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The Enablers and Barriers of Down-Scheduling Medicine Policies: A Systematic Review

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ABSTRACT

Introduction: Down-scheduling medicine policies aim to increase the availability of medicines by reclassifying certain prescription-only medicines to non-prescription classification. While these policies offer potential benefits, there is limited knowledge about the factors that enable or hinder their implementation.
Methods: A systematic review of English language published literature from 2013-2024 was conducted. The literature was retrieved through web including PubMed, Scopus, Science Direct, Google Scholar, Cochrane, and Cinahl. The review focused on studies that explored the enablers and barriers to down-scheduling policies, with the keywords "drug reclassification" OR "medicine reclassification" OR "drug switching" OR "medicine switching" OR "drug down scheduling" OR "medicine down scheduling" OR "Rx-to-OTC".
Results: A total of twenty-two eligible studies were identified. The analysis revealed that supportive policymakers, clear and transparent regulatory frameworks, positive perceptions of pharmacists, increased consumer awareness, and support from medical professionals are key enablers of successful down-scheduling policies. Conversely, risk-averse regulators and pharmacists' lack of confidence in self-medication emerged as significant barriers.
Conclusion: Down-scheduling has been progressively implemented worldwide, enhancing consumer access to medicines and encouraging self-care. Nevertheless, regulatory challenges and concerns about safety and misuse continue to impede the broader adoption of such policies. Continuous evaluation, training, and regulatory clarity are essential for optimizing the benefits of down-scheduling policy.

Keywords: Down-scheduling; Prescription-only to non-prescription; Medicine policies; Enablers and barriers; Health Policy

INTRODUCTION

Medicines are an essential element of a nation's health system. Regulatory authorities enforce various regulations to ensure the safety, effectiveness, quality, and access to medicines, including medicine classification and reclassification[1]. Generally, consumers legally have access to medicines by two mechanisms: with prescription provided by a licensed healthcare professional and over-the-counter (OTC) sales, which do not require a prescription and are available directly at retail outlets. Additionally, several countries have introduced a third mechanism where certain

medicines can be sold without a prescription but require consultation with a pharmacist. This policy has been widely adopted in countries such as the United Kingdom, Australia, Canada, Singapore, Japan, and New Zealand[2].

Down-scheduling, the process of reclassifying medicines from prescription-only to non-prescription, has emerged as a notable practice within the global pharmaceutical market. In addition to the term down-scheduling, various countries employ alternative terminologies, such as reclassification, switching, or Rx-to-OTC transition, to refer to the regulatory process of altering a medicine's status from prescription-only (Rx) to non-prescription availability. Most new medicines initially enter the market as prescription-only medicines; however, after a certain period, they may undergo down-scheduled. This down-scheduling often serves as a logical extension of the product's life-cycle management, enabling the originating company to develop a defense strategy against generic competitors[3]. Down-scheduling is a common policy aimed at increasing access to medicines and empowering patients to manage minor ailments, thereby improving the efficiency of healthcare utilization. By facilitating patient access to non-prescription medicines, this approach can lead to a decrease in physician visits, potentially lowering overall healthcare costs while positively impacting pharmacy turnover. Ultimately, this strategy aligns with the broader objectives of improving public health outcomes through increased accessibility to effective treatments[3,4].

Despite the advantages associated with down-scheduling, it remains a contentious issue in several countries. A notable example is the United Kingdom has revised the classification of diclofenac from non-prescription to prescription. This change is driven by emerging evidence correlating its use with increased cardiovascular risks[5]. In Australia and New Zealand, the classification of codeine has been revised from non-prescription to prescription, considering severe adverse health outcomes, including difficulty breathing, liver damage, and death[6]. Given its extensive implementation in nearly all countries, down-scheduling presents a fascinating topic for study. The diversity of down-scheduling policies makes it worthwhile to explore the various factors that drive and influence policy implementation.

Each country establishes its own regulatory framework regarding the availability of medicines without a prescription. While these policies can provide certain advantages, the overall impact of making medicines available as non-prescription on healthcare utilization remains inadequately understood. The clinical safety and efficacy of these policies are still uncertain, and their effectiveness in achieving intended outcomes continues to be debated. Furthermore, there is a limited understanding of the factors that facilitate or impede the decision-making process related to down-scheduling policy.

Indonesia reintroduced its down-scheduling policy for medicines in 2021 after a twelve-year hiatus, marking a renewed commitment to enhancing public access to safe and effective treatments[7,8]. The Ministry of Health has recently implemented a policy that reclassifies several medicines from prescription-only to over-the-counter availability. Despite their acknowledged safety in various international contexts, the Indonesian policy lacks publicly accessible evidence to support its reclassification. There is a significant absence of national data or published risk-benefit analyses assessing the use of these medicines without medical supervision within the Indonesian population. This lack of transparency in the regulatory process raises concerns about the robustness of the decision-making, especially in a healthcare system where self-medication is already prevalent and regulatory oversight encounters challenges related to regional disparities in access and pharmaceutical control. In the absence of evidence-based justification, such policy

shifts could lead to risks of inappropriate usage, inadequate patient guidance, and deficiencies in pharmacovigilance.

This study aims to explore the enablers and barriers associated with down-scheduling policies and to analyze the impact of such policies based on historical precedents. By identifying the key factors that influence the success or failure of these policies, the research offers valuable insights for policymakers. Additionally, it provides a historical context for previous events, enhancing our understanding of how down-scheduling has evolved and what lessons can be drawn to address future challenges. This research not only contributes to the academic literature but also delivers practical recommendations for optimizing down-scheduling decisions, ultimately ensuring patient safety and well-being.

METHOD

This study follows the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA). The literature was retrieved through database including PubMed, Scopus, Science Direct, Google Scholar, Cochrane, and Cinahl. A search strategy combines key words “drug reclassification" OR "medicine reclassification" OR "drug switching" OR "medicine switching" OR "drug down scheduling" OR "medicine down scheduling" OR "Rx-to-OTC". Studies qualified for inclusion were peer-reviewed articles published in English, with no restrictions on countries; published between January 2013 and December 2024; providing empirical evidence or document-based analysis related to the down-scheduling of medicines; research focusing on enablers, barriers, stakeholder perspectives, or policy implications of down-scheduling; and involving healthcare professionals, regulators, policymakers, or consumers. Conversely, the exclusion criteria included: articles not published in English; publications outside the defined time range; theses, dissertations, book chapters, conference proceedings, and editorial opinions; literature reviews without empirical data; and studies based solely on conceptual models or providing general advice without analytic or outcome-based content.

A comprehensive literature search was conducted across six databases utilizing the designated search terms. The references were imported into Mendeley Reference Manager for duplicate detection, and any duplicates were eliminated. Subsequently, we performed an initial screening based on titles and abstracts to identify relevant articles. Abstracts meeting the inclusion criteria underwent a full-text assessment. Data extraction from the selected studies was carried out, organizing the information into an Excel database under the following categories: author, year of the study, title, country studied, down-scheduled medicine, type of study, key finding, enabler identified, barrier identified and implication for practice. The processes of literature search, title and abstract screening, data extraction, and quality evaluation were executed by ACD and AH, with oversight from UA. Discrepancies among the authors were resolved through discussion.

The included studies predominantly emerged from high-income countries such as Australia, the United Kingdom, Germany, and the United States. Most employed an observational design, including surveys, document analyses, and retrospective data reviews, reflecting a strong focus on regulatory frameworks and professional readiness. Key findings across these studies consistently highlighted the dual role of pharmacists in the context of down-scheduling policies, they frequently served as both as facilitators and as barriers, influenced by their level of confidence, training, and systemic support. Core themes such as regulatory transparency, pharmacist preparedness, and collaboration among stakeholders were prevalent across various

settings, underscoring their critical importance in facilitating safe and effective transitions from prescription-only to non-prescription medication access.

RESULT

A PRISMA flow diagram (Figure 1), shows the number of: articles obtained from the searches and screened; papers assessed for eligibility; and article included in the review. 27.660 articles were found in the initial search. In total, 22 studies were eligible for inclusion in the review. The summary of the studies included in the review are presented in Table 1.

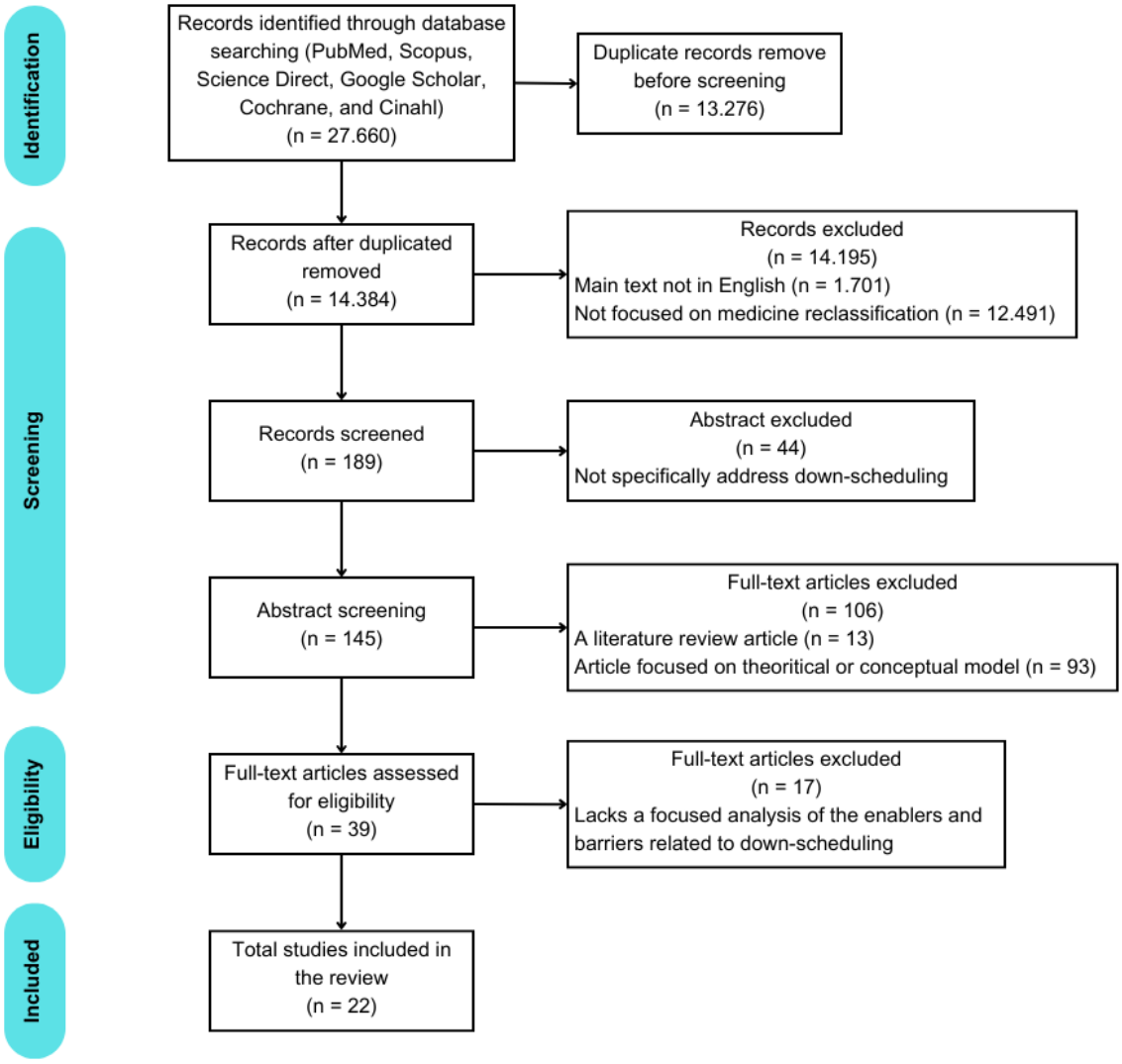

Figure 1. Flow Diagram of Systematic Review Search Procedures

Table 1. Summary of the studies included

Author	Year	Title	Country	Medicine Category	Type of study	Key Findings	Enabler Identified	Barrier Identified	Implication for Practice
Alkhatib *et.al*[9]	2015	An Evaluation of The Reclassification of Ophthalmic Chloramphenicol for The Management of Acute Bacterial Conjunctivitis in Community Pharmacies in Western Australia	Australia	Antibiotic	Observational study (survey)	Down-scheduling of medicine enhanced pharmacists' ability to manage acute bacterial conjunctivitis, largely as a replacement for products previously available non-prescription, rather than a reduction in consultations with general practitioners	Positive perception of pharmacists	Concerns about misuse or inappropriate self-treatment by consumers	Pharmacists need continuous education and additional training to supply non-prescription medicine
Booth *et.al*[10]	2019	Managing Migraine with Over-the-Counter Provision of Triptans: The Perspectives and Readiness of Western Australian Community Pharmacists	Australia	Analgesic	Observational study (survey)	Pharmacists are ready to manage non-prescription triptans but express concerns about safety	Readiness of pharmacists, increased access for patients	Pharmacists confidence	Pharmacists highlighted a need for further training and resources to support migraine diagnosis and provision of non-prescription triptans
Barrenberg & Garbe[11]	2017	From Prescription-Only (Rx) to Over-the Counter (OTC) Status in Germany 2006 2015:	Germany	Analgesic, gastrointestinal disorder, antiinflammatory, decongestant, antidiarrheal, antiallergy,	Observational study (document analysis)	Regulatory bodies ensure safety of down-scheduled medicine through stringent criteria	Transparent regulatory framework	Risk aversion, concerns about self-diagnosis	Regulatory bodies could develop a set of guiding questions and identify research needs to facilitate structured and

Author	Year	Title	Country	Medicine Category	Type of study	Key Findings	Enabler Identified	Barrier Identified	Implication for Practice
		Pharmacological Perspectives on Regulatory Decisions		hormone contraceptive					evidence-based assessments of down-scheduling applications.
Chang *et.al*[12]	2016	Prescription To Over-the-Counter Switches in The United States	The United States America	Not specific	Observational study (document analysis)	Down-scheduling medications results in enhanced patient access to care, improved convenience, and increased peace of mind for patients and healthcare providers. It also promotes a competitive market and allows physicians and pharmacists to focus more on patient management and therapeutic oversight	Supportive regulatory framework, support from the medical professionals	Risk of consumer misuse, misdiagnosis by consumers	It is important to make sure that there is a proper labeling (with appropriate font size) that is clear and straightforward is important for proper medication adherence
Chang *et.al*[13]	2017	Time Trends in Physician Visits for Gastroesophageal Reflux Disease Before and After the Rx-to-OTC Switch of Proton Pump Inhibitors	The United States	Gastrointestinal disorder	Observational study (data analysis)	The down-scheduling of Proton Pump Inhibitors (PPIs) to non-prescription has resulted in a notable reduction in physician consultations for gastroesophageal reflux disease (GERD), indicating enhanced	Support from the medical professionals	Concerns about misuse or misdiagnosis due to non-prescription availability	The down-scheduling of medicine treating common medical conditions may have a profound and sustained impact on outpatient healthcare utilization

Author	Year	Title	Country	Medicine Category	Type of study	Key Findings	Enabler Identified	Barrier Identified	Implication for Practice
						accessibility to therapeutic options for patients			
Fix *et.al*[14]	2024	Rx -to- OTC Switch Increased Access and Lowered Cost of Topical Adapalene	The United States America	Dermatological disorder	Observational study (data analysis)	The down-scheduling resulted in enhanced consumer accessibility and higher sales volumes, alongside a reduction in out-of-pocket expenses, and contributed to cost savings for payers within the healthcare system by lowering overall expenditure	Consumer awareness, positive perception of pharmacists, support from the medical professionals	Risk of misuse, concerns over inappropriate use	Possibility of down-scheduling the other dermatologic medicines with suitable safety profiles
Gauld *et.al*[15]	2014	Widening Consumer Access to Medicines through Switching Medicines to Non-Prescription: A Six Country Comparison	Australia and New Zealand	Not specific	Observational study (document analysis)	Consumer access to medicines through down-scheduling varies by country, even among similarly educated populations. In nations with proactive regulatory frameworks, the availability of pharmacies and pharmacist-only medicine significantly enhances access to medicines	Supportive policy, regulatory clarity, pharmacist readiness	Risk aversion, misdiagnosis concerns, resistance from some medical professionals	Outcome data, including multi-country comparisons of outcomes from differences in down-scheduling, could be used to explore realized benefits and risks of the differences are seen and help to inform further down-scheduling.

Author	Year	Title	Country	Medicine Category	Type of study	Key Findings	Enabler Identified	Barrier Identified	Implication for Practice
Gauld *et.al*[16]	2015	Widening Consumer Access to Medicines: A Comparison of Prescription to Non-Prescription Medicine Switch in Australia and New Zealand	The United States, The United Kingdom, Australia, Japan, The Netherland, and New Zealand	Not specific	Observational study (document analysis)	The willingness of committees and regulatory bodies to facilitate switching, along with the level of confidence in pharmaceutical services, seems to significantly impact consumer access to medications	Supportive policymakers, clear regulatory framework, positive perception from pharmacists	Risk averseness from regulators	The pharmacist-only medicine schedule, the rise of "third-party down-scheduling" and flexibility could be considered elsewhere to enable down-scheduling
Gruchala *et.al*[17]	2016	Rx-to-OTC Switch and Double Registration Occurrence in Poland - An Illuminative Case Study	Poland	Not specific	Observational study (case study)	Some medicines are the subject of double registration: prescription-only and non-prescription. This raise doubts as to whether the medicines are safe enough in terms of self-treatment	Clear regulations	Risk of misuse, concerns over self-diagnosis without professional oversight	The role of the pharmacist in the down-scheduling process should be legally increased in terms of medicine dispensing. The creation of a new class of drugs described as pharmacist-only should be taken under consideration.
Hope *et.al*[18]	2020	Australian Pharmacists: Ready For Increased Nonprescription Medicines Reclassification	Australia	Not specific	Observational study (survey)	Pharmacists are prepared to expand their role in the management of down-scheduled medicines, prioritizing patient safety, harm	Positive perception and readiness of pharmacists, consumer awareness	Opposition from other healthcare professionals	Recommendations for future down-scheduling were context-specific and underpinned by safety and quality considerations

Author	Year	Title	Country	Medicine Category	Type of study	Key Findings	Enabler Identified	Barrier Identified	Implication for Practice
						reduction, and the continuation of necessary therapies			
Kartha *et.al*[19]	2017	Switching Drugs from Rx to OTC Status – A Regulatory Perspective	The United States, The United Kingdom, Singapore, and Cina	Not specific	Observational study (document analysis)	Outlines the factors necessary for a successful down-scheduling, including medicine characteristics, consumer awareness, and regulatory processes	Supportive policymakers, clear regulatory framework, positive perception from pharmacists, consumer awareness	Risk averseness from regulators	Encourages better understanding of the regulatory process for down-scheduling to streamline approvals and ensure safety
Kuhler *et.al*[20]	2024	Real-World Data and Evidence to Support a Switch in Status from Prescription Drug to Over-the-Counter Drug as Applied by the EMA, the US FDA, the MHRA, and the BfArM	The United Kingdom, The United States, Germany	Not specific	Observational study (document analysis)	The availability of non-prescription medicines is greater in regulatory environments characterized by clear policies, comprehensive guidelines, and transparent decision-making processes at the regulatory authority level	Clear regulatory frameworks, Real-World Data (RWD) and Real-World Evidence (RWE)	Lack of standardization in evidence use, regulatory hurdles	Clear and transparent regulatory switch frameworks are conducive to growing the number of medicines available to consumers willing to self-manage their conditions
Nomura *et.al*[21]	2016	Medicine Reclassification Processes and Regulations for Proper Use of Over-the-Counter Self-Care	Japan	Not specific	Observational study (document analysis)	The study compares Japan's down-scheduling process with the UK, focusing on pharmacists' roles	Support from policymakers, safety framework, consumer awareness	Risk aversion from regulators, uncertainty in self-medication	The opinion of marketers, medical professionals, and the public will improve the discussion that

Author	Year	Title	Country	Medicine Category	Type of study	Key Findings	Enabler Identified	Barrier Identified	Implication for Practice
		Medicines in Japan							will greatly contribute to the safe use of medicine in the down-scheduling process
Otto *et.al*[22]	2018	The Economic Impact of a Switch from Prescription-Only to Non-prescription Drugs in Italy	Italy	Not specific	Observational study (case study)	The economic ramifications for patients are complex and vary based on the scenarios considered. While the net economic benefits warrant careful interpretation, the results demonstrate how down-scheduling can significantly enhance the long-term sustainability of the healthcare system	Support from the medical professionals, improved accessibility to treatments	Potential misuse	Down-scheduling of medicines has potential savings for the healthcare system, but it needs to ensure patient safety
Paudyal *et.al*[23]	2014	Pharmacists' Adoption into Practice of Newly Reclassified Medicines from Diverse Therapeutic Areas in Scotland: A Quantitative Study of Factors	The United Kingdom	Gastrointestinal disorder, analgesic, antibiotic, lipid-lower agent	Observational study (survey)	Pharmacists' adoption of newly down-scheduled medicines depends on perceived patient benefits and professional role	Positive perception and readiness of pharmacists	Pharmacist confidence	Down-scheduling give a direct impact on pharmacists' roles in healthcare delivery

Author	Year	Title	Country	Medicine Category	Type of study	Key Findings	Enabler Identified	Barrier Identified	Implication for Practice
		Associated with Decision-Making							
Pricolo & Nielsen[24]	2018	Naloxone Rescheduling in Australia: Processes, Implementation and Challenges with Supply of Naloxone as A 'Pharmacist Only' Over-The-Counter Medicine	Australia	Naloxone (opioid antagonist)	Observational study (document analysis)	A public initiative successfully prompted a submission for down-scheduling, thereby eliminating access barriers to medication by enabling pharmacist dispensing	Support from medical professionals, positive perception of pharmacists	Risk of abuse, concerns over the misuse of medicine	Need for continuous training and monitoring for pharmacists.
Shaw *et.al*[25]	2016	Barriers to Positive Policy Change That Aims to Increase Access to Medicines Through Reclassification: The Case of Oseltamivir in New Zealand	New Zealand	Antivirus	Observational study (survey)	The intricate interplay of factors affecting pharmacists' motivation to dispense medicine without a prescription underscores how potential policy advancements may be obstructed by various barriers	Consumer awareness	Lack of pharmacist and pharmacy support staff training, concerns over product safety	Addressing barriers of down-scheduling medicines, regulators should increase training and address concerns of pharmacy support staff
Stippler *et.al*[26]	2019	To Switch or Not to Switch – German Physicians′ Views On Proposed New OTC Medicines	Germany	Not specific	Observational study (survey)	The majority of physicians supported down-scheduling; yet still concerned about safety and misuse	Support from policymakers, support from the medical professionals	Safety concern	Ensures patient safety while easing healthcare burdens

Author	Year	Title	Country	Medicine Category	Type of study	Key Findings	Enabler Identified	Barrier Identified	Implication for Practice
Stippler *et.al*[27]	2022	Key Results of A Series of Surveys Among German Pharmacies, Physicians, Patients and Stakeholders Regarding Further Triptans As Potential OTC Products	Germany	Analgesic	Observational study (survey)	There is a need for clear communication and more comprehensive training for healthcare providers to ensure that down-scheduled medicines are handled safely and effectively	Support from the medical professionals, readiness of pharmacists	Concerns over safety	Understanding stakeholders' opinions is critical for advancing down-scheduling processes
Yeung *et.al*[28]	2023	Pharmacists' Perspectives and Attitudes Towards The 2021 Down-Scheduling of Melatonin in Australia Using the Theoretical Domains Framework: A Mixed-Methods Study	Australia	Melatonin (hypnotic and sedative)	Observational study (survey)	Pharmacists support the down-scheduling but need the importance of clear guidance and training. There is necessity of educate the public about the risk-benefit profile of medicine	Supportive policies, pharmacist readiness	Concern over misinformation by consumers	Pharmacists need additional training to manage non-prescription products effectively
Yuen & Chong[29]	2018	Rx-to-OTC Switch – An Overview and its Implications to Public Health	Hong Kong	Not specific	Observational study (document analysis)	The benefits of down-scheduling for public health include reduced healthcare burden, but increased pharmacist involvement through medication therapy management	Supportive policymakers, clear and transparent regulatory framework	Patient misuse risk	Strengthening regulatory frameworks and improving pharmacy care delivery

Author	Year	Title	Country	Medicine Category	Type of study	Key Findings	Enabler Identified	Barrier Identified	Implication for Practice
Zaprutko *et.al*[30]	2019	The Prescription to Over-The-Counter Switches and Double Registration of Medicines – The Perspective of Pharmacists from Greater Poland	Poland	Gastrointestinal disorder, antiallergy, analgesic	Observational study (survey)	The phenomenon of dual registration for medicines appears to create significant confusion and may play a role in the ambivalence exhibited by Polish pharmacists toward the process of down-scheduling	Support from health professionals, clear policy frameworks	Risk averseness of regulators, lack of training	Policymakers should encourage further flexibility in down-scheduling of medicines

DISCUSSION

A total of twenty-two eligible studies were identified from twelve countries: Australia, New Zealand, the United States, Germany, Poland, Japan, the United Kingdom, Italy, Singapore, Cina, Hong Kong, and the Netherland introduced down-scheduling policy within the past decade. Notably, the bulk of research on the down-scheduling of medicines has originated from developed countries, highlighting a significant gap in the literature from developing nations, despite the widespread global implementation of this policy. This observation is consistent with findings that regulatory frameworks for the reclassification of prescription medications to over-the-counter status in low- and middle-income countries are often underdeveloped or lack the transparency seen in high-income countries[4].

The policy was implemented to widen access of medicines including antiallergy, antibiotic, analgesic, decongestant, and medicine for dermatological disorder and gastrointestinal disorder. Comparable trends have been noted in countries with more permissive switch policies, where consumers exhibit increased access to treatments for common self-limiting conditions[3,31]. This evidence suggests that variations in policy flexibility can substantially impact self-medication accessibility, which is influenced by multiple contextual factors.

The studies highlight various enablers and barriers in the context of down-scheduling policies. Key enablers include supportive policymakers, a clear and transparent regulatory framework, positive perception and readiness of pharmacists, increased consumer awareness, and support from the medical professionals were identified. However, significant barriers persist, such as risk-averse regulators and pharmacists' lack of confidence in assisting self-medication. Over the past decade, countries around the world have made strides in reforming their down-scheduling policy. Moreover, the down-scheduling was expected to facilitate better patient self-care.

Enabler factors

Supportive policymakers, clear and transparent regulatory framework

The support of policymakers, coupled with a clear and transparent regulatory framework, has been pivotal in the successful down-scheduling of medicines across various countries[12,15]. Clear and transparent down-scheduling guidelines issued by regulatory authorities encourage manufacturers to actively pursue reclassification, thereby enhancing the accessibility of a broader range of medicines for consumers who are willing to self-manage their conditions[11,20,28]. Conversely, in countries lacking such guidelines, the down-scheduling process can become complex and burdensome[29].

During the down-scheduling process, it is crucial for the government to conduct public hearings involving stakeholders such as manufacturers, consumers, and academic experts. Countries such as Japan, New Zealand, and Australia have successfully encouraged down-scheduling proposals not only from manufacturers but also from the general public. A noteworthy example of this is the initiative to reschedule naloxone. In this instance, the governments of Australia demonstrated a willingness to remove barriers to access, recognizing the medicine as safe and characterized by low to no abuse potential[21,24]. Prompt administration of naloxone is essential for mitigating the morbidity and mortality associated with opioid overdoses. Expanding access by making naloxone available over-the-counter represents a significant advancement in harm reduction strategies aimed at decreasing the adverse outcomes linked to opioid misuse[32].

Within the European Union (EU), although numerous aspects of pharmaceutical legislation have been harmonized, the classification of medicines as prescription-only, non-prescription, or

suitable for mass markets remains under the jurisdiction of individual EU member states. This allows each member state to tailor its regulatory approach based on national healthcare priorities and patient safety considerations[26]. However, this decentralization approach has led to disparities in down-scheduling activities across countries. A study from Germany indicates a notable decline in down-scheduling initiatives compared to previous decades, potentially attributable to a saturation effect in the availability of viable candidates for such changes. Most prevailing regulatory frameworks continue to rely on traditional risk-benefit analyses, which inadequately reflect the complexities of real-world patient behaviors and the associated risks related to access to medications[31].

In this context, transparency in disclosing Real-World Data (RWD) and Real-World Evidence (RWE) from prior successful applications for down-scheduling is particularly beneficial. The dissemination of such data can facilitate future attempts to down-schedule medications, mitigate uncertainty for manufacturers, and enhance trust in the regulatory framework. This transparency ultimately bolsters evidence-based decision-making and ensures that the down-scheduling process is not only founded on scientific evidence but also responsive to social considerations[20].

As the landscape of self-medication evolves, integrating regulatory flexibility with socioeconomic and behavioral insights will be essential. Down-scheduling is no longer a purely pharmacological perspective. it represents a multidimensional public health strategy that intersects with issues of access, equity, and systemic efficiency[31].

Positive Perception and Readiness of Pharmacists

Pharmacists have demonstrated strong support for the down-scheduling of certain medicines, as this policy enhances their ability to leverage professional expertise effectively. Medicines commonly approved for down-scheduling are frequently employed to manage the minor ailments, such as frequent headaches, allergy, common cold, minor pain and gastrointestinal disorders. This policy also facilitates improved patient access to a broader range of treatment alternatives[9,14,18,23,26]. They believe that the pharmacy profession is well-prepared to safely and effectively manage a broader array of non-prescription medicines through increased down-scheduling, particularly regarding patient safety and risk management[10,16,19]. This highlights that pharmacists' preparedness and favorable views regarding down-scheduling are essential factors in enabling the policy. In nations with highly skilled pharmacists, like New Zealand, the role of pharmacists in administering vaccinations exemplifies how expanding their responsibilities can alleviate access barriers and deliver significant public health advantages[15].

The down-scheduling of medicines is more actively pursued in countries that utilize two mechanisms for accessing non-prescription medicines: pharmacy or pharmacist-supply and over-the-counter. The primary distinction between these two approaches is that over-the-counter medicines can be acquired in retail settings without the oversight of a pharmacist, which raises concerns about potential misuse. In contrast, pharmacy or pharmacist-supply medicines necessitate pharmacist supervision, providing a safer alternative to ensure appropriate usage. The design of each medicine classification system is likely dependent on health professionals' responsibility as the evidence suggests that pharmacists' responsibility impacts the stipulations of the down-scheduling. Countries which have the pharmacy or pharmacist-supply medicine classification allow pharmacists to respond to patient's symptoms themselves, while countries that do not allow pharmacists to respond to patient's symptoms independently do not have this medicine classification[4]. Consequently, the readiness of pharmacists is a crucial factor driving the process of medicine down-scheduling, as they are well-positioned to support consumer self-medication and play a pivotal role

in offering guidance, advice, and information regarding medicines available for self-care[33]. Establishing an intermittent pharmacy or pharmacist-supply medicines classification would empower pharmacists to leverage their expertise in guiding patients through informed self-medication decisions. This approach allows for a more tailored use of pharmacists' clinical skills while ensuring that consumers have access to necessary medications under appropriate oversight[15,24].

Consumer awareness

Down-scheduling is designed to improve community access to the management of various minor health conditions. It also support enhanced self-management for diseases that are frequently associated with social stigma and psychological barriers[18]. A pertinent example is Overactive Bladder (OAB), a common ailment among women, which often remains unaddressed due to embarrassment and the widespread misconception that its symptoms are a typical aspect of aging. In response, the United States has approved the down-scheduling of oxybutynin in a transdermal patch formulation to over-the-counter status. This regulatory shift is intended to improve treatment accessibility and empower women to manage their OAB symptoms independently through nonprescription alternatives[34]. The rising interest in non-prescription medicines is underscored by significant increases in online search activity, indicating that greater availability of these products correlates with heightened public awareness and interest[25].

Patient responses to targeted advertising campaigns have been notably positive, with weekly direct product requests fluctuating between 2 and 70, reflecting a strong engagement with the promotional efforts[25]. This highlights that while factors such as manufacturer support and advertising have been acknowledged, consumer awareness is pivotal in driving product sales. A lack of awareness among consumers regarding the availability of certain products could substantially hinder sales performance[14].

As consumer awareness increases, the opportunity for down-scheduling a broader range of medicines rises. Conditions such as cholesterol management, menorrhagia, incontinence, and obesity—previously deemed necessitating physician oversight—are now viable candidates for down-scheduling, depending on consumer literacy and awareness in each country. This emphasizes the vital role of consumer awareness as a key enabler, empowering individuals to take greater control of their health[19,21].

Support from the medical professionals

One important consideration for down-scheduling is the support from medical professionals, particularly in light of the current shortages of primary care physicians[12]. By expanding the range of pharmacy-only medicines, patients would have the opportunity to seek consultation from community pharmacists for minor ailments[13,24]. This would alleviate some of the burden on physicians, allowing them to focus their appointments on acute and severe cases more effectively. Research from Germany indicates that a majority of physicians recognize that pharmacy-based self-medication benefits patient care, highlighting substantial support from the medical community for the down-scheduling of certain medicines[26]. Access to low-threshold care is vital in deciding whether minor health issues suitable for self-management are effectively treated. Untreated conditions, despite the availability of safe and effective therapies, can lead to lost opportunities for improving health-related quality of life and result in productivity losses. Additionally, therapeutic nihilism in non-treatment populations can worsen or prolong health issues, highlighting the need for proactive intervention and prevention[31].

Scarcity-related risks in healthcare refer to challenges arising from limited access to healthcare services. When sufficient self-care options are unavailable for certain medical conditions, patients are more likely to seek care from hospitals or primary care providers. This increased demand can lead to longer wait times for physician appointments, affecting even those with severe health issues who require timely attention. The result is often extended wait times in the physician's office and reduced consultation durations per patient. These constraints on treatment time and delays can compromise the quality of care, leading to heightened medical risks when necessary treatments are postponed or neglected[31]. Consequently, promoting self-diagnosis and facilitating access to non-prescription treatment options may alleviate the burden on healthcare providers, enhancing overall patient care efficiency[14,22,27,30].

Barrier factors

Risk averseness regulators

Supportive policymakers are essential in facilitating down-scheduling; however, regulatory risk aversion remains the most significant barrier to successful implementation in various countries. This risk aversion stems from various concerns, including the possibility of misdiagnosis, misuse, or inappropriate self-treatment by consumers[11–15,21,22,24,25,28,29].

The United States has generally taken a more conservative stance on down-scheduling compared to the United Kingdom, particularly in the context of medications for long-term use. This is exemplified by the repeated rejections by the U.S. Food and Drug Administration (FDA) of proposals to switch statins to non-prescription status, despite the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) having approved their availability as non-prescription medicines. The FDA's position appears to be driven by a risk-benefit analysis that leans toward caution, particularly concerning patient understanding of the associated risks and the potential overprescribing to individuals who may not require statin therapy. Furthermore, the FDA has made label modifications to statins to highlight possible cognitive side effects and elevated blood sugar levels, underscoring its conservative regulatory stance. Another factor influencing this cautious approach is the existence of the pharmacy-only medicine category in the United Kingdom. This regulatory model, by enabling pharmacist oversight without fully transitioning to non-prescription status, may reduce the perceived need for broader down-scheduling and reflects a risk-averse culture in down-scheduling policy[19].

In Australia, stakeholders from industry, pharmacy, and regulatory committees have frequently characterized these regulatory bodies as conservative and risk-averse. Concerns voiced by industry representatives, including a committee member from outside the industry, point to issues such as a lack of transparency, unexplained delays, or outright stagnation in the down-scheduling process following a positive committee recommendation. Perceived risk aversion in down-scheduling and advertising has discouraged the industry from pursuing these initiatives[18,27]. Many participants, including committee members, suggested that jurisdictional members—often viewed as inherently conservative—hindered down-scheduling, sometimes due to directives from higher authorities[16,26].

One notable distinction in the down-scheduling practices between Singapore and China compared to other countries is their reliance on the approval status of reference countries, such as the United States, the United Kingdom, and Australia. Consequently, sponsors typically seek down-scheduling only after achieving approval from a major health authority[19].

The lack of well-defined regulatory frameworks has resulted in the phenomenon of double registration—where the same medicine is available both with and without a prescription—which

creates confusion and may contribute to pharmacists' ambivalence toward down-scheduling. In Poland, certain medicines are classified as prescription-only, whereas the same products, marketed under different trade names, are registered as over-the-counter medicines. This phenomenon of dual registration is exemplified by substances such as cetirizine, omeprazole, and ranitidine. Consequently, the perception emerges that medicines are being down-scheduled primarily to enhance consumer access, despite ongoing concerns about their potential risks when misused or improperly administered. Inconsistencies in legal guidelines may raise concerns about the safety of these medicines in self-medication contexts and their suitability for general sale. A majority of study participants expressed negative attitudes toward down-scheduling, highlighting the need for more specific information about potential side effects of medicines that have been down-scheduled. Such apprehensions about regulatory decisions undermine pharmacists' confidence, leading to a lack of trust when dispensing medicines[17,30].

Pharmacist confidence

Interestingly, pharmacists play a dual role in the implementation of down-scheduling policies, serving as both key enablers and potential barriers depending on the specific context and available support levels. The facilitative aspect underscores their readiness and favorable attitudes, notably in countries like New Zealand and the United Kingdom, where robust professional training and supportive frameworks are in place. Conversely, the obstructive aspect unveils a more complex landscape in particular jurisdictions, where varying degrees of regulatory challenges and resource limitations may hinder their effectiveness. The concept of pharmacist confidence extends beyond mere theoretical knowledge and general preparedness. It is significantly influenced by practical experience, institutional support, and well-defined responsibilities within the healthcare framework. For instance, in Australia, although pharmacists recognize the benefits of down-scheduling medications, many express a lack of confidence in diagnosing conditions such as migraines. This issue is largely attributed to inadequate updates in clinical training. In contrast, New Zealand showcases more advanced pharmacist-led services, resulting in enhanced confidence among pharmacists in clinical settings[10,29]. In the case of simvastatin, barriers to its acceptance have arisen from perceived inadequacies in both the evidence supporting its efficacy and the demand from patients. This hesitance consequently influences the down-scheduling of other statins[23].

In this context, pharmacist readiness denotes a structural or systemic capability, while confidence pertains to an individual or situational reaction to professional exigencies. The disparity between these two constructs is particularly pronounced in nations where pharmacists possess favorable positioning yet experience deficiencies in continuous education, policy endorsement, or interprofessional collaboration. These shortcomings ultimately undermine their self-efficacy in the practice environment. This duality emphasizes the complex role of pharmacists as a "double-edged sword" in the down-scheduling process of medications. On one hand, pharmacists are trusted healthcare professionals who can facilitate responsible self-medication practices. Conversely, in the absence of adequate empowerment and support, they may become reluctant to embrace expanded responsibilities, thus inadvertently hindering the implementation of relevant policies. Research conducted in Poland and Australia illustrates that pharmacists' inconsistent confidence levels are often attributable to a lack of robust training frameworks, ambiguous legal responsibilities, and apprehensions regarding making clinical decisions without direct physician oversight. Therefore, it is imperative to enhance the training programs for pharmacists, delineate more precise scopes of practice, and foster interprofessional

trust. By harmonizing systemic preparedness with pharmacists' individual competencies, we can empower them to play a pivotal role in the safe and efficient transition of medicines from prescription to non-prescription status[10,24,25,28].

Implications for Practice

The implications for practice across studies on down-scheduling medicines highlight the necessity for a balanced approach that prioritizes patient safety while enhancing access to medicines. The findings underscore the significance of clear regulatory frameworks that facilitate down-scheduling[11,19,20,22,29,30], complemented by targeted educational initiatives for both healthcare providers and consumers. Pharmacists, in particular, play a pivotal role in the success of this policy, serving as the primary point of contact for patients[16,17]. This underscores the need for enhanced training programs aimed at increasing pharmacists' confidence and competence in facilitating safe medication use[9,10,23–25,28].

Additionally, support from healthcare professionals and policymakers is crucial, as their endorsement not only promotes smoother implementation but also fosters community trust. Nevertheless, barriers such as regulatory caution and concerns regarding misuse or self-diagnosis must be addressed through continuous public health campaigns and evidence-based advocacy to ensure that down-scheduling does not compromise patient well-being. For countries with more conservative regulatory frameworks, it is essential to establish collaborative platforms between regulators, healthcare professionals, and the public to align on the benefits and risks associated with non-prescription medicine availability[12,13,15,18,21,26,27].

In summary, while the movement toward greater access to medications can alleviate pressures on healthcare systems and enhance patient autonomy, it necessitates comprehensive policy adaptation, active stakeholder involvement, and ongoing monitoring to ensure positive health outcomes and mitigate potential risks.

This study has several limitations that should be acknowledged. First, the review included only articles published in English, which may have excluded relevant studies conducted in non-English-speaking countries, potentially limiting the global generalizability of findings. Second, despite comprehensive searches across multiple databases, there is still a risk of publication bias, as grey literature and unpublished studies were not included. Third, the diversity in study designs and outcome measures among the included articles hindered the ability to conduct a meta-analysis or make direct comparisons. Lastly, while efforts were made to maintain objectivity in study selection and data extraction through the involvement of multiple reviewers, the inherently subjective nature of thematic synthesis may still introduce interpretative bias.

CONCLUSION

The findings from this study emphasize the significance of a supportive regulatory environment and the active participation of both healthcare professionals and consumers in the successful implementation of down-scheduling policies. While the establishment of clear guidelines and a proactive approach from policymakers have emerged as key facilitators, challenges such as regulatory risk aversion and a lack of confidence among pharmacists present notable obstacles.

While the primary objective of down-scheduling is to enhance medicine accessibility, continuous improvement in regulatory practices and mitigation of safety and misuse concerns remain essential. Additionally, enhancing training for pharmacists and educating the public on the responsible use of non-prescription medicines is important.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interests.

REFERENCES

1. Gauld NJ, Kelly FS, Emmerton LM, Kurosawa N, Bryant LJM, Buetow SA. Medicines reclassification from a pharmaceutical industry perspective: An international qualitative study. Res Soc Adm Pharm. 2019;15(4):387-394. https://10.1016/j.sapharm.2018.06.004

2. Mey A, King M, Kelly F, et al. Australian pharmacy perspectives on increasing access to medicines through reclassification. J Heal Serv Res Policy. 2019;24(2):81-90. doi:10.1177/1355819618799112

3. G M, Swetha K SG, Reddy J RK, Raju K V. Review of Regulations Governing Switching Drugs From Rx To Over-the-Counter in the Usa, India, and Eu. Asian J Pharm Clin Res. 2021;14(9):12-19. doi:10.22159/ajpcr.2021.v14i9.42393

4. Leelavanich D, Adjimatera N, Broese Van Groenou L, Anantachoti P. Prescription and non-prescription drug classification systems across countries: Lessons learned for thailand. Risk Manag Healthc Policy. 2020;13:2753-2768. doi:10.2147/RMHP.S281629

5. GOV.UK. Oral diclofenac presentations with legal status 'P' – reclassified to POM. 2015. Accessed March 26, 2025. https://www.gov.uk/drug-device-alerts/drug-alert-oral-diclofenac-presentations-with-legal-status-p-reclassified-to-pom

6. Therapeutic Good Administration. Final decision on re-scheduling of codeine: frequently asked questions. 2016. Accessed March 26, 2025. https://www.tga.gov.au/final-decision-re-scheduling-codeine-frequently-asked-questions

7. Ministry of Health Republic Indonesia. Regulation of the Minister of Health of the Republic of Indonesia Number 3 year 2021 regarding the Medicine Reclassification, Restrictions, and Categories. Published online 2021.

8. Ministry of Health Republic Indonesia. Regulation of the Minister of Health of the Republic of Indonesia Number 28 year 2022 regarding the Medicine Reclassification, Restrictions, and Categories. Kementeri Kesehat Republik Indones. Published online 2022.

9. Alkhatib L, Parsons R, Czarniak P, Sunderland VB. An evaluation of the reclassification of ophthalmic chloramphenicol for the management of acute bacterial conjunctivitis in community pharmacies in Western Australia. Int J Pharm Pract. 2015;23(2):111-120. doi:10.1111/ijpp.12119

10. Booth S, Parsons R, Sunderland B, Sim TF. Managing migraine with over-the-counter provision of triptans: The perspectives and readiness of Western Australian community pharmacists. PeerJ. 2019;2019(12). doi:10.7717/peerj.8134

11. Barrenberg E, Garbe E. From prescription-only (Rx) to over-the-counter (OTC) status in Germany 2006–2015: pharmacological perspectives on regulatory decisions. Eur J Clin Pharmacol. 2017;73(7):901-910. doi:10.1007/s00228-017-2240-4

12. Chang J, Lizer A, Patel I, Bhatia D, Tan X, Balkrishnan R. Prescription to over-the-counter switches

in the United States. J Res Pharm Pract. 2016;5(3):149. doi:10.4103/2279-042x.185706

13. Chang DW, Grotts J, Tseng CH, Brass EP. Time Trends in Physician Visits for Gastroesophageal Reflux Disease Before and After the Rx-to-OTC Switch of Proton Pump Inhibitors. J Clin Pharmacol. 2017;57(4):452-458. doi:10.1002/jcph.825

14. Fix W, Desai S, Nussbaum D, Friedman A. Rx -to- OTC switch increased access and lowered cost of topical adapalene. Arch Dermatol Res. 2024;316(5):1-5. doi:10.1007/s00403-024-02890-9

15. Gauld NJ, Kelly FS, Kurosawa N, Bryant LJM, Emmerton LM, Buetow SA. Widening consumer access to medicines through switching medicines to non-prescription: A six country comparison. PLoS One. 2014;9(9):1-7. doi:10.1371/journal.pone.0107726

16. Gauld NJ, Kelly FS, Emmerton LM, Buetow SA. Widening consumer access to medicines: A comparison of prescription to non-prescription medicine switch in Australia and New Zealand. PLoS One. 2015;10(3):1-22. doi:10.1371/journal.pone.0119011

17. GruchaŁa K, Zimmermann A, Kawczak P. Rx-to-OTC switch and double registration occurrence in Poland - An illuminative case study. Acta Pol Pharm - Drug Res. 2016;73(1):247-254.

18. Hope DL, Woods P, Mey A, et al. Australian pharmacists: ready for increased non-prescription medicines reclassification. Int J Pharm Pract. 2020;28(3):246-254. doi:10.1111/ijpp.12594

19. Kartha SS, Kulyadi GP, Bhat K, Sathyanarayana MB. Switching Drugs from Rx to OTC status – A Regulatory Perspective. J Young Pharm. 2017;9(2):230-233. doi:10.5530/jyp.2017

20. Kühler TC, Ateka A, Lassoued Z, Routhier FX, Mékary-Sawaya S. Real-world Data and Evidence to support a switch in status from Prescription drug to Over the Counter drug as applied by the EMA, the US FDA, the MHRA, and the BfArM. Clin Ther. 2024;46(3):208-216. doi:10.1016/j.clinthera.2023.12.013

21. Nomura K, Kitagawa Y, Yuda Y, Takano-Ohmuro H. Medicine reclassification processes and regulations for proper use of over-the-counter self-care medicines in Japan. Risk Manag Healthc Policy. 2016;9:173-183. doi:10.2147/RMHP.S98099

22. Otto MH, Pillarella C, Jommi C. The economic impact of a switch from prescription-only to nonprescription drugs in Italy. Front Pharmacol. 2018;9(OCT):1-10. doi:10.3389/fphar.2018.01069

23. Paudyal V, Hansford D, Cunningham S, Stewart D. Pharmacists' adoption into practice of newly reclassified medicines from diverse therapeutic areas in Scotland: A quantitative study of factors associated with decision-making. Res Soc Adm Pharm. 2014;10(1):88-105. doi:10.1016/j.sapharm.2013.04.007

24. Pricolo A, Nielsen S. Naloxone rescheduling in Australia: Processes, implementation and challenges with supply of naloxone as a 'pharmacist only' over-the-counter medicine. Drug Alcohol Rev. 2018;37(4):450-453. doi:10.1111/dar.12547

25. Shaw JP, Gauld N, Kelly F. Barriers to positive policy change that aims to increase access to medicines through reclassification: The case of oseltamivir in New Zealand. Int J Pharm Pract. 2016;24(1):6-12. doi:10.1111/ijpp.12200

26. Stippler A, Eckstein N, Kroth E. To Switch or Not To Switch – German Physicians' Views on Proposed New OTC Medicine. 2019;10(1):11-23.

27. Stippler A, Eckstein N, Kroth E. Key results of a series of surveys among German pharmacies, physicians, patients and stakeholders regarding further triptans as potential OTC products. J Public Heal. 2022;30(2):409-415. doi:10.1007/s10389-020-01310-2

28. Yeung KWCM, Lee SKM, Bin YS, Cheung JMY. Pharmacists' perspectives and attitudes towards the 2021 down-scheduling of melatonin in Australia using the Theoretical Domains Framework: a mixed-methods study. Int J Clin Pharm. 2023;45(5):1153-1166. doi:10.1007/s11096-023-01605-w

29. Yuen CWS, Chong DWK. Rx-to-OTC Switch – An Overview and its Implications to Public Health. Hong Kong Pharm J. 2018;25(Oct-Dec):110.

30. Zaprutko T, Kopciuch D, Ratajczak P, et al. The prescription to over-the-counter switches and double registration of medicines ñ the perspective of pharmacists from Greater Poland. Acta Pol Pharm - Drug Res. 2019;76(5):907-912. doi:10.32383/appdr/106014

31. Bauer C, May U, Schneider-Ziebe A, Giulini-Limbach C, Pham TK. Socioeconomic Considerations in Choosing and Evaluating Candidates for RX-to-OTC Switch Author Afilliations. https://selfcarejournal.com/article/socioeconomic-considerations-in-choosing-and-evaluating-candidates-for-rx-to-otc-switch/

32. Lenton SR, Dietze PM, Jauncey M. Australia reschedules naloxone for opioid overdose. Med J Aust. 2016;204(4):146-147.e1. doi:10.5694/mja15.01181

33. Rutter P. Role of community pharmacists in patients' self-care and self-medication. Integr Pharm Res Pract. Published online 2015:57. doi:10.2147/iprp.s70403

34. Hemwall E, Replogle A, Neumann RS, Licata K, Vassil T. Nonprescription Oxybutinin Transdermal Patch: Improving Self Care Options for Overactive Bladder in Women. SelfCare. 2013;4(May):66-74.