

POSITION PAPER

UN guidance on antimicrobial resistance (AMR)

Proposal of the UN Political Declaration on AMR
to regulate sales of over-the-counter antimicrobials

July 2024



Contents

4 Overview

6 Rationale

6 Health systems burden

7 Individual health and financial outcomes

8 Public health implications

9 Role of pharmacists in correct use

9 Health literacy

10 Conclusion





Overview

The Global Self-Care Federation (GSCF) and member organizations fully support the public health goal of containing antimicrobial resistance (AMR), the World Health Organization’s Global Strategy on Infection Prevention and Control (IPC) aimed at addressing drug-resistant bacterial infections in the human and animal health sector, and global efforts towards achieving a consensual, concise, and action-oriented Political Declaration on AMR at the High-level Meeting at the UN General Assembly in September this year.

However, we are concerned about the consequences of the endorsement of the Political Declaration on AMR (2024) on proposed increased regulation of over-the-counter (OTC) antimicrobials to reduce the burden of AMR:

“ **Acknowledge the drivers of antimicrobial resistance, including lack of regulation of over-the-counter use of antimicrobials¹.** ”

Antimicrobials are used in a wide range of household products including soaps, disinfectants, wound dressings, and oral hygiene products. They are used as preservatives in products such as foods, cosmetics and medicines. In addition, antimicrobials are found in medicines approved for non-prescription use. The current wording of the draft Political Declaration could therefore result in **restricted access** to these self-care products (for example by switching them to prescription status) which will have a negative impact on individual health outcomes and place an additional burden on health professionals and national health systems overall. OTC medicines containing “antimicrobials” include:



Antifungals

Treatments for athlete’s foot, intertrigo, dandruff, thrush, fungal nail



Antiseptics

Treatments for wounds, sore throat



Antivirals

Treatments for cold sores, genital warts



Antibiotics

Topical treatments for mitigating infection of cuts, scrapes, burns

¹ United Nations. (2024). Political Declaration of the High-level Meeting on Antimicrobial Resistance.



Before being approved for sale, non-prescription medicines are evaluated by a scientific panel who consider resistance risk as part of their assessment.

Conversely, in some countries, there can be misuse of prescription products, which may result in prescription medicines being supplied or sold to a consumer illegally, without proper prescription, diagnosis or healthcare professional interaction. This can happen in markets where there is a lack of regulation or enforcement of regulation.

RECOMMENDATION

Qualify OTC wording to differentiate between safe-use of non-prescription medicines containing antimicrobials and the misuse of high-risk prescription antimicrobials (such as antibiotics for serious infections) that are made available without required controls.

This differentiation should be made clear:

1. **Before August 2024**, in the Draft UN Political Declaration on AMR (Rev2).

Specifically, we suggest the following change:

- a. Remove “acknowledge the drivers of antimicrobial resistance, including lack of regulation of over-the-counter use of antimicrobials”.
 - b. Replace with: “acknowledge the drivers of antimicrobial resistance, including the misuse of prescription antimicrobials and low health literacy”.
2. **After the September UN General Assembly (UNGA)**, in any subsequent IPC and AMR guides and plans developed by involved UN organizations and implementing partners that combat AMR at the national and subnational levels.



Rationale

Our position is based on current scientific evidence and socio-economic considerations.

There is no significant evidence to show AMR-related risks with non-prescription antimicrobials, when used appropriately and as directed. Licensed non-prescription antimicrobials vary by country, but broadly include antiseptics, antivirals and anti-fungals² for which AMR tends to be a far smaller risk than for antibiotics (which are generally restricted to prescription use) due to the different mechanisms involved. Misuse and over-prescription of antibiotics are the primary drivers of AMR, not the regulated use of non-prescription antimicrobial products³. Regulatory decisions should be based on individual risk assessments rather than blanket measures, ensuring that only products posing significant risks are the target of increased regulation. Changing current non-prescription antimicrobials to prescription status will impact the following areas:

01 Health systems burden



Switching non-prescription antimicrobial products to prescription status will affect health systems by significantly increasing the demand for medical consultations, straining health systems unnecessarily and diverting resources from more critical health needs.

Non-prescription antifungal and antiviral products prevent the need for additional medical consultations. These additional consultations would place a considerable burden on already stretched health professionals. This is true in all regions of the world, given the current and predicted global health workforce shortage.⁴

² Association of the European Self-Care Industry. (2024). Overview on Antifungals and Antivirals available in Self-Care

³ Association of the European Self-Care Industry. (2023). Position Paper on the revision of EU general pharmaceutical legislation.

⁴ Predicted by WHO to be 10 million by 2030; this shortage is expected to be concentrated in low- and lower-middle income countries. World Health Organization. (2016). Global strategy on human resources for health: workforce 2030.

02 Individual health and financial outcomes

Requiring prescriptions for common ailments risks delaying treatment, potentially leading to more serious health issues for affected individuals. Antifungals and antivirals used to treat mild to moderate localized infections have proven to be safe over several decades.

Restricting access to these products will delay treatment and worsen health outcomes – without cause, since there is no substantial evidence that non-prescription antifungals or antivirals contribute to resistance in the general population. Non-prescription antiviral and antimicrobial products offer a cost-effective means of managing self-treatable health conditions. This reduces the financial burden on individuals and healthcare systems and ensures all populations can manage their health effectively and affordably.



03 Public health implications



Moving non-prescription products to prescription status also has broader implications for public health.

Non-prescription antimicrobials and antivirals enable individuals to manage self-treatable conditions promptly, preventing complications and reducing the spread of infections. Including OTCs with non-antibiotic active ingredients within the scope of proposed regulatory restrictions will have negative public health outcomes.

These products include antiseptics and disinfectants used in medicinal products to treat or prevent self-curable infections including wound care, acne, dandruff, sore throat, oral hygiene, cold sores and vaginal thrush. Changes may result in the following:

Adversely impact WHO's Global Action Plan on AMR⁵ goal to achieve

“ better hygiene and infection prevention measures to limit the development and spread of antimicrobial resistant infections and multidrug resistant bacteria. ”

Act as a major barrier to treatment in countries where access to a qualified health professional is limited and/or stock-outs of antibiotics are widespread.

04 Role of pharmacists in correct use



Pharmacists worldwide deliver easily accessible and trusted healthcare advice and are well-positioned to promote the responsible and rational use of antimicrobials through health literacy campaigns.

In low-income settings with significant access barriers to health, community pharmacists play a crucial role in educating individuals about the proper use of all antimicrobials, ensuring the right treatment duration and dosage.

05 Health literacy

Enhancing public health literacy is more sustainable than imposing restrictive regulations on products lacking significant proof that they generate resistance.

The importance of self-care, “health care in your own hands”, health literacy, knowledgeable patient/consumer, and lifting the burden on healthcare systems, is emphasized in many countries’ national health plans. Switching above mentioned non-prescription medicines to compulsory prescription is likely to reduce individual selfcare literacy, leaving individuals feeling disempowered to take care of themselves.



Conclusion

To conclude, maintaining access to nonprescription medicines that contain antimicrobials for self-treatable conditions is essential for public health, health systems efficiency, and equitable access to healthcare.

To maintain this access, a clear difference between safe nonprescription medicines containing antimicrobials and the misuse of high-risk antimicrobials as over-the-counter has to be made in any high-level guidance documents on AMR.





As such, GSCF calls for a wording change in the reference of Paragraph 58 of the UN Political Declaration on AMR (see above recommendation on [page 5](#)) ahead of the September High Level Meeting on AMR at the UN General Assembly.

We also recommend that any subsequent guidance relating to the implementation of this declaration clarifies the above, to prevent adverse consequences that may result from the use of such wording.



We are committed to engaging constructively with all relevant stakeholders in formulating the Political Declaration on AMR between now and September 2024, and any subsequent related documents.

We welcome the opportunity to discuss these points further and collaborate on developing effective strategies to combat AMR while preserving the benefits of access to nonprescription antimicrobial products.



About GSCF



The Global Self-Care Federation is dedicated to a world where self-care increasingly contributes to better health and more sustainable healthcare systems. We represent associations and manufacturers in the self-care industry, working closely with our members and relevant stakeholder groups to ensure evidence-based self-care products and solutions are recognized as key contributors to health for individuals and systems worldwide.

www.selfcarefederation.org

 +41 (22) 362 5384

 [@Selfcarefed_org](https://twitter.com/Selfcarefed_org)

 [@selfcarefederation](https://www.linkedin.com/company/selfcarefederation)