

Global campaign to phase out over-the-counter sales of antibiotics Meeting report

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World Health
Organization

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Acknowledgements

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Abbreviations

AMR	antimicrobial resistance
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AWaRe	access, watch, reserve
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LMIC	low-and middle-income countries
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OTC	over the counter
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SWOT	strengths, weaknesses, opportunities and threats
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1 Introduction

Sales of antibiotics without a prescription, commonly referred to as over-the-counter (OTC) sales, are a global concern, as acknowledged in the Global Action Plan on Antimicrobial Resistance (AMR) (1), the report of the Inter-agency coordination group on AMR (2) and the recently launched People-centred approach to addressing AMR in human health (3). The extent of OTC antibiotic sales varies regionally, with a generally higher prevalence documented in low- and middle-income countries (LMIC) (4). Various factors have been identified that contribute to OTC antibiotic sales. Although they may be specific to certain contexts, common challenges have been identified in LMICs.

As part of work to reduce the global burden of AMR, in 2022, the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, WHO and the World Organisation for Animal Health, which constitute the Quadripartite, hosted a global consultation, which identified “regulation and enforcement of antibiotic sales without prescription” as one of four priorities for joint work to raise awareness (5). Subsequently, in 2023, the Quadripartite convened the first Global Joint Summit of Human and Veterinary Medicines Regulatory Authorities to Preserve Antimicrobials (6). One of its objectives was to foster innovative, “smart” solutions to reducing OTC sales of antibiotics. Concurrently, WHO launched an electronic consultation of key stakeholders to discuss possible interventions and a campaign to phase out OTC sales of antibiotics. To investigate the feasibility of such a campaign, WHO convened a 2-day meeting, which took place on 1 and 2 November 2023, at WHO headquarters. The meeting brought together 21 participants from civil society, academia, representatives from WHO headquarters and regional offices and other experts in the field.

2 Meeting objectives

The objectives of the meeting were to:

- review the findings of mapping policies on dispensing antibiotics without a prescription in 20 countries; and
- build consensus on moving forward with a campaign and, if that was decided, to agree on the concept and expected outcomes of such a campaign.

3 Methods

The meeting comprised presentations followed by facilitated group discussions to address the feasibility of a WHO-led OTC campaign and to make recommendations for developing such a campaign. Group chairs and rapporteurs were given working guidelines and templates for reporting on the deliberations of each group. Three documents were prepared for participants and provided before the meeting: an analysis of OTC antibiotic sale practices in the context of AMR, including its drivers and challenges; a scoping review of policies and interventions in 36 countries to phase out OTC antibiotic sales; and a review of policies, regulations and interventions to phase out OTC antibiotics in 20 countries. These provided participants with background information for discussion in the groups. On the first day, participants identified strengths, weaknesses, opportunities and threats (SWOT) to such a global campaign and enabling actions. On the second day, participants discussed the issue of reducing excess use of antibiotics while guaranteeing access to essential antibiotics, particularly in resource-limited health systems. Participants then made recommendations for planning the campaign.

4 Priorities for action

The group identified the following priorities for action.

- Provide clear definitions: define OTC in the contexts in which the campaign is to be conducted.
- Adapt the campaign for inclusion in other campaigns, such as for universal health coverage, primary health care and appropriate use of medicines, that could be complementary.
- Address the campaign to policy-makers and other stakeholders to influence policy and secure financing by developing a brief document based on case studies of successful initiatives, to encourage political commitment to the issue.
- Strengthen professional capacity and provide appropriate incentives to pharmacists, such as mandatory education on antimicrobial stewardship and promoting behaviour change and understanding the reasons (such as financial incentives) for OTC sales from pharmacists' perspective.
- Strengthen regulation and oversight of antibiotic distribution and sale by identifying gaps in OTC regulations, collecting evidence on possible solutions and better understanding the requirements of government regulators for implementing regulations, including increasing the capacity of regulators for better oversight of the antibiotic supply chain and points of sale.
- Understand the impact of pharmaceutical industry practices on the behaviour of retailers of antibiotics and the role of incentives for supply, manufacture, distribution and OTC sales from their point of view.
- Plan a campaign that is inclusive, ensuring that it informs stakeholders, including patients, the public and health-care providers, to garner support for the proposed actions.
- Design a creative, engaging campaign, with interactive messages on the basics of AMR.
- Focus the campaign on regions that have high OTC sales, even if they have good access, as access can differ widely even in a national context and influence the demand for OTC antibiotics. Access to health care should be documented with standard metrics (e.g. the number of doctors per 10 000 population or percentage of out-of-pocket expenditure).

5 Analysis of strengths, weaknesses, opportunities and threats of the campaign

The strengths of the campaign are:

- **an acknowledged problem:** recognition in the Global Action Plan on AMR that OTC sales of antibiotics should be addressed;
- **working with health-care workers:** health-care workers such as pharmacists are already actively engaged and interested in AMR;
- **social media:** use of social media channels for promoting AMR education, including awareness of the risks associated with antibiotic self-medication ;
- **legal and regulatory provisions:** existing laws and regulations to stop OTC sales of antibiotics that could be used as a basis for a campaign;
- **implemented or partially implemented interventions:** reference to previous pharmacy prescription registries, electronic prescriptions, surveys and other relevant interventions;
- **valuable resources:** use of resources such as the “access, watch, reserve” (AWaRe) book (7), the WHO Model List of Essential Medicine (8), People-centred approach (3), other global and regional guidelines on responsible prescribing and national action plans with the objective of phasing out OTC sales of antibiotics; and
- **training programmes:** such as the WHO toolkit on Antimicrobial stewardship programmes in health-care facilities in LMICs (9) and Policy guidance on antimicrobial stewardship (10) for pharmacists and other health-care professionals.

The potential weaknesses of the campaign are:

- **systemic factors:** including health-care delivery capacity and limited resources (such as shortages of medicines, doctors, pharmacists), antibiotic access, the segmented nature of AMR (such as infection prevention and control, water, sanitation, hygiene, vaccines), variable oversight of private health systems and outdated lists of essential medicines that are not aligned with the AWaRe antibiotic book;
- **regulatory capacity:** variable regulatory capacity for oversight of pharmacies’ licenses and retail and on-line antibiotic sales;
- **regulations and policies for dispensing antibiotics:** not all countries have regulations to require that antibiotics be sold only with a valid medical prescription, and some regulations require revision or updating;
- **informal vendors:** informal drug sellers and circulation of substandard and falsified medicines;
- **awareness and behaviour:** even health-care professionals, including pharmacists, are insufficiently aware of AMR, regulations for prescribing antibiotics and the AWaRe book, and many populations are insufficiently aware of AMR and the risks of self-medication with antibiotics;
- **stigmatization of some diseases:** some infectious diseases (such as urinary tract and sexually transmitted infections) may be socially stigmatized, prompting people to seek informal treatment;
- **insufficient evidence:** difficulty in measuring impact due to lack of normative guidance on situations in LMICs, incomplete understanding of the positive and negative impacts of interventions against OTC antibiotic sales and fragmented data on the burden of AMR in communities;

- **conflicting messaging on antibiotic use:** including permitted use of non-prescription antibiotics by minimally trained community health workers, such as in integrated management of childhood illnesses and syndromic management of sexually transmitted infections, which creates confusion in communities about whether a prescription is required for antibiotics; and
- **focus only on OTC sales of antibiotics for use in humans:** which could diminish the significance and importance of also limiting OTC antibiotic sales for animal health.

The opportunities for conducting the campaign are:

- **parliamentarians, civil society and pharmacists' associations:** engaging these networks to create opportunities for collaboration and support;
- **existing initiatives and campaigns:** leveraging campaigns and initiatives such as the World AMR Awareness Week, the recently established WHO taskforce of AMR survivors and the Quadripartite Working Group on Youth Engagement for AMR as well as the Regulatory Agencies' Global Network against AMR to enhance collective action;
- **technology options:** using digital tools to track movement of medicines in supply chains to ensure sale only with a valid prescription to ensure accountability, especially when regulatory capacity is limited;
- **public awareness of infectious diseases:** ensuring heightened public awareness of infectious diseases and basic health measures;
- **United Nations General Assembly 2024 high-level meeting on AMR and the fourth high-level Ministerial Conference on AMR:** leveraging the United Nations General Assembly, the high-level ministerial meeting and other events on AMR in 2024 as platforms for drawing politicians' attention to the problem of OTC sales of antibiotics.

The threats to the campaign are:

- **competing priorities:** funding, political commitment and stakeholder coordination for AMR interventions, including correcting the view that AMR is an issue that affects only health and science rather than a threat to development;
- **no alternative solutions:** lack of solutions to accessing antibiotics once OTC sales are phased out; viable alternatives must be found before banning such sales;
- **resistance from the pharmaceutical industry:** vested interest of the pharmaceutical industry in promoting OTC sales to increase profits, rather than preventing misuse and overuse of antibiotics;
- **health systems strengthening:** insufficiently resourced health systems reducing access to good-quality health care for infectious diseases, driving people to seek informal or poor-quality sources of care;
- **political instability and conflicts:** long-term conflicts and political instability weakening health systems and diluting efforts to control AMR in regions with the additional burden of health care for refugees and internally displaced populations, who often rely on informal sellers to access medicines;
- **lack of societal trust in public health systems:** reducing health care-seeking and vaccine acceptance and contributing to use of informal systems, usually outside regulatory control, including because of stigmatization and discrimination;
- **many target audiences:** health-care workers, including pharmacists, patients, regulators, pharmaceutical associations and others are potential targets for this campaign, and a tailored approach is necessary to avoid diluting the campaign messages;
- **lack of dedicated funding:** particularly for national advocacy campaigns in LMICs; resources for launching and sustaining a campaign are critical; and
- **difficulty in sustaining the campaign:** especially in settings in which data on antibiotic consumption are not available and feedback on the impact of the campaign is difficult to obtain.

6 Reflections on access to versus excessive use of antibiotics

In the intricate landscape of access to health care, many complex issues and both systemic and individual challenges drive OTC sales of antibiotics. The participants made recommendations to bridge the gap between access to and excessive use of antibiotics

Gaps and challenges

- OTC antibiotic sales have become a makeshift means to ensure access to medicines in inefficient or inadequate health systems.
- Inadequate formal health-care infrastructure impels individuals to seek quick solutions independently, especially for non-life-threatening conditions that do not require hospitalization.
- The convenience and accessibility of OTC purchase of antibiotics makes them a much easier option than a doctor's consultation in many settings, including cost and time for travel to a health-care facility.
- The potential risks and consequences of self-medication are significant but are not widely known by the public. Often, individuals rely on their experience and their research to request specific products and treatments.
- In rural and suburban settings, antibiotics sold OTC at community pharmacies and by informal drug sellers are often the first point of access.
- Profound disparities in health care make OTC options a lifeline in resource-challenged regions.

Potential campaign framework

- The campaign could focus on “reserve and watch” antibiotics to ensure that they are not dispensed anywhere without a prescription, as these antibiotics have the highest potential for inducing resistance, and “access” antibiotics can be used in outpatient settings to treat most bacterial infections.
- The campaign could adjust its messages and recommendations to each context. Settings with ready access to prescribers might also advocate for restrictions on OTC sale of “access” antibiotics in addition to “watch and reserve” antibiotics after thorough evaluation of the impact of the restrictions on vulnerable populations. Settings in which access to prescribers is limited could exclude advocacy for restricting OTC sale of “access” antibiotics, given the likelihood of increased harm due lack of access to these medicines.
- The campaign should focus on training and providing recommendations for alternative means for dispensing antibiotics, as OTC sales may be the only option in some settings. Community health-care workers and pharmacists should be trained in appropriate use of antibiotics in community-acquired infections, such as uncomplicated urinary tract infections and upper respiratory tract infections, acute diarrhoea and simple wound infection.
- The campaign should advocate for prevention of antibiotics reaching informal markets and roadside vendors, especially in urban and suburban settings, by increasing the accountability of pharmaceutical companies and stronger oversight by regulatory systems. As sales of antibiotics by untrained vendors cannot be measured or monitored, the practice should be phased out or formalized and the vendors made accountable.
- Although supply-side interventions are more feasible in the short-term, patient engagement and education on appropriate use of antibiotics and AMR should continue, as this may be the key to a sustainable reduction or end to OTC sales of antibiotics.

7 Conclusions and general recommendations

Participants agreed that a WHO-led campaign should be developed. Countries should foster active engagement but tailor the campaign to different populations, such as parliamentarians, pharmacists' associations and civil society. As the issue is complex, and there are regional differences in OTC dispensing of antibiotics, health systems and the stakeholders involved, there was agreement that a stepwise approach would be suitable. The following recommendations were proposed for planning and designing a campaign.

- 1 **Select countries:** Instead of immediately launching a global campaign, the campaign could be pilot-tested in a few countries in which OTC sale of antibiotics is perceived as a significant problem and the country wishes to intervene. The campaign could be scaled up later according to this experience.
- 2 **Systematically collect evidence on OTC practices in countries, with a clear, concise definition of OTC sales:** Define and build consensus on a definition of OTC to ensure clarity in the campaign and its messaging; and collect evidence of practices and activities related to OTC sales of antibiotics, including revenue, through key informant interviews, to complement the initial desk review of 20 countries. This information could be used to design the campaign and measure its impact.
- 3 **Support countries in developing a context-appropriate campaign on OTC sales of antibiotics:** Develop a toolkit of options for campaign messages, targets and interventions for different audiences so that countries can tailor their campaign to their context. The toolkit could include examples of successful interventions to limit OTC sales. Campaign materials should be accessible and practical to use by both high-level bodies (such as a national One Health and AMR steering or coordinating committee that includes the ministry of health) and users in rural areas. The campaign should be tailored to the health system and address appropriate targets.
- 4 **Engage a diverse group of stakeholders:** Encourage active targeting and involvement of policy-makers, parliamentarians and related stakeholders who ultimately change policy in designing and promoting the campaign and building support for its wider implementation. Any existing relations of WHO with such stakeholders could be used. Also, involve pharmacist associations in developing tailored interventions to improve pharmacists' knowledge and agency in improving OTC dispensing of antibiotics, and include messages for pharmacists about safeguarding "watch and reserve" antibiotics. Target the pharmaceutical industry and its associations with ad-hoc advocacy on OTC sales of antibiotics and on transparency in their manufacture, supply and distribution. Civil society groups can be engaged in disseminating and amplifying messages about phasing out OTC sales of antibiotic.
- 5 **Preserve "watch and reserve" antibiotics:** initially, focus the campaign on restricting OTC sales of "reserve and watch" antibiotics, as these antibiotics are more likely to induce resistance in bacteria than "access" antibiotics, to ensure that "reserve and watch" antibiotics are not dispensed anywhere without a prescription, in line with recommendations for WHO lists of essential medicines, the AWaRe book and the People-centred approach. Tiered dispensing should thus be advocated.
- 6 **Strengthen behavioural and educational initiatives:** Ensure that health-care workers, including pharmacists and other dispensers, are well trained in AMR and optimal antibiotic use with guidance such as the AWaRe book.
- 7 **Integrate the campaign into the national action plan and the United Nations General Assembly high-level meeting:** Frame the campaign as part of the national action plan to emphasize its importance for continuity and alignment with other strategies, and explore possible inclusion in the political declaration and targets of the high-level meeting at the United Nations General Assembly and the outcome document of the fourth international ministerial conference on antimicrobial resistance in 2024.
- 8 **Advocate for regulatory strengthening:** Ensure appropriate handling and distribution and broader accountability in the antibiotic supply chain. National regulatory systems should be made accountable for effective oversight of the supply chain and sales, including updating lists of essential medicines if necessary, particularly in countries with strong health systems. Evaluate the wording and impact of regulations and improve the wording if necessary. Ensure that the regulation is disseminated and readily accessible.
- 9 **Analyse and understand the value chain for antibiotics in countries:** Such an analysis can provide insights into local production or importation and the movement of products on the market, add value at various levels and incentives for sales and indicate opportunities to prevent antibiotics from reaching informal markets.

References

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Annex 1. Agenda

▼ DAY 1		
Time		Chair/Speakers
9:30–9:45	Introductions	All
9:45–9:50	A personal story from a member of the WHO AMR Survivors' Taskforce	Nour Shamas , Consultant, WHO EMRO
9:50–9:55	Welcome remarks	Dr Haileyesus Getahun , Director, Global Coordination and Partnership Department, WHO
9:55–10:00	Setting the scene	Thomas Joseph , Unit Head, AMR, WHO
10:00–11:00	Session I: Key findings from the policy mapping review <ul style="list-style-type: none"> • Plenary discussion 	Francesca Chiara , Consultant, AMR, WHO
11:00–11:30	Coffee break	
11:30–12:00	Session II: Campaign concept	Mimi Melles-Brewer , Technical officer, AMR, WHO
12:00–13:15	Lunch	
13:15–14:00	Campaign concept <ul style="list-style-type: none"> • Group work 	Group rapporteurs
14:00–14:45	Campaign concept <ul style="list-style-type: none"> • Plenary report back 	Group rapporteurs
14:4–15:15	Coffee break	
15:15–17:00	Session III: SWOT analysis <ul style="list-style-type: none"> • Group work 	Group rapporteurs
▼ DAY 2		
Time		Chair/Speakers
9:30–10:00	SWOT analysis <ul style="list-style-type: none"> • Plenary report back 	Group rapporteurs
10:00–10:15	Session IV: Ensuring access while preventing excess	Dr Clare Chandler , Professor, London School Hygiene & Tropical Medicine
10:15–11:00	Ensuring access while preventing excess <ul style="list-style-type: none"> • Group work 	Group rapporteurs
11:00–11:30	Coffee break	
11:30–12:15	Ensuring access while preventing excess <ul style="list-style-type: none"> • Plenary report back 	Group rapporteurs
12:15–13:30	Lunch	
13:30–14:15	Session V: What are the key issues in taking this forward? <ul style="list-style-type: none"> • Group work 	Group rapporteurs
14:15–15:15	What are the key issues in taking this forward? <ul style="list-style-type: none"> • Plenary report back 	Group rapporteurs
15:15–15:20	Wrap-up	

Annex 2. List of Participants

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