THE ECONOMIC AND SOCIAL VALUE OF **NON-PRESCRIPTION ANTIMICROBIAL MEDICINES FOR** THE TREATMENT OF FUNGAL **AND VIRAL**





INFECTIONS





This document summarizes the research study "Health economic study on impact of reverse-switching antifungal and antiviral non-prescription medicines" conducted on behalf of AESGP by IQVIA. For more details and bibliographical references, please consult the main study.

Copyright © 2024 AESGP, All rights reserved.

About AESGP

AESGP, the Association of the European Self-Care Industry, is the voice of the manufacturers of non-prescription medicines, food supplements, and self-care medical devices in Europe, an area also referred to as "self-care" or "consumer healthcare" products.

Because staying healthy as a society starts with each of us, our mission at AESGP is to support everyone in Europe's access to safe, effective and sustainable self-care, empowering people to take better care of their own and their families' health.

Table of contents

Conclusion

Introduction		
About antimicrobial resistance	5	
Which infections can today be self-treate with non-prescription antifungals and ant		
Economic and social value of non-prantifungals and antivirals	rescription 9	
Scope of the study	10	
Economic impact	12	
Value for individuals, healthcare systems	and society 15	



17



Introduction

Antimicrobials are medicines used to prevent and treat infectious diseases in humans, animals and plants. They include antibiotics, antivirals, antifungals and antiparasitics. A few antivirals and antifungals are available without prescription in well-defined conditions, for example athlete's foot, intertrigo, dandruff, vaginal thrush, cold sores or genital warts in EU countries and in the UK.

About antimicrobial resistance

Antimicrobial resistance (AMR) is a pressing threat to public health that can affect anyone. It occurs when microorganisms such as bacteria, viruses, fungi and parasites evolve in such a way as to render ineffective the medicines used to treat the diseases they cause. Although it is a natural phenomenon, its appearance can be accelerated by the inappropriate use of antibiotics (misuse, overuse, failure to follow therapeutic guidelines), their accidental release into the environment, or their inadequate disposal.

Antimicrobial resistance is a major concern because it means that common bacterial infections may soon become impossible to treat with current existing medication. A resistant infection can kill, spread to others and impose huge costs on individuals and society. The Council's recent recommendation¹ states that "more than 35,000 people die each year in the EU/EEA as a direct consequence of an infection due to bacteria resistant to antibiotics. The health impact of AMR is comparable to that of influenza, tuberculosis and HIV/AIDS combined".

It is clear that global efforts are needed to combat antimicrobial resistance². However, it is often wrongly assumed that restricting access to antimicrobials, for example by making them available on prescription only, will reduce the burden of antimicrobial resistance.

It is equally important to recognise the significant role and value of non-prescription antimicrobials, in particular antivirals and antifungals, and the negative public health impact of making these products prescription-only. Most importantly, it should be noted that before being made available as non-prescription medicines, the risk of resistance is investigated. When these products are used correctly³, there is little to no evidence of antimicrobial resistance. Access to these non-prescription medicines, and therefore rapid access to treatment options for common infections, is essential for public health and the efficiency of healthcare systems.

^{1 –} Council of the European Union, Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach, https://data.consilium.europa.eu/doc/document/ST-9581-2023-INIT/en/pdf.2 – EU Action on Antimicrobial Resistance, <a href="https://health.ec.europa.eu/antimicrobial-resistance/eu-action-antimicrobial-resi

^{3 –} AESGP, Position Paper on the European Commission's proposal for a revision of EU general pharmaceutical legislation, July 2023, https://aesgp.eu/content/uploads/2023/07/AESGP_PP_Pharma-Law-Review-Proposal_2023-EINAL.pdf.

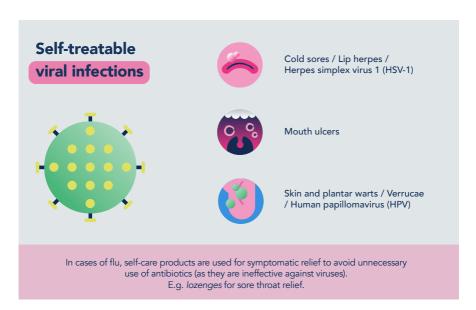


Which infections can today be self-treated in the European Union with non-prescription antifungals and antivirals?

A few antivirals and antifungals are available without prescription in well-defined conditions, when speed of treatment is key to avoiding aggravation (e.g. athletes' foot, labial herpes, dandruff, sore throat and vaginal thrush).

Non-prescription antivirals and antifungals are usually available for topical use, at a lower dosage than their prescription (Rx) equivalent and/or for shorter time treatments. These products have a number of units per pack corresponding to the standard duration of treatment, and the product information leaflet tells the user to stop the treatment and consult a doctor if the treatment does not have a positive effect within a defined period of time.

The share of infections currently treatable with non-prescription antifungals and antivirals varies from one European country to another⁴, but generally includes the following:



Self-treatable Athlete's foot - Tinea pedis fungal infections Ringworm – Tinea corporis Jock itch – Tinea inguinalis Sweat rash / Skin patches / Pityriasis versicolor - Tinea versicolour Intertrigo / Skin fold rash - Tinea cruris Dandruff / Scalp yeast infection -Malassezia furfur (and other) Vaginal thrush / Vaginal candidiasis – Candida albicans Nappy rash / Baby diaper rash Fungal nail infection -Onychomycosis Other common topical fungi that are effectively removed by self-care antifungals include: Candida glabrata, Candida krusei, Pityrosporum ovale, Pityrosporum orbiculare, Trichophyton, Microsporum,

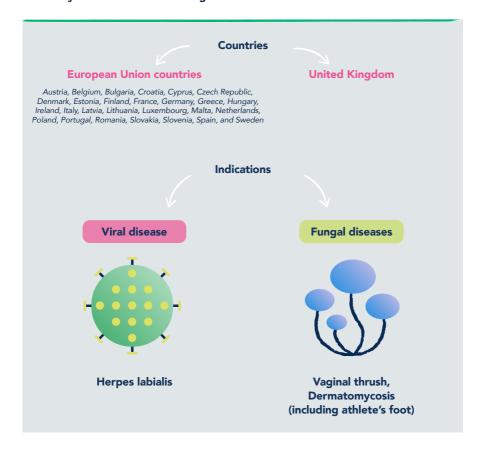
Epidermophyton, Scopulariopsis



Economic and social value of non-prescription antifungals and antivirals

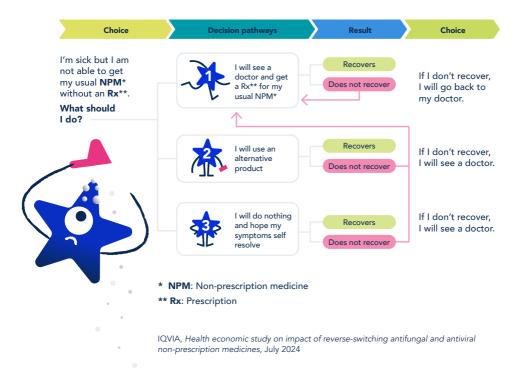
To analyse and quantify the socio-economic value of antifungal and antiviral non-prescription medicines to society, IQVIA conducted research⁵ which monetised health system expenses and health outcomes if those antimicrobials were not available without a prescription.

The study focused on the following countries and indications:

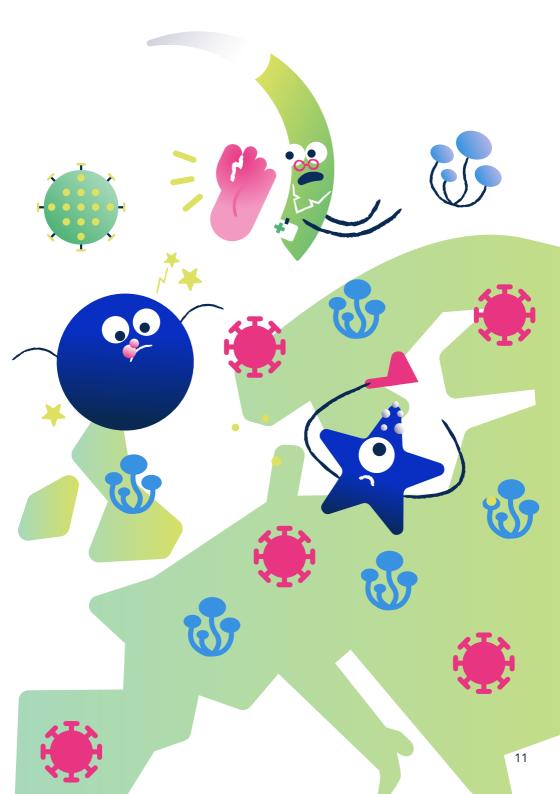


Scope of the study

IQVIA's research was based on the hypothesis that if non-prescription antimicrobial medicines were not available, individuals confronted with a viral or fungal infection would have three choices: to visit a doctor and get a prescription; to switch to an alternative treatment available as self-care; or to do nothing and wait for the symptoms to self-resolve.

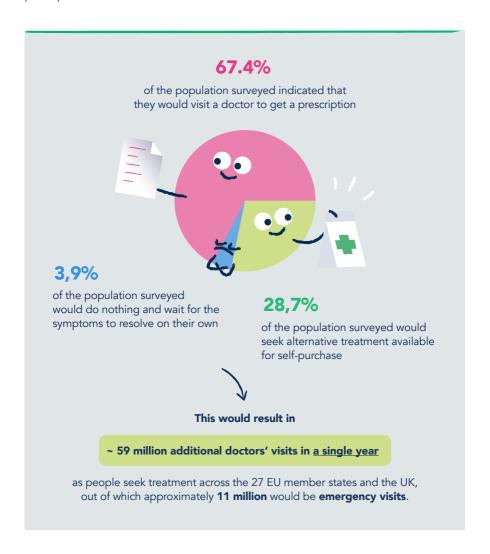


To test the hypothesis, a total of 378 people from 5 countries (France, Germany, Italy, Poland and the United Kingdom) were surveyed to understand what actions they would take in case their non-prescription antimicrobial treatment became available only upon prescription. The results were then extrapolated to the rest of the countries in scope, based on several key factors, ensuring that the results were contextually relevant to the specific characteristics of each non-surveyed country.



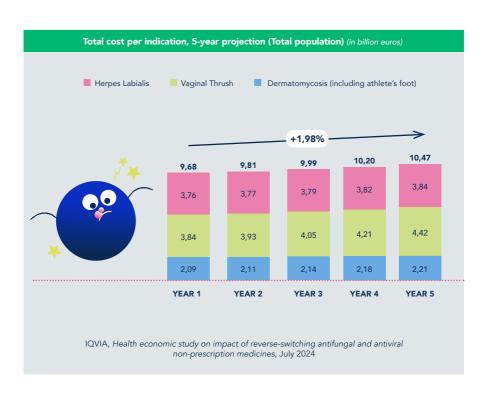
Economic impact

If antifungal and antiviral non-prescription medicines were not available without a prescription in the countries and for the indications studied:

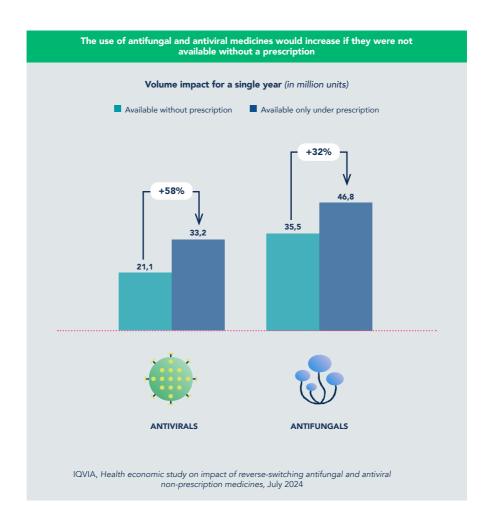


Cumulatively, the total cost of the non-availability of antifungal and antiviral non-prescription medicines for a single year would amount to \leqslant 9.68 billion. They are projected to cumulatively amount to \leqslant 50.1 billion over five years, increasing by 1.98% year-on-year.

- Approximately 81% of these costs, equivalent to €40.7 billion, are healthcare-related expenditures which are mainly driven by the doctor's visits. Of these healthcare costs, 81% would be borne by public payers, followed by 14% by individuals, and 5% by private health insurance.
- The remaining **19%** of the total costs, equivalent to €9.4 billion, are attributed to productivity losses due to individuals visiting a doctor and to a lesser extent, disability due to severity of the diseases.
- The **largest costs** are attributed to vaginal thrush (€20.4 billion), followed by herpes labialis (€19 billion), and dermatomycosis (€10.7 billion).



Counterintuitively, the total volume of the use of antifungal and antiviral medicines would increase in this scenario where they would be available only under prescription. Patients who choose to visit a doctor will receive a prescription, whereas patients who explore alternative options or take no action, may experience delay in appropriate treatment, which could lead to worsened symptoms. Eventually, they may require a doctor's appointment and a prescription for a more severe condition. Based on detailed assumptions and factors, the volume impact of antivirals shows a potential 58% increase, with consumption rising from 21.1 million units to 33.2 million units. Meanwhile, antifungals show a potential 32% increase, with consumption jumping from 35.5 million units to 46.8 million units.



Value for individuals, healthcare systems and society

Echoing findings of a previous study on the socio-economic value of non-prescription medicines in Europe⁶, the IQVIA study highlighted the significant benefits brought by antifungal and antiviral non-prescription medicines to European health systems, economies and individuals.

Benefits of non-prescription antifungals and antivirals



1. Timely care

The availability of antifungal and antiviral nonprescription medicines helps people take timely action and avoid exacerbation of conditions or infection transmission. By enabling rapid care, these treatments lead to better health outcomes and lower incidence in the population.



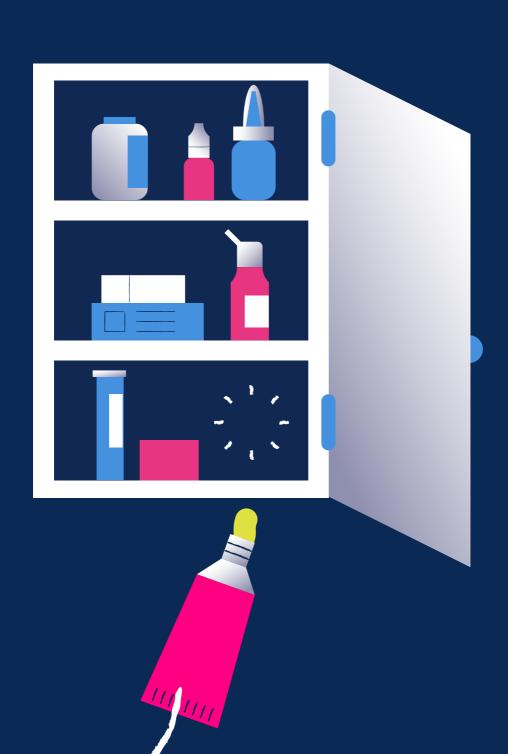
2. Reduced burden and costs for the healthcare system

As people can access self-care products instead of seeking medical advice from doctors to resolve their conditions, visits to health facilities decrease, resulting in a reduced burden on healthcare systems and freeing doctors for more complex conditions. As a consequence, healthcare-related spendings decrease as well as waiting times.



3. Avoided productivity losses

Beyond the benefits linked to the healthcare system, society is also spared indirect costs, such as the loss of productivity of individuals, due to time lost in the event of disability and in seeking outpatient care.



Conclusion

The availability of antifungal and antiviral medicines as non-prescription medicines is of crucial importance to individuals and health systems. A fast onset of treatment is mandatory for minor conditions not to spread or aggravate (e.g. herpes labialis), which may result in worsened clinical outcomes. By causing delays in treating fungal or viral infections, requiring a doctor's visit and prescription all the time could have an extremely negative impact on the success of treatment and well-being.

In the context of tackling antimicrobial resistance (AMR), increased regulation of non-prescription antimicrobials to reduce the burden of AMR may in fact have unintended consequences, such as delays in care-seeking, worsened symptoms and the need for prescriptions for more severe conditions, as highlighted by this IQVIA study. Therefore, prescription status of antimicrobial products (in particular, antifungals and antivirals) should be restricted to those products for which an AMR risk has been confirmed as a public health threat and where it is not possible to implement effective risk mitigation measures (reducing the pack size, strengthening product information, etc.).

Restricting access to all antimicrobials as a precautionary measure, without considering the real potential for the development of antimicrobial resistance in these medicines on a case-by-case basis, would not address the current problem of AMR. Instead, it would deprive people suffering from self-limiting conditions of timely access to effective treatments, leading to an increase in unnecessary medical consultations, and potentially lead to more severe conditions, increasing the costs of already stretched national health funds.

Due to their proximity and availability with a dense network, community pharmacists are often the first healthcare professionals to whom a patient will speak about their condition. Pharmacists can provide reliable health advice and are ideally placed to promote the responsible and rational use of antimicrobials. They ensure that non-prescription antimicrobial medicines are appropriate for the patient's condition and needs, offering alternatives if necessary.

The IQVIA study is a unique piece of evidence that aims to support regulators and policymakers in adopting effective, balanced policies to combat antimicrobial resistance, reconciling the need to protect public health with the need to minimise unintended consequences of those policies.

Notes

The eco	nomic and social value of non-prescription antir	microbial medicines for the	e treatment of fungal and vir	al infections
	•			
	•			

iomic and social value of non-	prescription antimicrobia	armedicines for the tre	atment of fungal and	viral infections

onomic and social value of non-prescription antimicrobial medicines for the treatment of lungal and viral if	nections

