

# Over-the-counter sales of antibiotics: a call to action to ensure access and prevent excess



Over-the-counter (OTC) sale of antibiotics refers to the practice of selling antibiotics without a valid prescription from a health-care professional authorised to issue it. OTC sales are a global concern, as acknowledged in the global action plan on antimicrobial resistance,<sup>1</sup> the report of the Inter-Agency Coordination Group on antimicrobial resistance,<sup>2</sup> and the recently launched people-centred approach to addressing antimicrobial resistance in human health.<sup>3</sup>

Typically, antibiotics are prescription-only medications because their misuse or overuse can contribute to the spread of antimicrobial resistance and they have potential for drug interactions and serious adverse effects. However, in some countries, certain antibiotics are still available OTC for specific conditions. Additionally, the availability of antibiotics without a prescription can vary by country and region, with a generally higher prevalence documented in low-income and middle-income countries.<sup>4</sup> Although countries have established various measures to control the sale of antibiotics, the main challenge is enforcement. On the demand side, self-diagnosis and self-medication are driven by lack of knowledge on appropriate use of antibiotics and lack of access to health care.<sup>5</sup> The availability of OTC antibiotics is a global concern as it can lead to inappropriate use, incomplete treatment, and antimicrobial resistance.

In May, 2023, the Quadripartite Organizations (the UN Food and Agriculture Organization, the UN Environment Programme, WHO, and the World Organisation for Animal Health) convened the first Global Joint Summit of Human and Veterinary Medicines Regulatory Authorities to Preserve Antimicrobials.<sup>6</sup> One of its objectives was to foster innovative, smart solutions to reduce OTC sales of antibiotics. Concurrently, WHO launched an electronic consultation and later convened a consultation of key stakeholders to discuss possible interventions including the feasibility of a global campaign to phase out OTC sales of antibiotics.<sup>7</sup>

Furthermore, the Global Database for Tracking Antimicrobial Resistance Country Self-Assessment Survey<sup>8</sup> reported that, out of 177 surveyed countries, 160 declared that they have regulations or laws on

prescription and sales of antibiotics for human use. The prevalence of OTC antibiotics varies considerably, even within the same country, and between urban and rural areas, though its prevalence is higher in low-income and middle-income country settings.<sup>9</sup>

There were several key findings from the WHO global consultation to phase out OTC antibiotics.<sup>7</sup> Access to free, high-quality primary health care, the availability of universal health coverage, and a trusted public health system are critical aspects across all countries influencing patients' health-care-seeking behaviour. Inefficiencies in the public health-care system, time, and convenience in accessing pharmacies or other drug sellers all contribute substantially to the prevalence of self-medication. A substantial portion of sales of antibiotics in low-income and middle-income countries still occurs in the private health sector, where there is variable oversight.<sup>7</sup> Additionally, unregistered pharmacies and informal drug sellers operate beyond the reach of regulatory authorities, yet serve as the primary and, in some cases, the sole point of access to health care for poor and disadvantaged groups, particularly in contexts with poor access to health services.<sup>10</sup>

Balancing access to antibiotics for those in need and curbing excessive use is crucial and requires a comprehensive approach that is at the base of well-functioning health-care systems. In low-income and middle-income country settings, lack of access to appropriate antibiotics is a significant driver for mortality in infectious diseases. Therefore, completely stopping all OTC sales, without robust health systems in place which can ensure effective treatment for infectious diseases for all, can be problematic. In many low-income and middle-income countries, community health-care workers play a crucial role in appropriate use of antibiotics, or in some cases are the sole point of access to health-care information or treatment for infectious diseases, especially where health-care infrastructures are poor.<sup>7</sup>

Due to the visibility of the issue and the interest from many key stakeholders, there is a strong need for country-level action to reduce OTC antibiotic use.

Notably, interventions should be multifaceted and complementary. There is no single right solution to the issue and the approach would likely need to be multidisciplinary and iterated depending on country and regional contexts and should ensure sustainable access to antibiotics.

Several interventions have been implemented globally to reduce OTC antibiotic sales. Some interventions have targeted the supply of antibiotics or the strengthening and enforcement of regulations, to increase inspection capacity as well as regulations for pharmacies and drug sellers' licensing. Others have focused on reducing inappropriate demand which generally require long-term and sustained behaviour change interventions through community engagement. However, more operational and implementation research is required to better understand the impact of such interventions in different settings.

Acknowledging the varying systemic factors between countries, including health-care delivery capacity and antibiotic access, a decision was made to not move forward with a WHO global campaign at this stage. The UN General Assembly High-Level Meeting on antimicrobial resistance in September, 2024, poses a timely opportunity to mobilise political commitments and financial resources for such an issue that is severely underfunded. WHO will nevertheless continue to encourage and collaborate with countries to prioritise the issue in respective national action plans on antimicrobial resistance.

We declare no competing interests.

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