospitals.

We found that in all three countries we studied, the highest proportion of registered antibiotics were in the Access group, and the lowest proportion were in the Reserve group. This is as it should be.

Setting priorities

But the high numbers of non-essential antimicrobials registered for use are of great concern. Registered medicines which are not on the essential medicine lists are not included in treatment guidelines. They are likely to be used inappropriately and contribute to antimicrobial resistance. At the same time, the lack of registration of around three quarters of the antimicrobials listed on the essential medicine of each country is very worrying as these are vital for treating infections.

Governments should ensure that the regulatory agencies responsible for registering medicines prioritise and restrict the

registration of antimicrobials to only those that are on the lists of essential medicines. In tandem with standard treatment guidelines, this would help healthcare professionals to prescribe them appropriately. It would also ensure that priority medicines are available to the population.

Future work must also focus on updating essential medicines lists based on local antimicrobial resistance data and monitoring the use of registered antimicrobial medicines.

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ABOUT THE AUTHOR

Allyson M Pollock, professor of public health, Newcastle University; Moses Ocan, lecturer, Makerere University, and Petra Sevcikova, researcher, Newcastle University

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