

Socioeconomic Impact of Reverse Switching Over-the-Counter (OTC) Antifungal and Antiviral Medicines to Prescription Only Medicines (POM) in Europe

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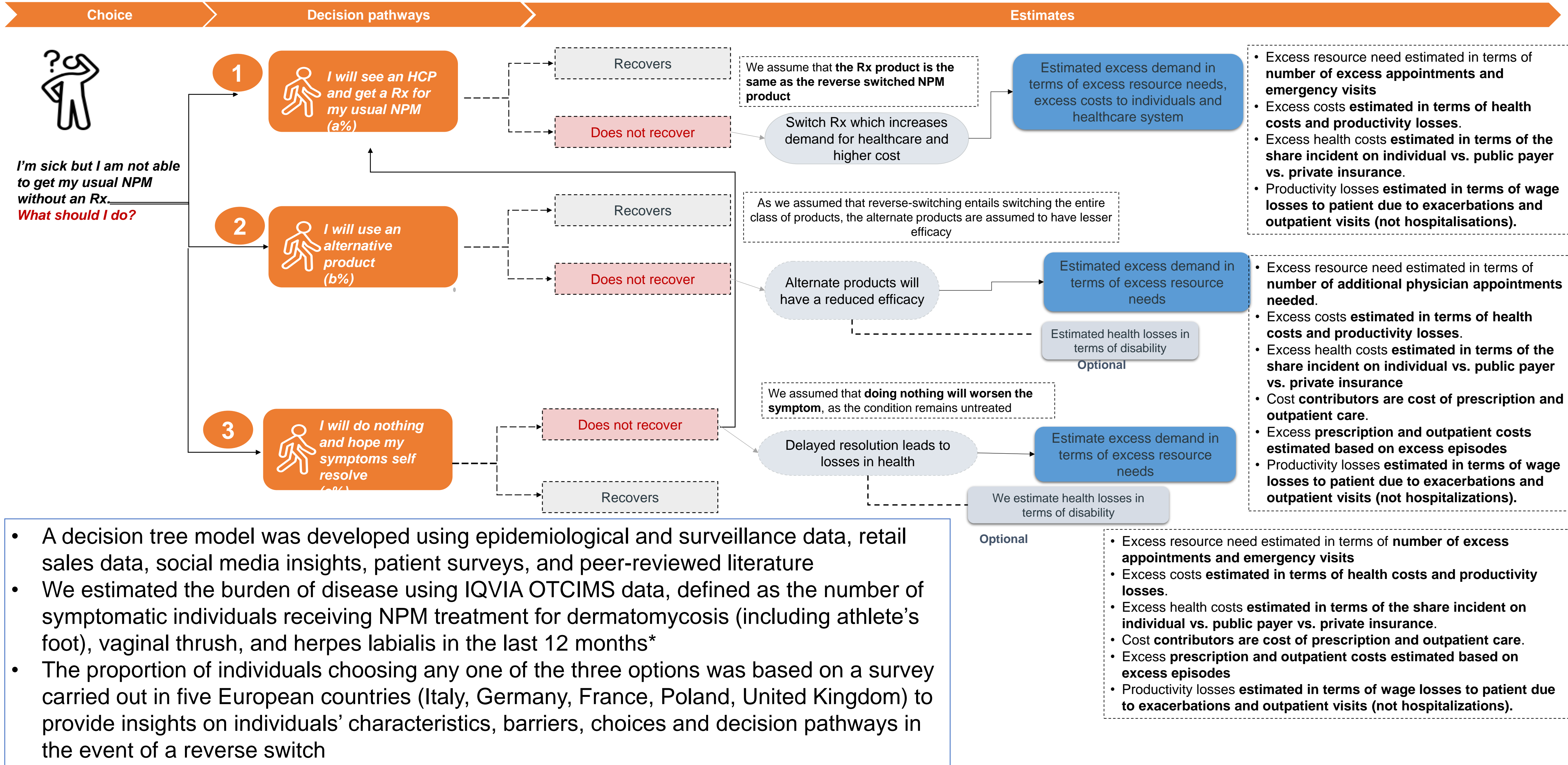
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BACKGROUND

- Non-prescription antimicrobial medicines play a crucial role in public health by providing accessible treatment options for common conditions.
- The European Commission (EC) has developed a new proposal for its pharmaceutical legislation framework, including an amendment to Article 51, classifying all antimicrobials as prescription-only medicines (POMs) to reduce antimicrobial resistance (AMR).
- This policy shift targets a wide array of antimicrobial products, many of which are currently available as non-prescription medicines (NPM).
- This proposal is logical for antibiotics but risk of such in antivirals and antifungals is less obvious where resistance risk is mainly linked to high-dose, long-term, and systemic use in immunocompromised patients.
- This study analysed and quantified the socio-economic implications and health consequences associated with the potential reclassification of NPM antifungal and antiviral medicines to prescription-only status.
- This analysis is critical to inform the EC's proposed reform of the pharmaceutical legislation framework, which aims to reduce antimicrobial resistance by restricting access to these products.

METHODS



RESULTS

- The total costs of reverse-switching for 5 years is estimated as €50,1 billion increasing by 1,98% year-on-year.
- Approximately 81% of the total costs equivalent to €40,7 B are estimated to be healthcare related spendings.
- Of the €40,7 billion over 5 years, 81% of these costs will be borne by public payer, followed 14% individuals and 5% private health insurance
- Approximately 19% of the total costs, equivalent to €9,4 billion are estimated to be productivity losses due to individuals seeking care at doctor's practice and disability.
- The largest costs are attributed to vaginal thrush (€20,4 billion), followed by herpes labialis (€19 billion) and dermatomycosis (€ 10,7 billion)
- Approximately 59 million additional visits to doctor's practice will occur in a year as people seek treatment with 11 million from emergency department visits
- Across 28 countries, the total cost of reverse-switching per year is estimated as €9,6 billion with approximately €7,8 billion as healthcare costs, €1.8 billion as productivity
- Reverse-switching may not reduce the volume of antiviral and antifungal medicines use with a potential increase of 58% and 32% respectively.

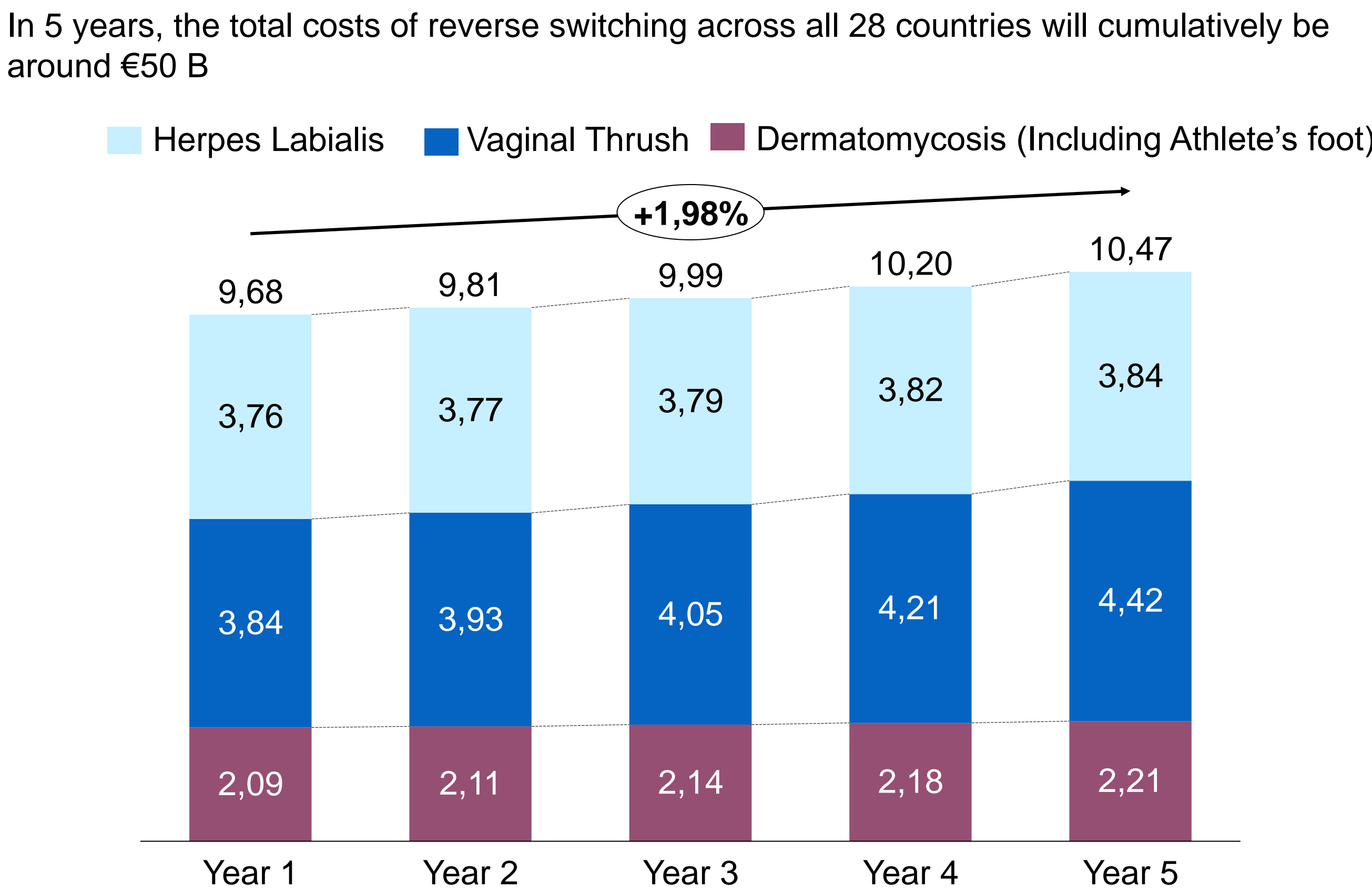


Figure 1: Total cost per indication, 5-year projection (Total population) (in Billion)

Reverse-switching may not reduce the use of antifungals and antivirals NPMs

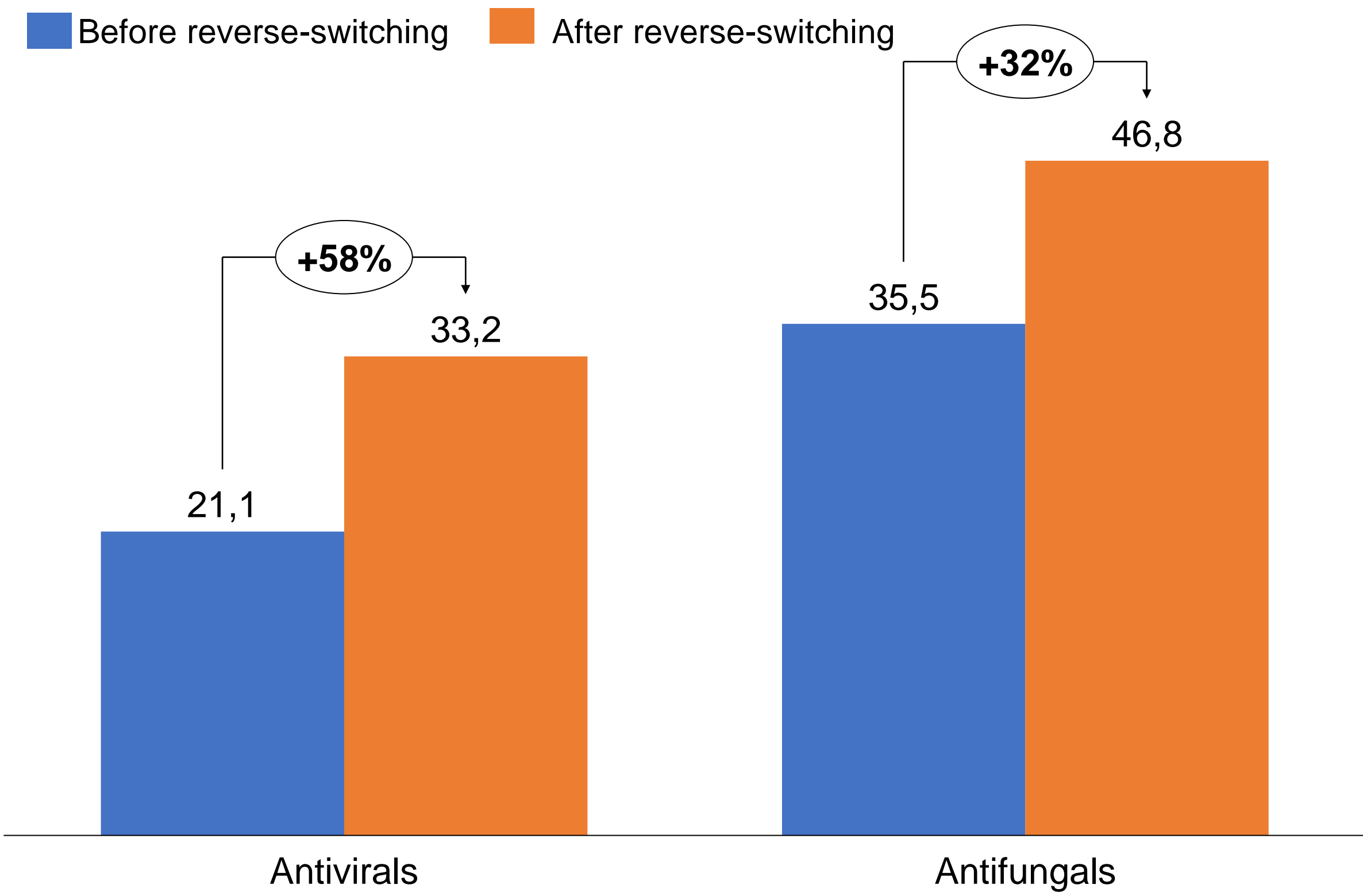


Figure 2: Volume impact for a single year (in million units)

CONCLUSION

- Reverse-switching may cause individuals to delay seeking appropriate treatment, opting instead to either use an alternative treatment or do nothing, due to existing physical and social barriers in accessing healthcare.
- The shift of patients to the healthcare system will create substantial additional burdens and costs.
- 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
- Contrary to the intended outcome, prescribing practices may shift, such as moving from topical/external to oral/systemic treatment.
- Individuals who do require antimicrobials might eventually get a prescription and may require this for longer period, hence the proposed action may not achieve the desired objective of reducing AMR.

*Definition was selected to reflect the population that will be directly impacted by the reverse-switch of antifungals and antivirals NPM