



GLOBAL
SELF-CARE
FEDERATION



Risk-Based Regulatory Framework for Non- Prescription Medicines

NOVEMBER 2025



Contents

- 3 Introduction
- 5 Foundations of Risk-Based Regulation
- 8 Benefits of Adopting a Risk-Based Framework
- 10 Operationalizing a Risk-Based Framework
- 12 Conclusion and Call to Action
- 14 References
- 15 Appendix



Introduction

Self-care is a foundational element for achieving universal health coverage (UHC).

Empowering individuals to manage minor ailments through appropriate self-care reduces pressure on health services and improves overall health outcomes, even as healthcare systems grapple with demographic shifts, rising chronic disease burdens, and limited resources. Non-prescription medicines (NPM) play a central role in this transformation. These products, which can be used safely and effectively without the direct supervision of a healthcare provider, allow individuals to treat self-treatable conditions and minor ailments such as pain, allergies, and gastrointestinal discomfort, thereby reserving clinical care for more complex needs.¹

The World Health Organization (WHO) recognizes the importance of self-care – including access to NPM – as a critical strategy to achieve UHC, promote equity, and increase the efficiency of health systems.² It's estimated that by 2030, self-care enabled by NPM could save \$179 billion in healthcare costs, free up 2.8 billion hours in physician time, and generate 72 billion additional productive days globally.³ Despite these immense benefits, access to these essential products remains uneven. Around 2 billion people lack access to essential medicines, including many widely available non-prescription products, largely due to regulatory capacity limitations, particularly in low- and middle-income countries (LMICs).⁴

**BY 2030,
SELF-CARE
COULD:**

SAVE

\$179 bn

in healthcare costs globally

FREE UP

\$2.8 bn

hours in physician time

GENERATE

72 bn

additional productive days

Although NPMs are lower-risk and long-established, and, according to current standards, generally recognized as safe and effective, they are often assessed under frameworks built for high-risk prescription medicines. This can mean extensive dossier reviews, clinical data submissions and months-to-years waiting times, even for ingredients safely marketed for decades. There is a need to look at a modern, risk-proportionate approach that updates the evaluation of existing studies and allows appropriate alternatives to full clinical trials. The current “one-size-fits-all” model delays access to essential self-care products and diverts scarce regulatory resources without improving outcomes. Since NPMs generally present a lower risk to consumers compared to prescription medications. Implementing risk-based regulatory pathways allows for

a more proportional approach, ensuring that regulatory scrutiny is aligned with the actual risk profile of the product.

A risk-based regulatory framework that ensures consumer safety while fostering innovation and technological advancement offers a pragmatic solution. By recognizing the inherent differences between profiles of both prescription and NPMs, such a framework allows well-understood, low-risk NPMs to be authorized through streamlined processes whilst ensuring that novel or higher-risk medicines receive appropriate scrutiny. At the same time, it helps regulators focus their limited resources on the most pressing public health priorities, preserving safety while accelerating access and strengthening healthcare systems.



The challenges of current regulatory practices are particularly pronounced in LMICs, where limited expertise is stretched thinly across both straightforward non-prescription applications and complex, high-risk products such as biologics or vaccines. Time and capacity are spent re-reviewing well-established medicines already authorized in trusted jurisdictions, while more urgent public health priorities, like surveillance of higher-risk therapies may receive inadequate attention. Streamlined pathways for well-understood NPMs particularly those covered by WHO-listed monographs or already approved in reference countries can enable sufficient scrutiny while accelerating access, relieve pressure on healthcare systems, and support universal health coverage.



Foundations of Risk-Based Regulation

Risk-proportionate regulation aligns oversight with the actual public health benefit v/s potential risk a medicine poses, its intended use, and the context in which it is marketed.

For NPMs and other well-established products used for self-treatable conditions and common ailments with well-characterised safety profiles and clear instructions, prescription-level scrutiny is rarely warranted. Instead, clinical requirements should be managed proportionately: first assess whether updated clinical data are needed, leverage real-world evidence, and ensure modern risk-management plans and pharmacovigilance documentation are in place, even when a product has a long history of safe use. Maintaining a strong quality management system and providing clear, science-based justifications for any deviations from current standards are crucial to stewarding these legacy products within evolving regulatory frameworks. Applying full prescription-level reviews to such products consumes resources, slows access, and adds little public-health value.



The guiding principle is proportionality.

Oversight should match the level of risk. Where risks are well understood and outcomes are predictable, streamlined review can maintain safety while reducing unnecessary delays. This approach is supported internationally: the *WHO's Good Regulatory Practices* guidelines emphasize proportionality, and organizations such as the OECD, EMA, and ICMRA recommend flexible, outcome-focused frameworks that adapt to national capacity and priorities.

EFFECTIVE RISK-BASED REGULATION RESTS ON FIVE CORE PILLARS



These principles provide a clear framework for implementation.⁵



Classify Products by Risk

Not all NPMs present the same level of potential harm. Regulators should assess factors such as the safety of active ingredients, dosage, route of administration, intended population, expected duration of use, and complexity of self-selection. Well established products (e.g. analgesics, pain killers, paracetamol, supplements, or basic topical antiseptics) can follow streamlined pathways. Conversely products that contain novel ingredients, new dosage forms, or that are transitioning from prescription to non-prescription use warrant more rigorous assessment dependent on the level of change. The UK has adopted a novel, condition-led approach to prescription to NPM switches: instead of listing eligible active ingredients, DHSC/MHRA has published priority medical conditions and therapeutic categories for which it is inviting reclassification applications.⁶



Regulatory Review Pathways

Classification allows regulators to match products to appropriate review mechanisms. Well-understood, low-risk NPMs can be authorized through notification, self-certification, or adherence to established monographs or ingredients lists. These products have low risk of serious side effects when used as directed and formulated to minimize the risk of misuse and dependence. Several countries have implemented such pathways successfully, showing that low-risk products can reach the market efficiently without compromising safety (see [Appendix](#)). Higher-risk products follow proportionate review, including additional data requirements or clinical studies as needed. Since 2024, Singapore's HSA offers an abridged evaluation route for NPMs: non-clinical and clinical data may be waived when the product treats short-term, self-limiting conditions, is already non-prescription with a reference regulator, and its actives are well documented in standard texts. HSA Quality requirements remain equivalent to prescription medicines; CTD Modules 4/5 are generally not required, though HSA may still request the full data set.⁷

Apply Proportionate Oversight Post-Market

An ideal proportionate model will deliberately balance pre-market assessment and post-market monitoring. For NPMs, pre-market controls should be minimal yet explicit, through compliance with recognized monographs and permitted lists, standard labeling, and no new clinical package (except for novel claims), while safety is ensured through post-market compliance audits, routine pharmacovigilance, targeted inspections, and periodic sampling/testing. In contrast for higher-risk or novel products, the oversight should shift to more rigorous pre-market evaluation (quality plus non-clinical/clinical evidence as warranted, supported by risk-management plans), followed by proportionate post-market follow-up. This allocation focuses regulatory effort where it delivers the greatest public-health value, accelerates access for NPMs, and maintains robust safeguards for higher-risk medicines.



Benefits of Adopting a Risk-Based Framework

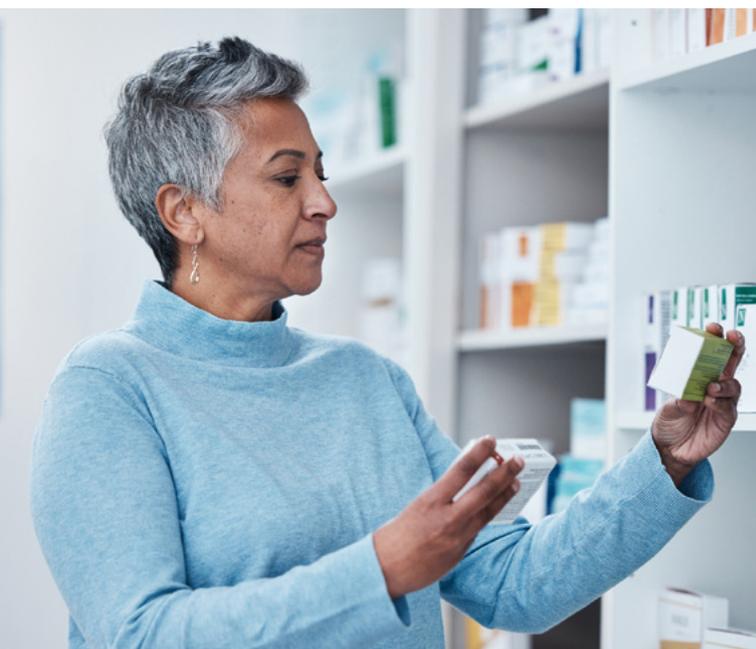
A well-designed risk-based framework delivers multiple, reinforcing benefits that strengthen both regulatory systems and public health outcomes.

By aligning oversight with product risk, regulators can work more efficiently, expand access to safe self-care products, and focus attention where it matters most.

Regulatory Efficiency

Risk-based pathways reduce the workload for regulators. Streamlined processes, reliance on monographs, and simplified filings (with abbreviated data/dossier package) allow well-understood, low-risk NPMs to enter the market without repetitive pre-market reviews. Resources previously spent on low-risk products can be redirected toward complex, high-risk medicines, post-market monitoring, and other priority areas. This efficiency improves review timelines, reduces administrative burden, and creates predictable processes that benefit regulators, industry, and consumers alike.





Encouraging Innovation and Market Responsiveness

Predictable, proportionate pathways create incentives for innovation. Manufacturers can develop new dosage forms, user-friendly packaging, or e-labelling solutions with confidence that low-risk products will not face unnecessary regulatory delay. These factors stimulate competition, diversify product offerings, and support resilient supply chains, particularly important for local manufacturers in LMICs.



Faster Access and System Relief

When low-risk products reach the market quickly, healthcare systems benefit. Consumers can treat minor, self-limiting conditions without occupying clinical resources, allowing healthcare providers to direct resources to focus on serious or complex cases. In low- and middle-income countries, faster access reduces unnecessary clinic visits, lowers out-of-pocket costs, and strengthens progress toward universal health coverage. Risk-based regulation also enables reliance on trusted reference authorities and regional harmonization, further accelerating access.



Maintaining and Strengthening Public Health

By ensuring oversight is applied where it matters most, risk-based regulation safeguards safety while improving access. Expanding availability of essential NPMs (such as analgesics, oral rehydration salts, and topical antiseptics, some of which also fall under WHO's Essential Medicines List)⁸ supports underserved populations and allows clinicians to concentrate on higher-risk care, creating more equitable and resilient health systems.



Operationalizing a Risk-Based Framework

Implementing a risk-based approach requires clear, practical steps that translate principles into consistent, effective action.

Regulators can follow a logical sequence to ensure safety, efficiency, and timely access:

1

Define Clear Risk Criteria

Regulators should establish transparent, evidence-based criteria that reflect product risk. International experience provides useful models (e.g. on toxicity, potential for abuse, dependency, for self-limiting condition): the WHO Essential Medicines List, the EU Well-Established Use pathway, and the U.S. OTC monograph system all identify products with long-standing safety records. Publishing these criteria ensures predictable pathways, strengthens confidence in decisions, and guides manufacturers on expectations.

2

Engage Stakeholders Through Formal Consultation

Any changes to the regulatory framework should be co-developed with a broad stakeholder community. Regulators should run structured consultations (published proposals, fixed comment periods, open hearings/workshops) with manufacturers, pharmacists, healthcare professionals, consumer/patient groups, academia, and public-health bodies, and publish a summary of comments and dispositions. Engagement should include pilots where appropriate, plain-language materials for the public, and guidance templates/training to help stakeholders implement new requirements.

3**Apply Harmonization, Reliance, and Work-Sharing Mechanisms**

Regulatory efficiency can be enhanced by adopting standards and procedures from trusted authorities while retaining national decision-making. Regional collaboration and work-sharing (e.g., joint assessments, shared templates, coordinated queries) allow agencies to align evaluations, reduce duplication, and accelerate access. Mechanisms such as the WHO Collaborative Registration Procedure and regional harmonization initiatives in Africa show how reliance saves resources without compromising safety.

4**Ensure Proportionate Post-Marketing Monitoring and Adaptability**

Operationalizing a risk-based framework requires targeted post-market oversight: routine pharmacovigilance and signal detection, compliance audits, targeted inspections, periodic sampling/testing, and the ability to update labelling or withdraw products when needed. Regulators should maintain staff training and data systems to act on real-world evidence quickly, ensuring safety while using resources efficiently.

By following these steps, regulators can implement a system that preserves safety, accelerates access, and optimizes limited resources, while creating predictable, transparent processes that encourage compliance and innovation. This operational approach ensures that low-risk NPMs reach consumers quickly, while higher-risk products receive the attention they require.



Conclusion and Call to Action

NPM are a critical component of self-care and UHC.

They provide safe, effective treatment for self-treatable conditions and minor ailments while reducing unnecessary doctor visits, lowering costs, and freeing healthcare resources for higher-risk care. Yet, in many countries, regulatory frameworks treat all medicines alike, applying resource-intensive requirements designed for high-risk prescription drugs. This one-size-fits-all approach delays access, strains regulatory capacity, and diverts attention from higher-priority public health needs.

A risk-based framework offers a practical, evidence-informed solution.

By aligning oversight with product risk, regulators can streamline approvals for well-characterized, low-risk NPMs, maintain safety through proportionate monitoring, and focus expertise where it has the greatest impact. Such a framework also fosters innovation, supports market competition, and strengthens healthcare system resilience, particularly in low- and middle-income countries.

For National Regulatory Authorities

Regulators are encouraged to implement risk-based frameworks by following a logical sequence:

- Define transparent, evidence-based risk categories to classify products.
- Establish differentiated regulatory pathways that match oversight to risk.
- Build capacity and engage stakeholders to ensure policies reflect real-world use.
- Leverage harmonization and reliance mechanisms from trusted authorities.
- Apply proportionate monitoring to respond efficiently to emerging safety data.



Following these steps enables regulators to optimize limited resources, expand access to essential self-care medicines, and maintain public trust.

For Global and Regional Organizations

International bodies, including the WHO, can support countries by providing guidance, technical assistance, and harmonized standards that facilitate reliance and shared learning. By promoting evidence-based risk classification, offering capacity-building initiatives, and supporting regional or global reference standards, these organizations help regulators adopt frameworks that improve access, safeguard public health, and advance universal health coverage.

Adopting a risk-based, principle-driven approach is a strategic investment. It allows safe, effective self-care options to reach those who need them most while preserving regulatory capacity for higher-risk products.



By operationalizing these principles thoughtfully, regulators can achieve a balanced, resilient system that benefits public health, supports innovation, and strengthens healthcare systems for the long term.

References

1. GSCF. Self-care readiness index. 2022. Global Self Care Federation. Available from: [link](#)
2. WHO. Self-care for health and well-being. April 2024. [Accessed 25 November 2025]. Available from: [link](#)
3. GSCF. Economic and Social Value of Self-Care. 2022. Global Self Care Federation. Available from: [link](#)
4. Ozawa S, Shankar R, Leopold C, Orubu S. Access to medicines through health systems in low-and middle-income countries. Health Policy and Planning. 2019;34(Supplement_3):iii1-3. doi. Available from: [link](#)
5. Ngum, N. et al., 2024. Evaluation of the review models and approval timelines of authorities participating in the East African Medicine Regulatory Harmonization initiative: alignment and strategies for moving forward. Frontiers in Medicine.
6. Gov.uk. Department of Health and Social Care Media Centre. Feb 2025. [Accessed 25 November 2025]. Available from: [link](#)
7. Gov.uk. Appendix 6 Guideline on Submission for Non-prescription Therapeutic Products. August 2024. [Accessed 25 November 2025]. Available from: [link](#)
8. WHO. Essential Medicines List. Sep 2025. World Health Organisation. [Accessed 25 November 2025]. Available from: [link](#)

Appendix

Case Studies in Risk-Based Non-Prescription Medicine Regulation

This appendix provides examples from various countries that have implemented or are moving towards risk-based regulatory frameworks for NPM. These case studies highlight diverse approaches to tiered classification, simplified registration, reclassification, and the benefits and challenges encountered.

Case Study 1

Japan – Tiered Classification and Monograph System

Overview

Japan employs a comprehensive tiered classification system for Over-the-Counter (OTC) drugs, categorizing them into eight distinct groups based on factors such as active ingredients, routes of administration, indications, dosage, and dosage forms. This approach dictates the required dossier for application, differentiating between novel products and those equivalent to existing OTCs.

Key Features

- **Eight Categories:** Products with new active ingredients or those undergoing Rx-to-OTC switch (Category 1 & 4) require extensive data submission, similar to prescription drugs. In contrast, products equivalent to approved OTCs (Category 7 & 8) have significantly reduced data requirements, primarily focusing on equivalency confirmation.
- **Approval Standards (Monographs):** For products that conform to established “approval standards” (monographs detailing active ingredients, doses, indications, etc., across 15 efficacy groups), the approval authority is delegated from the Pharmaceuticals and Medical Devices Agency (PMDA) to the prefectural government.
- **Consultation System:** PMDA offers pre-development and pre-application consultations to provide guidance and advice, aiming to shorten overall review times.

Benefits/Outcomes

- **Reduced Review Time:** Products conforming to approval standards can be approved in approximately 3 months by prefectural governments, compared to about 7 months for PMDA-reviewed products.
- **Efficient Resource Allocation:** This system allows PMDA to focus its resources on higher-risk or novel products, while lower-risk, well-understood OTCs follow an expedited path.
- **Predictability for Industry:** Clear categories and standards provide predictability for manufacturers.

Case Study 2

Thailand – Low-Risk Medicine Framework

Overview

Thailand's Food and Drug Administration (FDA) is introducing a simplified, science-based regulatory framework for low-risk medicines (LRMs) in 2024. The reform modernizes self-care regulation, aligning Thai rules with international best practices while keeping health products safe, accessible, and diverse.

Key Features

- **Definition of Low Risk Medicines (LRMs):**
 - Wide safety margins, limited indications, minimal adverse events.
 - Generally non-prescription.
 - Used for health promotion, maintenance, supplementation, and mild conditions.
- **Policy Goals:**
 - Improve public access to safe, diverse self care products.
 - Promote domestic research and innovation, including herbal medicines.
 - Reduce regulatory burden with simplified registration.
 - Create more opportunities for industry and entrepreneurs.
- **Monograph Based Registration Pathway:**
 - Active substances and excipients.
 - Dosage forms and indications.
 - Recommended daily intake (e.g., Thai DRIs for vitamins/minerals).
 - Manufacturing processes and technical specifications.
 - Warnings, contraindications, and risk information.
 - Shelf life and storage conditions.

Specific Case Studies

- **International Models Referenced:**
 - South Korea – Listed Medicines (permitted ingredients and indications).
 - Australia – Natural Health Products under TGA NHP monographs.
 - Canada – OTC Drugs via Health Canada OTC monographs.
 - United States – OTC medicines under U.S. FDA regulations.
- **Thai Monograph Examples:**
 - *Multivitamins:* minimum nutrient levels, maximum safe limits, rules on combinations to avoid nutrient imbalance.
 - *Herbal Products:* propolis extract, Terminalia chebula and others with controlled active compound levels to ensure quality and safety.

Benefits/Outcomes

- 80 monographs already published (multivitamins, minerals, herbal products, probiotics, household remedies).
- 45 registration applications submitted through the simplified pathway.
- More efficient, transparent, and consistent regulatory decisions.
- Expanded consumer choice and better access to safe self care products.
- Reduced regulatory complexity and strengthened domestic industry and innovation.

Case Study 3

Malaysia – Abridged Evaluation for OTC Products

Overview

Malaysia has implemented an “Abridged Evaluation” pathway for specific categories of low-risk OTC products, aiming to expedite their registration compared to full evaluations.

Key Features

- **Defined Categories:** The abridged pathway covers 11 specific categories, primarily external (skin) preparations and locally-acting dosage forms (e.g., antiseptics, lozenges, topical analgesics, anti-dandruff, oral care).
- **Reduced Dossier Requirements:** For products in these categories, major documents such as pharmacodynamics, pharmacokinetics, BA/BE study reports, and manufacturing process validation reports are exempted.
- **Reference to International Standards:** Malaysia utilizes the latest version of British Pharmacopoeia (BP) and United States Pharmacopeia (USP) as references for OTC product evaluation.

Benefits/Outcomes

- **Faster Timelines:** Abridged evaluations take significantly less time (116-136 working days) compared to full evaluations (210 working days).
- **Reduced Burden:** Less documentation is required for industry, and regulatory resources are optimized.

Challenges

- The classification of OTC products is heavily tied to the Poison Act 1952, requiring reclassification by the Poison Board, which can complicate the simplification process.
- The current abridged process, while faster, is not a full monograph/notification system, indicating further potential for streamlining.

Case Study 4

Australia – Non-Prescription Medicines Risk-Based Framework

Overview

Australia operates a two-tiered system for non-prescription medicines that allows for streamlined applications based on risk. Registered OTC medicines are typically fully evaluated, although streamlined assessments are available for some OTCs that are well-established and meet an approved monograph. Listed medicines are considered to be very low risk medicines (including sunscreens and complementary medicines) and these are not subject to premarket evaluation.

Key Features for Streamlined Registered Medicines

- **Monograph System:** Streamlined process supported by 13 monographs that define acceptable APIs, dosage forms, and routes of administration.
- **Reduced Documentation:** Requires reduced submission documentation, such as finished product specifications, certificates of analysis, and compliance assurance statements.

Key Features for Listed Medicines

- **Positive List:** Based on a positive list of approved ingredients (both actives and excipients) and permitted indications.
- **No Pre-Market Evaluation:** If a product strictly conforms to the established positive lists and other criteria, the submission will be processed without evaluation of the data package. The supporting data package is required to be held by the sponsor and provided if requested.
- **Electronic Application Form:** Products are entered on the register of medicines through a validation-controlled, self-certification process.
- **Post-Market Surveillance:** Robust post-market surveillance ensures ongoing safety and quality.

Benefits/Outcomes

- **Highly Expedited Access:** Listed medicines market authorizations can be applied for and issued electronically on the same day if they meet the criteria, leading to very fast time-to-market.
- **Monograph-Based Application:** Reduced evaluation time and cost compared to full premarket evaluation for established Registered OTC medicines.
- **Reduced Regulatory Burden:** Minimal pre-market review for listed medicines and monograph medicines frees up regulatory resources.
- **Predictability:** Clear standards for Listed medicine ingredients and indications allow manufacturers to design products for rapid market entry.

Case Study 5

Canada – Natural Health Product (NHP) Framework

Overview

Health Canada regulates non-prescription drugs, natural health products (NHPs), and biocides through a structured submission and labelling framework. Core tools include Drug Identification Numbers (DINs), Category IV Monographs, labelling standards, NHP product licence application (PLA) classes, and ingredient/monograph databases, all aimed at ensuring safety, quality, and effectiveness while facilitating timely market access.

Key Features

- **Non-Prescription Drugs:**
 - Require a valid DIN to be sold, confirming the product meets Health Canada's standards for safety, quality, and efficacy.
- **Category IV Monographs:**
 - Used when a drug has a well characterized safety and efficacy profile under specified conditions.
 - Sponsors may reference a monograph if the product and labelling match the document exactly.
 - If no relevant monograph exists or the product falls outside its scope, full evidence for safety, efficacy, and quality must be submitted.
- **Labeling Standards:**
 - Define permissible conditions of use and labelling (dose, intended use, directions, warnings, active ingredients, combinations).
 - If no standard applies, the sponsor must provide supporting evidence.
- **New Drug Submission (NDS):**
 - Required for novel ingredients considered a "New Drug," via new or abbreviated NDS routes.

- **Natural Health Products (NHPs):**
 - **PLA Classes (under MAP):**
 - **Class I:** Must comply exactly with a single Natural and Non-Prescription Health Products Directorate's (NHPPD) monograph.
 - **Class II:** Supported entirely by a combination of two or more NNHPD monographs and defined scenarios.
 - **Class III:** Require full assessment (e.g., novel products, new dosage forms, complex combinations or partial monograph use that goes beyond set parameters).
 - **NHP Ingredients Database:**
 - Repository of approved medicinal/non medicinal ingredients, NNHPD monographs, and abbreviated labeling standards.
 - Supports evidence of safety, efficacy, and quality in PLAs.
 - **Use of Monographs in Review:**
 - Monographs are **scientific standards** describing properties, acceptable uses, dose, duration, and risk information.
 - Developed for many NHPs and some non-prescription and disinfectant drugs.
 - Products that follow a monograph exactly qualify for an expedited review because information is "pre cleared".

Specific Case Studies

- **Category IV Monograph vs. Full Submission:**
 - A non-prescription product whose formulation and labeling fully match an existing Category IV Monograph can reference it in the drug submission, resulting in a streamlined review.
 - A similar product with a different dose, indication, or combination outside the monograph must undergo a full evidence based review.
- **Use of Labeling Standards:**
 - Non-prescription cough, cold, and flu products can follow a published labeling standard (e.g., updated standard under the Action Plan) to define dose, indications, and warnings, rather than submitting full clinical data—if they remain within the standard's scope.
- **NHP PLA Classes in Practice:**
 - **Class I:** A single ingredient NHP that matches an NNHPD monograph word for word (e.g., a vitamin supplement).
 - **Class II:** A multi ingredient traditional remedy fully supported by several monographs.
 - **Class III:** A novel herbal combination using some monograph ingredients but at new doses or in a new delivery system requires in depth review.

- **Non-Prescription Drug Action Plan (2022):**
 - *Short term:* Added guidance on Canadian Drug Facts Table, product monograph and patient information leaflets, and label mock up requirements.
 - *Medium term:* Clarified post authorization quality changes, inactive ingredient policies, and updated cough/cold/flu labelling standard.
 - *Long term:* Ongoing regulatory modernization for non-prescription drugs.
- **NHP Labelling Exemption Order (March 2025):**
 - Delays the coming into force of new NHP labelling regulations for all products until **June 21, 2028** (originally 2025 for new products and 2028 for existing ones).
 - Provides time to refine flexibilities, maintain product availability and competition, and finalize guidance/tools for implementation.

Benefits/Outcomes

- **Faster Market Access & Streamlined Review:**
 - Monograph based and labelling standard pathways allow sponsors to avoid duplicative evidence submissions when products remain within defined parameters.
 - NNHPD product licensing system enables expedited approval for DIN/PLAs when monographs are followed exactly.
- **Regulatory Clarity and Predictability:**
 - Clear classes of PLAs, defined use of Category IV Monographs, and labelling standards give industry standardized expectations for data and labelling.
 - The NHP Ingredients Database centralizes accepted ingredients and conditions of use.
- **Support for Innovation and Modernization:**
 - New Drug Submission pathways accommodate novel ingredients and dosage forms.
 - The Non-Prescription Drug Action Plan and ongoing modernization efforts adjust guidance and standards to current science and market needs.
- **Balanced Consumer Protection and Access:**
 - DIN requirements, scientific monographs, and dedicated biocide regulations protect safety and product quality.
 - The NHP labelling Exemption Order temporarily eases compliance timelines, preserving consumer choice and competition while Health Canada refines implementation tools and guidance.

Case Study 6

Chinese Taipei – Streamlined Monograph Process

Overview

Chinese Taipei has adopted an OTC Monograph System, referencing models from the US and Japan, to streamline the registration process for certain NPM.

Key Features

- **Monograph System:** Relies on established monographs that define specific standards for approved ingredients, dosages, and labeling requirements.
- **Reduced Documentation:** For products conforming to these monographs, only Module 3 (Quality/CMC documentation) is required for submission. No substantiation on safety and efficacy is needed, as these are covered by the monograph.
- **Broad Coverage:** A total of 18 categories of monographs are available, covering various therapeutic areas such as cold remedies, antibiotics, ophthalmological, and dermatological products.

Benefits/Outcomes

- **Simplified Submissions:** Significantly reduces the documentation burden for manufacturers.
- **Faster Market Access:** Eliminates the need for redundant safety and efficacy reviews for well-established products.
- **Increased Efficiency:** Streamlines the regulatory process, allowing for quicker availability of common OTCs.
- **Standardized labeling in consumer language.**

Case Study 7

United States – Monograph and NDA Pathways

Overview

The United States Food and Drug Administration (FDA) employs a dual-pathway system for NPM, utilizing both the OTC Monograph system for well-established, low-risk products and the New Drug Application (NDA) pathway for novel or higher-risk products, including prescription-to-OTC switches. This illustrates a foundational risk-based approach to regulation.

Key Features

- **OTC Monograph Pathway:**
 - **Class-Based Regulation:** This pathway establishes “rules” (monographs) for specific categories of OTC drugs (e.g., antacids, analgesics, cough/cold products) that define acceptable active ingredients, dosages, indications, labeling, and other conditions.
 - **No Pre-Market Approval:** Products that strictly conform to an established monograph can be marketed without individual FDA pre-market approval. This is a “generally recognized as safe and effective” (GRASE) approach.
 - **Modernization (CARES Act 2020):** The CARES Act significantly modernized the monograph system, introducing user fees, electronic submissions, and a more streamlined administrative order process for making changes or adding new ingredients/indications to monographs.
 - **Focus:** Emphasizes class-based assessment and post-market compliance.
- **New Drug Application (NDA) Pathway:**
 - **Product-Specific Review:** Required for non-prescription drugs that do not fit an existing monograph, contain new active ingredients, propose new indications, or are being switched from prescription (Rx) to OTC status.
 - **Comprehensive Data:** Requires submission of a full dataset demonstrating safety and efficacy, including non-clinical data, chemistry, manufacturing, and controls (CMC), and clinical trials.
 - **Rx-to-OTC Switches:** For switches, additional studies are often required, such as label comprehension studies (to ensure consumers understand the labeling), self-selection studies (to confirm consumers can appropriately choose the product), and actual-use studies (to evaluate real-world safe use).
 - **Rigor:** Ensures a thorough scientific review for novel or higher-risk products before market entry.

Benefits/Outcomes

- **Efficient Market Access for Low-Risk:** The monograph system allows for rapid and cost-effective market entry for a vast array of common, well-understood OTC products, reducing regulatory burden for both industry and regulators.
- **Robust Oversight for Novel Products:** The NDA pathway ensures that new or reclassified non-prescription drugs undergo rigorous scientific scrutiny, safeguarding public health for products with higher inherent risks or complexities.
- **Adaptability and Innovation:** The modernized monograph system allows for more agile updates to keep pace with scientific advancements, while the NDA pathway facilitates innovation and the responsible transition of prescription medicines to OTC status, expanding self-care options.
- **Clear Framework:** Provides a transparent and predictable regulatory environment, balancing consumer access with appropriate safety controls.

Case Study 8

South Korea – OTC Renewal Requirements and Monograph Expansion

Overview

In South Korea, recent reforms in the OTC regulatory framework have focused on clarifying renewal application requirements and expanding the scope of the OTC monograph. These changes aim to enhance regulatory efficiency, support market stability, and broaden consumer choice.

Key Features

- **Improvement of OTC Drug Renewal Application Requirements:** In June 2025, the Ministry of Food and Drug Safety (MFDS) clarified OTC renewal application requirements. Companies seeking to renew OTC approvals, in cases where previously required data are unavailable, may now submit sufficient domestic and international post-marketing data along with a statement of reasons such as sustained domestic demand. This helps prevent unavoidable renewal failures and ensures continuity of supply.
- **Expansion of the OTC Monograph:** To promote OTC market growth and expand consumer choice, the scope of the monograph was revised in 2024. The revisions included the addition of new dosage forms and corresponding updates to dosage and administration, thereby creating a more flexible and comprehensive framework for OTC drug approval.

Benefits/Outcomes

- **Regulatory Efficiency:** By clarifying renewal requirements and broadening monograph criteria, regulatory processes have been streamlined, minimizing uncertainty for industry players and reducing unnecessary administrative burdens.
- **Market and Consumer Impact:** Expansion of the monograph system supports the development of new OTC products and dosage forms, thereby increasing accessibility and choice for consumers.

Case Studies References

- WHO. TRS 1033 – Annex 11: Good Regulatory Practices. October 2021. [Accessed 1 December 2025]. Available from: [link](#)
- Japan MHLW. OTC Drug System Overview. [Accessed 1 December 2025]. Available from: [link](#)
- FDA. CARES Act OTC Reform. Available from: [link](#)
- Health Canada. Compendium of Monographs: Available from: [link](#)
- Health Canada. Non-prescription Drugs: Labelling Standards - Drug Product. Available from: [link](#)
- European Medicines Agency. Well-Established Use Applications. [Accessed 1 December 2025]. Available from: [link](#)
- WHO. Rational Use of Medicines. [Accessed 1 December 2025]. Available from: [link](#)



About GSCF



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

www.selfcarefederation.org

 +41 (22) 362 5384

 @Selfcarefed_org

 @selfcarefederation