



Advancing Self-Care

The Critical Role of Rx-to-OTC Switches in Empowering Health and Expanding Access

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Introduction

Self-care, as defined by the World Health Organization (WHO), is the **ability of individuals, families, and communities to promote health, prevent disease, maintain health, and cope with illness and disability, with or without professional healthcare support.**



This broad concept encompasses everything from healthy diets and mindfulness to non-prescription medications and self-monitoring of health conditions ¹.

Self-care, when practiced through the use of non-prescription medicines (NPM), offers significant benefits to individuals, healthcare systems, and public health – yielding an estimated \$119 billion savings per year globally, with projections rising to an estimated \$179 billion by 2030 ². Self-care empowers individuals and communities to manage their health and well-being;

it strengthens national institutions by facilitating efficient use of domestic health resources; and it improves primary healthcare and accelerates progress towards achieving universal health care (UHC), a critical long-term goal for WHO ¹. These benefits are particularly important as healthcare systems face growing sustainability challenges, including workforce shortages, rising costs, and increasing demand for services, all of which create barriers to timely access and strain existing resources ³.

The Self-Care Readiness Index, developed by the Global Self-Care Federation (GSCF), identifies critical enablers that influence the adoption of evidence-based self-care products⁴. Among these, the reclassification of medicines from prescription to non-prescription status, commonly referred to as “Rx-to-OTC switch” is recognized as a pivotal mechanism for advancing self-care. This process is situated within the regulatory environment but intersects with broader determinants, including stakeholder engagement, consumer and patient empowerment, and the integration of self-care into health policy frameworks. Importantly, Rx-to-OTC switches do not introduce novel or untested molecules; rather, they transition well-established medicines with a documented history of prescription use to non-prescription status. This approach represents the most efficient and responsible strategy for expanding self-care options for consumers.

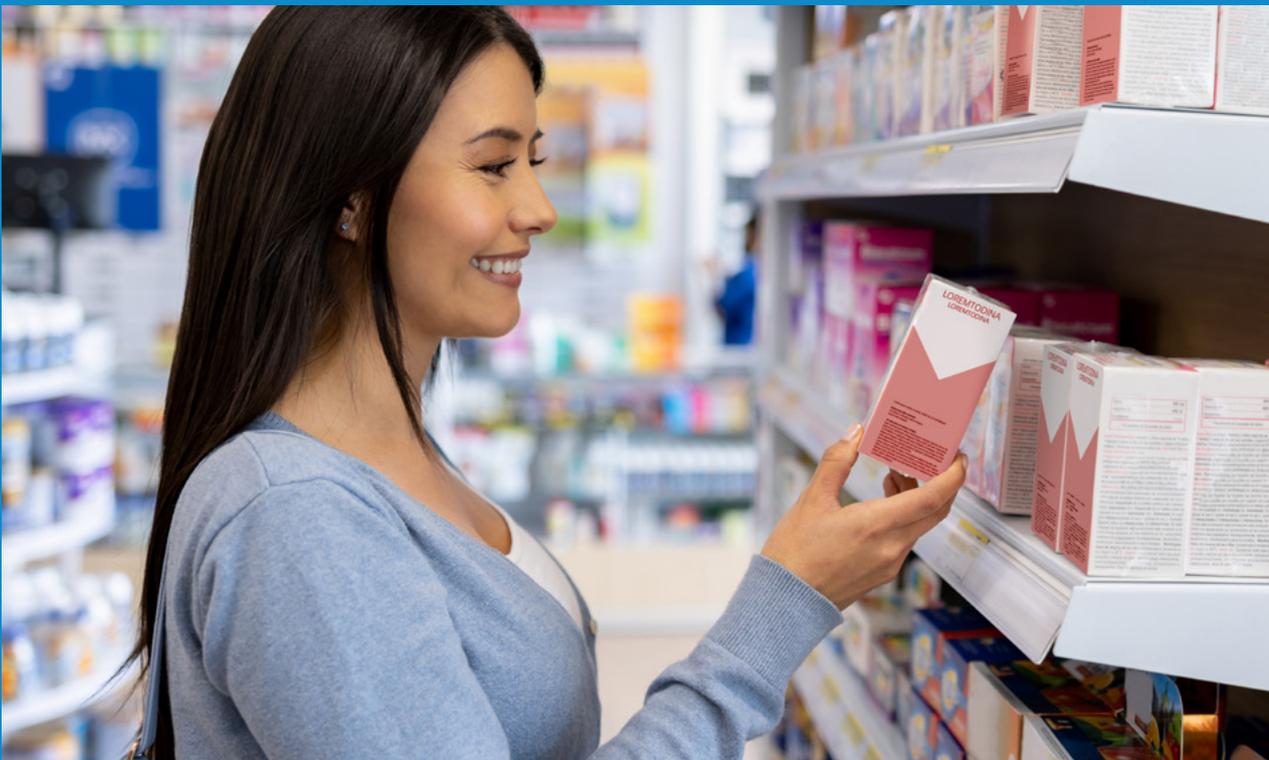
The benefits of such switches are substantial, encompassing improved public health outcomes, alleviation of healthcare system pressures, cost reductions, and enhanced accessibility to essential treatments.

By enabling individuals to manage common, self-treatable conditions and ailments, the availability of NPMs* promotes self-care and helps reduce unnecessary doctor visits.

This shift provides people with more options for treating common medical conditions and eases the burden on medical facilities – currently saving an estimated 1.8 billion physician hours, ensuring that healthcare providers can focus on more complex cases². In low- and middle-income countries, where sick leave is often unpaid, adopting this practice reduces absenteeism and helps people keep their daily earnings. In this context, NPMs typically cost less than prescription medicines and visiting doctor for self-treatable and common ailments, lowering expenses for individuals and healthcare systems alike². Early intervention with NPMs can prevent medical complications, thus minimizing long-term costs. Additionally, reclassification improves access, especially for rural and underserved communities, ensuring equitable healthcare availability by minimising unnecessary physician visits and reducing the existing shortage of healthcare professionals⁵.

* Also referred to as over-the-counter or OTC medicines.

Beyond accessibility, reclassification works best when it is paired with initiatives that build health literacy and personal responsibility – these are the catalysts for appropriate selection and use of NPM². Public education, clear labelling and pharmacist guidance mitigate risks and equip people to self-select and administer NPMs appropriately^{6,7,8}. With regulatory oversight in place, this shift balances empowerment with safety and supports a culture of informed self-care in which individuals can manage their health responsibly.



INDIVIDUALS BENEFIT IN SEVERAL WAYS IF NPMs ARE AVAILABLE WITHOUT A DOCTOR'S PRESCRIPTION:

- **They can visit a pharmacy rather than wait for an appointment with their doctor⁹.** Jurisdictions that leverage pharmacist expertise have successfully transitioned more complex molecules, demonstrating how these professionals can effectively bridge the gap between prescription-based care and self-care.
- **They can treat self-treatable conditions and common ailments** (e.g. Cough, cold, mild-to-moderate pain, smoking cessation, emergency contraception) reducing the time from the onset of symptoms to the treatment.
- **They can more easily obtain time-critical products which have to be taken early to be most effective** (e.g. Pain / headache medications, emergency contraception).



Reclassification of prescription medicines to NPM status can be complex. But a number of regulatory elements are critical to maximizing the opportunity to bring the benefits of NPMs to individuals, health systems, and public health:

- Clear definition of Rx and NPM enshrined in legislation with clear criteria.
- Dedicated and transparent Rx-to-OTC switch process at national/regional level depending on the accessibility of the medicine (e.g. guidance available on agency website, public assessment reports).
- Publication of list of products already available without prescription in the jurisdiction.
- Harmonisation of Rx-to-OTC switch regulatory best practices and consideration of these medicines switched in other jurisdictions based on the harmonised criteria.
- Well-defined and consistently applied benefit-risk model.
- Data protections for innovative Rx-to-OTC switches.
- Increased acceptance of Real World Evidence (RWE) to support Rx-to-OTC switches.
- Accelerating use of digital tools and other innovations.

Forward Looking Switch Continuum

Expanding access to medicines supports better health outcomes and empowers individuals to manage common conditions safely.

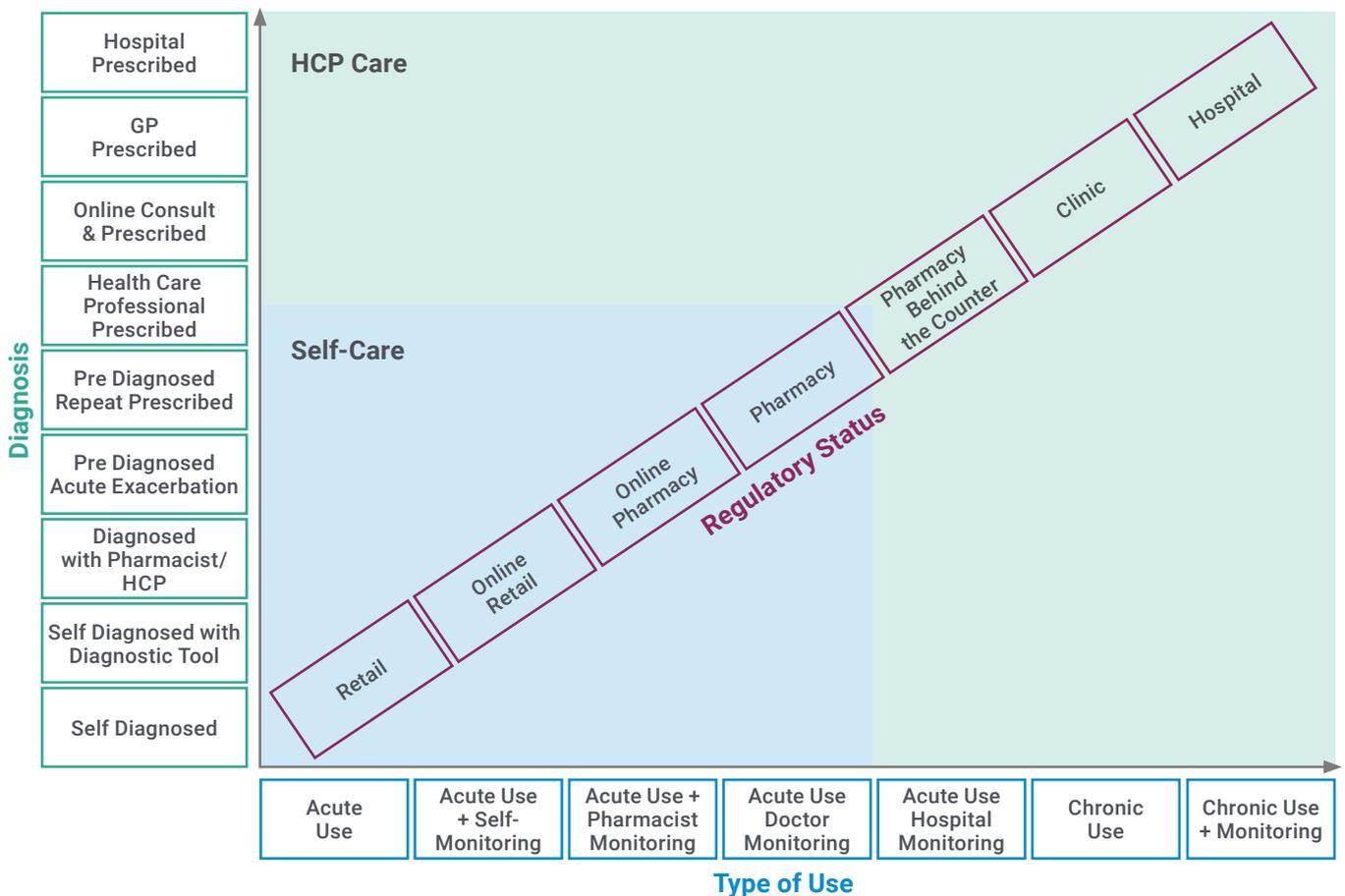
Rather than limiting access to two categories namely prescription-only or non-prescription, a forward-looking reclassification continuum approach that introduces flexible options tailored to patient needs and risk profiles is needed (Figure 1). The reclassification continuum approach ensures a seamless and progressive sequence, where adjacent elements blend into each other while the extremes remain distinct. It should be built on three pillars:

METHOD OF DIAGNOSIS: Self-diagnosis, aided diagnosis, pharmacist or healthcare professional diagnosis, prior diagnosis.

TYPE OF USE: Acute or chronic, with or without monitoring.

PLACE OF SUPPLY: Retail, online pharmacy, pharmacy counter, clinic, or hospital.

Figure 1: A Forward Looking Reclassification Continuum



Appropriate supply status should be determined on a case-by-case basis considering the full spectrum of appropriate:



**Ways to
diagnose**



**Places
of supply**

By adopting this approach, regulators can enable responsible self-care while maintaining necessary safeguards, drawing on clear scheduling factors e.g. TGA's framework that align the level of control with public health risk.



Options such as **pharmacy-only availability** e.g. for minor, easily recognised conditions where safe use can be supported by labelling and pharmacist advice, **behind-the-counter/ pharmacist-only supply** where pharmacist verification, counselling and monitoring are needed to manage higher risks or recurrent use, and **prescription-only access** where diagnosis, close monitoring, potential dependency or complex interactions require medical oversight leverage pharmacist expertise and digital tools to ensure safe use. This risk-based continuum reflects modern healthcare realities and creates opportunities for innovation, improved access, and harmonization across jurisdictions.

Regulatory Elements to Incentivize Rx-to-OTC Switches

Harmonisation of Rx-to-OTC Switch Regulatory Best Practices

Due to the global nature of medicine development and manufacturing, innovation often faces hurdles due to discordant regulations and regulatory processes.



However, harmonisation of technical and scientific standards across countries to streamline registration and approval, could play a critical role in increasing the number and quality of applications made to reclassify a medicine from prescription to non-prescription across multiple countries and regions. It could also ensure that a single data set supporting a reclassification would be equally valid across geographies.

There are many efforts to harmonise pharmaceutical regulations at the global (e.g., the World Health Organization and the International Council for Harmonisation) and regional (e.g., Pan American Network for Drug Regulatory Harmonization) levels. In the long term, these umbrella organizations should focus on harmonization specific to Rx-to-OTC switch. To-date, most switch

harmonization efforts have taken place at the local or sub-regional level; for instance, regulatory bodies in China, Mexico, and Australia/New Zealand have refined their switch regulations and regulatory processes by identifying, sharing and adopting best practices and innovations over many decades as they learned from other regulatory bodies and developed their own innovations.

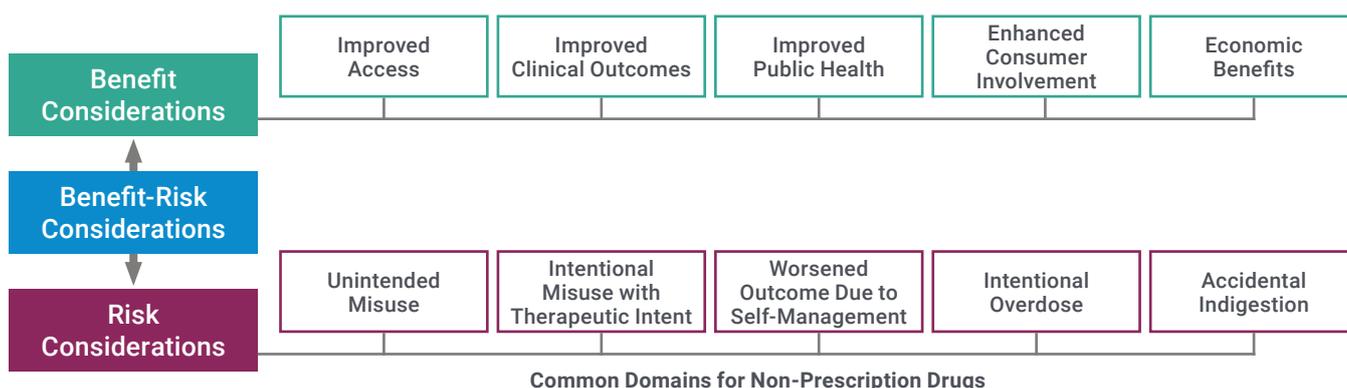
GSCF applauds these efforts. However, with the aim of reducing duplication, accelerating access to non-prescription medicines, and ensuring consistent safety and quality standards worldwide, GSCF calls on more regulatory bodies globally to prioritize Rx-to-OTC switch regulations and expand their efforts to further identify, share and adopt best practices.

Well-Defined and Consistently Applied Benefit-Risk Model

Regulatory agencies consistently stress the need for case-by-case benefit-risk assessments when considering switches. More than a decade ago, Brass et al. introduced a benefit–risk assessment model which offers a decision analysis to aid both companies and assessors to review both the benefits of improved access as well as the risks¹⁰. It can be customized to systematically evaluate the therapeutic and safety profiles of switch candidates. The model provides a value tree analysis to first detect, assess and mitigate data gaps and then aid communication between companies and authorities. It is grounded in the WHO’s principle that a drug’s safety profile remains consistent when used in comparable populations, regardless of Rx or OTC status. It shifts focus from molecule-specific risks to contextual risks associated with self-management, such as improper use or delayed treatment. Additionally, it considers factors like comparative therapies, health economics, timely access to care and appropriate risk mitigation elements (packaging, labeling, etc).

When applied as part of the switch process, this framework can facilitate early and structured dialogue between manufacturers and regulators, allowing for alignment of dossier requirements, safety concerns, and mitigation strategies. A strong, iterative dialogue, supplemented by input from expert scientific committees and medical opinion leaders can enhance decision-making, minimize last-minute issues, and encourage tailored safeguards like restricted sales channels, enhanced labeling, or post-marketing surveillance, where justified. While the Brass benefit-risk model has been incorporated into national guidelines in several countries, for instance, in the UK, New Zealand, and Canada, after more than a decade since its development, this approach is still not leveraged in most jurisdictions. Therefore, for nations interested in facilitating Rx-to-OTC switch, GSCF strongly believes that they should adopt the Brass model as a harmonized approach to assessing an Rx-to-OTC switch.

Figure 2: Pre Review Example of Value Tree



E P Brass, R Lofstedt and O Renn. Improving the Decision-Making Process for Nonprescription Drugs: A Framework for Benefit – Risk Assessment Clin. Pharmacol. Ther. 2011: doi: 10.1038/clpt.2011.231

Data Protections for Innovative Rx-to-OTC Switches

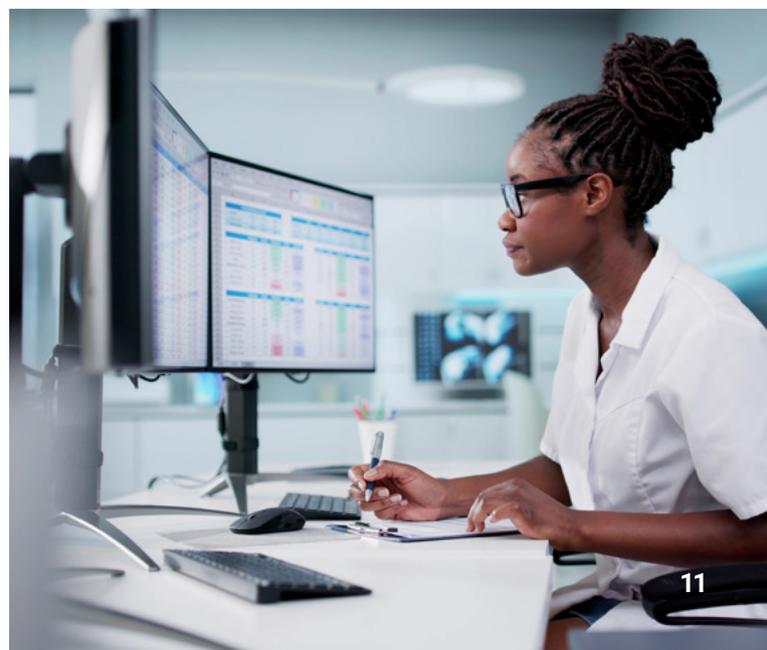
Data protection, which includes data and market exclusivity, offers time-limited protections, primarily for prescription drugs. Although the U.S. grants up to three years of exclusivity for switches involving new clinical studies, and Japan has similar provisions, neither fully accounts for costly consumer studies and usage testing now required for switches^{11,12}. Moreover, EU allows just one year of protection, and many countries offer none at all.

Switching from prescription to non-prescription status requires significant financial investment and research, yet data/market protections are often inadequate for non-prescription products^{11,13,14,15}. In many regions, switch approvals apply broadly to any product with the same ingredient, allowing competitors to benefit without sharing the development burden. This prevents manufacturers from recovering the substantial costs of investment in research and consumer studies, diminishing incentives to pursue new and improved OTC solutions that could benefit consumers.

Moreover, delays between approval and market launch (e.g. updates of list, communication to pharmacies and education) often erode the benefit of any short data exclusivity period that might be granted. Given the rising demands for safety demonstrations, behavioral studies, pharmacy-based studies, validated market research and other types of real-world studies that translate into real-world evidence should also be eligible for protection.

By establishing data protection and market exclusivity periods for innovative Rx-to-OTC switches, governments would be incentivizing more of them. At the same time, a further harmonized international approach to exclusivity will address disparities and inconsistencies in exclusivity periods between jurisdictions. It will, in turn, decrease complexity by creating consistent exclusivity rules across countries, allowing companies to align their regulatory strategies and launch timelines globally. Harmonization also reduces development and time costs since dossiers and supporting documentation can be prepared once and adapted for multiple markets with minimal changes.

GSCF recommends that health authorities adopt stronger data exclusivity rules, at least equivalent to the U.S. model, by granting three years of market exclusivity for switches supported by new clinical investigations and consumer-use studies, to ensure fair return on investment and encourage innovation in non-prescription medicine development.



Increase Acceptance of RWE to Support Rx-to-OTC Switches

RWD is defined by The Professional Society for Health Economics and Outcomes Research, better known as ISPOR, as “data used for decision making that are not collected in conventional randomized controlled trials”¹⁶. RWE is then simply defined as “the evidence deriving from the analysis of RWD”^{17,18}

Thus, RWD is different from, but complementary to, data obtained from conventional Randomized Controlled Trials (RCTs). RCTs are conducted in clinical settings with predefined inclusion and exclusion criteria to maximize efficacy signal(s) and identify potential adverse events, employing assessment schedules that may not necessarily reflect real-life medical practice to treat and manage the condition. Sources for RWD include, but are not limited to, electronic health records (EHRs); insurance claims and billing data; patient registries; wearable devices and mobile health apps.

RWE is increasingly used in the prescription medicine universe to support regulatory decisions, monitor post-market safety, and inform healthcare policy and clinical practice. It helps fill the gaps left by clinical trials by reflecting how treatments perform in broader, more diverse populations over longer periods.



Just as RWE has been applied to regulatory decisions around prescription medicines, regulatory bodies can increase their acceptance of RWE in the Rx-to-OTC switch process¹⁹. A wide range of data sources, broadly defined as RWD or RWE, are used to support switches, and many regulators now encourage sponsors, with some caveats, to leverage available RWD. By adopting this strategic approach, regulatory bodies can strengthen benefit-risk assessments and address other unique challenges in the switch process.

For regulators, the central concern in evaluating a switch is ensuring drug safety, both in terms of the product's inherent risks and how it is used in everyday consumer settings. RWE can be used to optimize product information and pharmacy tools, ensuring that a candidate medicine can be recommended and used safely by identifying real-world patterns such as adverse event rates, drug interactions, dose adjustments, and the influence of existing health conditions that traditional labeling and actual-use studies may overlook.



RWE can also be used to help fill evidentiary gaps where Randomized Clinical Trials (RCT's) are not feasible.

For example, a post-authorization observational study for ulipristal acetate (ellaOne) affirmed its efficacy and safety in real-world use, providing new knowledge (e.g. how consumers use products that are outside of the purview of controlled study, impact of new OTC on quality of life) beyond controlled trials, which influenced the EMA switch recommendation affirming its efficacy and safety. Similarly, a real-world study in the UK following the approval of non-prescription sildenafil (Viagra Connect) influenced the switch of that product and similar products in other European countries demonstrating studies after approval of a switch still help other jurisdictions. In both instances, RWE helped demonstrate how broadening drug access improves quality of life and reduces burdens on healthcare.



BEYOND BENEFIT-RISK ASSESSMENT AND POST-AUTHORIZATION MONITORING, RWE CAN PLAY AN ENABLING ROLE FOR MANUFACTURERS THROUGHOUT THE SWITCH PROCESS:

- **Early on**, during the feasibility stage, RWE can clarify indication incidence and support development of sales models; it can inform trial design and execution;
- **Before an application**, RWE can illuminate real-world standard of care and physician patterns;
- **During the switch process**, RWE can support evaluation of effectiveness and safety (e.g., comorbid conditions and adverse events);
- **After a switch**, it might support a product information update considering a patient-centric approach.



Overall, RWE presents valuable opportunities to support Rx-to-OTC switches by highlighting real-world benefits, risks, and consumer use patterns. When well-designed and validated, RWE can strengthen regulatory decision-making, improve safety and efficacy assessments, and help bring non-prescription products to market more efficiently. GSCF sees a clear need for industry and regulators to work collaboratively to ensure a robust future for Rx-to-OTC switches, utilizing advances in digital technologies and RWD/RWE.

This can be achieved by:

- Engaging in early product-specific consultations with health authorities to understand specific RWD/RWE requirements.
- Iteratively presenting findings and addressing concerns throughout the switch process.
- Establishing the credibility of RWD/RWE by sharing success stories via published studies and in other public forums.
- Collaborating with academia and learned societies to achieve common understanding and process on study design, analysis, and interpretation.

Embracing Innovative Digital Solutions as a Risk Mitigation Strategy

Digital health technologies represent a critical evolution in enabling safe and effective Rx-to-OTC switches. While these tools can support the collection of real-world data (RWD), their role extends far beyond evidence generation. They actively facilitate safe consumer self-selection, enhance product information, and enable ongoing monitoring and support. For example, AstraZeneca's TACTiC trial demonstrated a 98.1% concordance between consumer self-selection using web-based applications and clinical assessments, underscoring the potential of digital tools to ensure appropriate use without direct healthcare provider oversight^{22,23}.



KEY FUNCTIONALITIES INCLUDE:

- **Consumer Self-Selection Support:** Digital questionnaires and interactive symptom checkers help consumers determine suitability for OTC use.
- **Enhanced Product Information:** Electronic labelling (ePI) ensures timely access to accurate, updated product details.
- **Real-Time Monitoring and Support:** Mobile applications can provide dosage reminders, adherence tracking, and symptom monitoring with risk alerts.
- **Facilitating Pharmacist-Consumer Interactions:** Digital platforms enable remote consultations and structured guidance for complex switches.

ADVANCING SELF-CARE:

THE CRITICAL ROLE OF RX-TO-OTC SWITCHES IN EMPOWERING HEALTH AND EXPANDING ACCESS

These capabilities align with regulatory initiatives such as the U.S. Food and Drug Administration's Additional Condition for Non-prescription Use (ACNU) framework, introduced in late 2024. The ACNU rule aims to expand OTC availability for medicines that do not meet traditional self-selection or actual-use study requirements, provided manufacturers implement safeguards such as digital tools to ensure safe use^{24,25}.

By integrating these technologies, manufacturers can overcome barriers in complex switches, improve adherence, and enhance consumer education through interactive tutorials and progress tracking.



Furthermore, digital solutions streamline reordering processes via automated refill alerts and pharmacy integration, reinforcing continuity of care.

In summary, digital tools should be recognized as distinct enablers of safe OTC use, complementing but not limited to RWE generation. Their multifaceted role in risk mitigation positions them as indispensable components of modern switch strategies.

Call to Action

To fully realize the transformative potential of Rx-to-OTC switch and empower global self-care efforts, collaborative efforts across industry, regulators, policymakers, and healthcare stakeholders are essential. We urge:



WHO should explicitly endorse the forward looking reclassification continuum, within its guidance, to encourage regulators to think more flexibly about access pathways; such high-level endorsement would help shift regulatory mindsets, open up more switch and self-care opportunities in both developed and developing countries (while preserving switch decisions as a national competence), and legitimize this modality of access as part of a WHO-aligned framework.

Regulators should prioritize harmonizing switch regulations and adopting clear, science-based frameworks such as the Brass benefit-risk model, while increasing acceptance of real-world evidence (RWE); they should also define transparent criteria for Rx vs. OTC status and intermediate NPM categories, including whether the condition is self-diagnosable or requires healthcare professional involvement, the product's safety and toxicity profile, and its potential for abuse or misuse to ensure predictable, harmonized decisions and timely, safe consumer access to self-care options.



Policymakers to implement robust data protection and market exclusivity policies that incentivize innovation while ensuring affordable access.

Industry working through trade associations should shift from ad-hoc engagement to structured collaboration with regulators by co-hosting workshops to identify priority switch opportunities and quantify missed public health gains, submitting standardized evidence packages mapped to agreed classification criteria, leveraging real-world and digital data to demonstrate safe consumer use, and establishing joint “learning agendas” to clarify data needs and progressively expand switch boundaries.



Healthcare and patient communities to advocate for policies that support safe, informed self-care, and equitable access to non-prescription medicines globally.

Together, these actions can accelerate the availability of safe, effective non-prescription medicines, reduce healthcare burdens, enhance public health outcomes, and drive progress toward universal health coverage.

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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.

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