

Facing up to reality: over-the-counter access to antibiotics in low-income and middle-income countries needs a paradigm shift in thinking



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Almost half of the global population do not have access to universal health coverage and the current shortfall of health-care professionals (including doctors and nurses) is estimated to reach a deficit of 11 million by 2030, disproportionately affecting low-income and middle-income countries (LMICs). Against this backdrop, of the 8 million deaths per year from bacterial sepsis worldwide, over 3 million are from treatable antibiotic-sensitive infections. This number suggests that access to antibiotics under the current model is insufficient. In many LMICs, over-the-counter antibiotic sellers that range from informal drug procurers to small-sized and medium-sized private pharmacies are the primary and most accessible care providers. Yet global health narratives, often shaped by the traditional doctor-led prescribing model, portray them as drivers of misuse rather than recognising them as politically and economically embedded actors that meet unmet health and antibiotic needs. In this Viewpoint, we argue that over-the-counter antibiotic sellers need to be integrated into a solution for antibiotic misuse and overuse, rather than being seen as part of the problem. Furthermore, we provide a framework with which to achieve integration, so that the concept of global health care for all becomes a reality.

Access to medicines depends on a continuum that covers the procurement of active pharmaceutical ingredients and manufacture of the medication to acquisition by the end user.¹ Along the pathway, numerous potential barriers exist that more disproportionately affect low-income and middle-income countries (LMICs), where weaker health systems, poor implementation of pharmaceutical regulations, and financial constraints are particularly acute.² The need for a prescription from a doctor or nurse, such as in the case of antibiotics, creates an additional barrier.

Sustainable access to effective antibiotics is central to the global response to antibiotic resistance. Attention has been firmly focused on the need for access to new antibiotics—discovery of which has been in decline for the last four decades³—to treat antibiotic-resistant bacterial infections, which, in 2021, were associated with 4·71 million of the 7·75 million deaths from bacterial sepsis.⁴ Less focus has been given to the inaccessibility of working existing antibiotics, which is an equally compelling challenge given that 3·04 million people died in 2021 with an antibiotic-sensitive bacterial infection, the majority of whom lived in LMICs.⁴ Medical factors—such as complications arising during appropriate antibiotic treatment, comorbidities, or late presentation of illness and a concomitant delay in treatment—undoubtedly contributed to some of these deaths. Similarly, proximal systemic factors in the supply chain (eg, inadequate or poor forecasting, suboptimal procurement models, distribution challenges, and stockouts) can also impact the supply of antibiotics to formal health-care facilities.¹ In addition, in 2021, over half of the global population (approximately 4·5 billion people) were not fully covered by essential health services, including antibiotic access.⁵ The insufficient numbers of antibiotic prescribers (doctors

and nurses) further limits access to antibiotics, and 2030 projections indicate that the global shortfall in health workforce will reach a deficit of 11 million.⁶ Moreover, the currently disproportionate distribution of professionally trained health-care workers to urban centres rather than semi-urban and rural areas of LMICs compounds challenges to accessing health care. Bridging this gap would take many years, if it is feasible at all.

Often, these realities—coupled with deficits in health infrastructure—mean that vulnerable people in LMICs cannot access prescriptions from a doctor or nurse. Without these prescriptions, these vulnerable populations rely on the over-the-counter (OTC) sale of antibiotics. Points of access for OTC sale of antibiotics vary between and within countries, and unregulated outlets can coexist within the formal health-care sector. For example, people seeking health care in India rely on retail pharmacies in urban settings and informal health-care providers in rural areas,^{7,8} and The Pharmacists Council of Nigeria licenses patent and proprietary medicine vendors to provide some forms of OTC medicines, but these vendors might dispense antibiotics without prescription and against pharmaceutical regulations.⁹ A similar situation to the Nigerian system exists in Ghana.¹⁰ South Africa follows the prescription-only model and OTC antibiotic sales were thought to be absent until a recent study found that some informal township pharmacies were providing antibiotics without a prescription.¹¹ A systematic review of 162 studies of non-prescription antibiotic dispensing in community pharmacies across 52 countries found that around 63% (pooled prevalence 63·4% [95% CI 59·6–67·1]) of pharmacies were dispensing antibiotics without a prescription.¹²

Although 166 WHO member states have regulations restricting the sale of antibiotics without a prescription,¹³

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the use of OTC antibiotics remains widespread. This persistence highlights both implementation challenges and regulatory designs that are misaligned with local health system realities. Acknowledging these challenges, WHO has decided not to proceed with its proposed strategy to phase out OTC antibiotic sales.¹⁴ Instead, WHO has called upon countries to strengthen the evidence base for locally tailored interventions through operational and implementation research that accounts for the social, political, and economic contexts in which these practices function.

The persistence of OTC antibiotic sales in South Africa's independent pharmacies is partly rooted in a commercial-driven business model, where antibiotic dispensing is a revenue stream rather than a stewardship priority.¹¹ This finding aligns with discoveries from low-resource settings globally, where antibiotics are frequently viewed as commodities rather than restricted therapeutics (unpublished). Although pharmacists recognise their stewardship role, structural barriers (eg, inadequate public health-care access and socioeconomic disparities) force a precarious balance between ethical practice and economic survival. In LMICs, the spectrum of OTC antibiotic sellers ranges from highly trained pharmacists practising in tightly regulated environments to informal medicine shop operators with varying levels of health-care knowledge and training. Strengthening the regulatory and educational distinction between these groups could ensure that any move towards formalising OTC antibiotic dispensing is coupled with minimum competency and stewardship standards. In South Africa, both pharmacy support personnel and pharmacists are actively involved in dispensing, but only pharmacists are legally authorised to provide pharmaceutical care and clinical decision making related to antibiotics.

Some countries are starting to formalise the OTC sales of selected antibiotics. Since 2024, the Pharmacy First programme in England allows pharmacists to prescribe and dispense antibiotics and other prescription-only medicines for seven of the commonest community infections (ie, sinusitis, sore throat, earache, infected insect bite, impetigo, shingles, and uncomplicated urinary tract infections in women [younger than 65 years]) without the need for an appointment with or prescription from a general practitioner.¹⁵ In LMICs, this kind of task-shifting for the management of infectious diseases is not uncommon, as shown by HIV¹⁶ and tuberculosis¹⁷ programmes where nurses play a key role. In Ghana, OTC sellers have been trained to use rapid diagnostic test (RDT) kits for malaria to test clients who have symptoms of malaria before dispensing antimalarials.¹⁸ However, the Ministry of Health in Ghana has shown no interest in training OTC medicine sellers to dispense antibiotics more effectively. In India, the medical community has resisted both the dispensing of essential medicines by non-medically qualified providers and the fostering of private, mutually

supportive relationships to train and support these providers.⁸

Considering the current realities faced in delivering access to antibiotics in LMICs, we suggest that the prescription-only model for antibiotic access for end users is untenable, and that, rather than phasing out informal sales of OTC antibiotics or vilifying informal sellers as drivers of antibiotic resistance, the global health community needs a shift that situates these providers as part of a solution to accessing quality-assured antibiotics at primary health-care level. A recent pilot study in one of South Africa's rural provinces exemplifies how convenience drives OTC antibiotic access, finding that 75% of participants sought help for their infections from community pharmacies due to convenience, with travel distances to under-resourced clinics being cited as an important factor in their pathway to accessing antibiotics.¹⁹

To make OTC sellers part of the solution, the global health community will need to provide the tools to transition a potentially unsafe practice into a safer one. The toolkit should contain four main components.

First, investment is needed in training pharmacists (both informal and formal), OTC dispensers, and other stakeholders (such as community health workers, who are a key source of access to health care in many LMICs)²⁰ to use simple, algorithmic guidelines for a number of common, high-volume primary care infection syndromes where antibiotic use is commonly inappropriate, such as acute respiratory infection and non-bloody diarrhoea. Examples such as South Africa's Practical Approach to Care Kit²¹ or WHO and UNICEF's Integrated Management of Childhood Illness²² could be used as a template to build on. Both examples have the added advantage of directing users along pathways that specifically advise where antibiotic use is appropriate. Potential algorithms need to have clear diagnostic and antibiotic recommendation criteria, provide practical and stepped care pathways culminating in a referral to a medical facility when appropriate, and be co-designed with local experts to ensure that context is appreciated and buy-in by key stakeholders (ie, health-care professionals, administrators, and local and national governments) is optimised. In addition, ensuring that contextually relevant education and communication strategies are developed at access sites will be a key component to facilitating safe access. Clear procedures for referral and teleconsultation with leading health-care experts should be factored in when symptoms fall outside of specified guidelines. Due to variation in primary care structures and provision across LMICs, randomised controlled trials are needed to inform the optimal design and conduct of educational interventions for OTC antibiotic provision to improve antibiotic use in LMICs.

Second, access to point-of-care (POC) RDTs should facilitate stewardship. RDTs for malaria are crucial to the management of undifferentiated fever in

malaria-endemic countries and have been implemented both in formal health-care settings and community-based programmes that involve community health workers and drug shop vendors.²³ However, implementing and increasing the availability of RDTs for malaria and undifferentiated fever has unfortunately increased antibiotic prescribing in public and private health-care settings.²⁴ To combat this increase, the use of other biomarkers (such as C-reactive protein [CRP], which is generally regarded as a non-specific marker of inflammation) have been shown in both high-income countries²⁵ and LMICs—including Viet Nam,²⁶ Nigeria,²⁷ and Kyrgyzstan²⁸—to enable the safe withholding of antibiotics in patients presenting with respiratory tract infections, including at community pharmacies. Economic studies support POC CRP testing alongside RDTs for malaria as being cost-effective.²⁹ As technologies continue to develop, other POC RDTs could be included in algorithms for managing infections.

The third component of the toolkit would be a targeted number of quality-assured and affordable Access antibiotics, as defined by the WHO Access, Watch, and Reserve (AWaRe) classification.^{30,31} The WHO AWaRe antibiotic book advises Access antibiotics for the treatment of eight of the ten most common primary care infections (excluding bronchitis), including the different causes of respiratory tract infection presentations (ie, acute exacerbations of chronic obstructive pulmonary disease and community-acquired pneumonia).³² Only acute bloody diarrhoea requires a Watch antibiotic as a first-line treatment. Moreover, amoxicillin with or without clavulanate is recommended as a first-line Access treatment for 8 of the 10 most common primary care infections that require an antibiotic. This recommendation allows regulatory and monitoring bodies to focus on just two or three quality-assured Access antibiotics for OTC dispensing in combination with POC tests. This number could be expanded if needed as more specialised POC RDTs are developed. To limit OTC antibiotic sales purely for revenue, incentivising pharmacies to participate in stewardship campaigns and antibiotic data reporting could be linked to health system or community recognition. This motivation could form part of a wider effort that includes peer support, education on antibiotic stewardship, recognition, and community engagement.^{33,34} Furthermore, a promising avenue for enhancing antibiotic literacy and responsible use is the deployment of QR codes linked to short, multilingual video instructions proposed by the ABACUS project.³⁵ These QR codes could be embedded on antibiotic packaging or displayed prominently in shops that provide OTC medication, offering clear guidance on dosage, duration, and indications for use. By leveraging mobile technology, these interventions could overcome language barriers and provide consistent messaging across diverse populations. This approach not only empowers

consumers but also supports OTC sellers in making informed decisions and reducing reliance on verbal instructions alone.

The sale of substandard and falsified OTC antibiotics is a major concern in LMICs, where these medications are estimated to account for 10% of all medicines sold. A review of 106 prevalence surveys on substandard and falsified antibiotics from 67 countries that tested 13 555 samples found that 17.4% of antibiotics failed one or more quality-assurance assays, with the highest failure rates seen in Africa, Asia, and the Americas.³⁶ Local or national procurement and regulatory agencies ensuring access to a low number of quality-assured Access antibiotics for OTC sales need to be part of the programme.

Finally, a monitoring and evaluation programme will need to be initiated to ensure algorithm compliance, the correct procurement of quality-assured antibiotics and RDTs (ideally produced locally),³⁷ and compliance with stepped-care practices, including teleconsultations and that patients are referred to the formal health system sectors and providers when their medical condition does not qualify them for OTC antibiotic access. This programme could be managed through regulatory agencies with record-keeping and audit tools (possibly digital), facilitating regulatory oversight and stewardship monitoring. However, we appreciate that as OTC access is markedly heterogeneous,³⁸ design flexibility will be needed to accommodate this component of the model.

South Africa's legislative framework offers key insights for LMICs considering pharmacist-prescribing models. Although primary care drug therapy training for pharmacists has existed since 2007, recent regulatory updates (2021–23) have expanded the scope of this training to allow for pharmacists to formally authorise and order some diagnostic tests. Pharmacists have also been authorised to prescribe schedule 3 and schedule 4 drugs, which are prescription-only medicines. Schedule 3 drugs include many antibiotics, and schedule 4 drugs include a broader range of prescription-only medicines. Such prescribing is in line with the Primary Health Care Standard Treatment Guidelines for defined conditions under Section 22A (15) of the Medicines Act.³⁹ However, systemic barriers persist. In 2023, the Pretoria High Court upheld the South African Pharmacy Council's authority to implement the Pharmacist-Initiated Management of Antiretroviral Therapy programme, which enables accredited pharmacists to prescribe first-line HIV treatment.⁴⁰ This implementation had been challenged by the Independent Practitioners Association Foundation, which argued that the programme encroached on the scope of medical practitioners. The court action underscores entrenched resistance to pharmacist-led care, despite evidence of improved access in rural areas.⁴⁰ This inconsistency shows that, even with established training frameworks and legislative support, professional hierarchies and regulatory inertia can stall implementation.

For LMICs, this example emphasises the need for cohesive stakeholder engagement and that systemic inequities need to be addressed before scaling OTC antibiotic models. Implementation research designs would therefore need to integrate political economy frameworks to understand how power, interests, institutions, and historical trajectories might constrain or enable policy implementation and change in relation to OTC antibiotic sales and sellers.

We recognise the arguments that OTC antibiotic sales can cause harm in terms of patient outcomes, increase inappropriate antibiotic use, and drive antibiotic resistance. However, given that OTC antibiotic sales are already occurring with minimal oversight, implementing our recommended programme would likely be less harmful than the current situation. Rather than continuing to disregard the unrestricted availability of antibiotics in many settings, a targeted intervention that includes OTC sellers should focus on infection presentations (eg, acute respiratory illness and non-bloody diarrhoea) where evidence shows that antibiotics can be withheld for those meeting the inclusion criteria.^{26–28} This intervention could be expanded as evidence accrues for POC RDTs being able to direct the treatment of infection syndromes (eg, biomarkers or aetiological tests), such as POC urinary tract infection diagnostics. Improving public awareness relating to the appropriate use of antibiotics would complement our proposed intervention and should be considered when drawing up revised national action plans.

Paragraph 14 of the UN General Assembly 2024 political declaration of the high-level meeting on antimicrobial resistance states that signatories “acknowledge the need to leave no one behind and reach the furthest behind first, and to ensure equitable and timely access to quality essential healthcare services and safe, effective, quality, affordable essential medicines including antimicrobials”.⁴¹ Faced with the realities of LMIC health systems, it is time for a shift in thinking and attitude towards OTC antibiotic sellers, and a focused set of actions to make OTC antibiotic sellers part of the solution by enhancing the quality of their dispensing if we are to fulfil this political ideal.

Contributors

MMe conceived this Viewpoint and wrote the first draft. SA-A, NS, HW, MMp, and MG provided input, comments, and edits to all subsequent drafts, and approved the decision to submit for publication.

Declaration of interests

MaM has received payment from Combating Antibiotic Resistant Bacteria and has received travel expenses from the European Society for Clinical Microbiology and Infectious Diseases. SA-A has received travel expenses from the European Society for Clinical Microbiology and Infectious Diseases. HW has received travel expenses from the European Society for Clinical Microbiology and Infectious Diseases; has received consulting fees from WHO; holds a position as a member of the Strategic Advisory Group on Antimicrobial Resistance at WHO; and holds a position as a board member for the International Society of Antimicrobial Chemotherapy and the Dutch Society of Medical Microbiology. MG has received travel expenses from the Royal Society

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