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Comparison and Registration Pathway of Nutraceuticals in Canada, India, Australia, Japan and South Korea

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Abstract

One of the areas of healthcare that is expanding the fastest is nutraceuticals, which are dietary products that offer health advantages beyond simple nourishment. Nonetheless, there is still fragmentation in the global regulation of these items, with many nations implementing unique frameworks for post-market surveillance, approval and classification. This article compares the regulatory pathways for nutraceuticals in Canada, India, Australia, Japan and South Korea, highlighting similarities, differences and unique country-specific requirements. The review identifies that while Canada and South Korea emphasize pre-market approval systems, Australia and Japan employ tiered approaches, allowing both lighter oversight (notification-based) and stricter evaluations (clinical trial-based). India, meanwhile, classifies nutraceuticals primarily under food law, with emphasis on safety and compliance. The findings reveal a lack of global harmonization, leading to challenges in international trade, product registration and consumer protection. Recommendations include strengthening scientific validation, fostering regulatory convergence and enhancing post-market surveillance.

Keywords: Nutraceuticals; Regulatory Pathways; Health Supplements; Natural Health Products; AUST L; FSSAI; Product Licence (NPN); Health Functional Foods (HFF)

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1. Introduction

Dr. Stephen DeFelice first coined the term nutraceutical in 1989, combining "nutrition" and "pharmaceutical," referring to food or food-derived products that provide health or medical benefits, including disease prevention or treatment. Despite its popularity, the definition remains unstandardized across jurisdictions, contributing to significant regulatory ambiguity. (1-4)

The market for nutraceuticals is growing quickly on a global scale due to aging populations, lifestyle-related disorders and growing consumer demand for preventative healthcare. (5) Asia-Pacific is one of the regions with the quickest rate of growth in the worldwide nutraceuticals market, which is predicted to reach USD 600 billion by 2030. (6, 7)

Regulation of nutraceuticals varies widely. Some countries regulate them as dietary supplements (e.g., USA), others as natural health products (Canada), (8) complementary medicines (Australia), (9) functional foods (Japan), (10) or health functional foods (South Korea). (11) In India, nutraceuticals are placed under food laws with specific licensing by the Food Safety and Standards Authority of India (FSSAI). (2)

This lack of harmonization creates challenges for manufacturers, exporters and consumers. Safety, efficacy, labelling and claims differ significantly, making cross-border trade complex. (1) Therefore, a comparative analysis of regulatory frameworks is essential for identifying best practices and potential pathways for harmonization.

2. Methodology

This article adopts a comparative regulatory review methodology. Relevant legislation, official guidelines and regulatory documents were analyzed from the following authorities:

- Health Canada - Natural Health Products Directorate (NHPD) (8)
- FSSAI (India) - Food Safety and Standards Authority of India (2)
- Australia - Therapeutic Goods Administration (9)
- CAA (Japan) - Consumer Affairs Agency (10)
- MFDS (South Korea) - Ministry of Food and Drug Safety (11)

Secondary sources included published research articles, review papers, PubMed-indexed studies and official websites of international regulatory authorities. (7, 12) A

cross-comparison was made for key regulatory parameters such as:

- Classification and definition
- Approval requirements (safety, efficacy, quality)
- Good Manufacturing Practices (GMP) compliance
- Labeling and health claims
- Post-market surveillance systems

3. Country-Wise Regulatory Frameworks

3.1 Canada Natural Health Products (NHPs)

The Natural and Non-prescription Health Products Directorate (NNHPD) of Health Canada is in charge of regulating nutraceuticals in Canada under the Natural Health Products Regulations (NHPR), which went into effect in 2004. (8) Before being put on the market, the NNHPD makes sure that all natural health products are high-quality, safe and effective. (5)

Natural Health Products (NHPs), which include nutraceuticals, include the following (8):

- Vitamins and minerals
- Herbal remedies
- Probiotics
- Homeopathic medicines
- Traditional medicines (e.g., Ayurveda, Traditional Chinese Medicine)

3.1.1. Approval Pathway

Before marketing, every product must obtain a Natural Product Number (NPN) or a DIN-HM (for homeopathic medicines). The approval involves. (8)

A. Product Licence Application (PLA): Submission of detailed information including ingredients, dosage, potency and recommended use.
B. Evidence Requirements: Scientific data (clinical/pre-clinical) or traditional evidence supporting safety and efficacy.
C. Good Manufacturing Practice (GMP) Compliance: Mandatory inspections to ensure product quality, stability and identity.
D. Labeling: Products must clearly display NPN/DIN-HM, recommended use, risk information and storage conditions.
E. Post-Market Surveillance: Manufacturers must report adverse reactions; Health Canada maintains a Natural Health Products adverse reaction database.

3.1.2. Timelines

Approval timelines vary depending on the risk level of the product. (8)

- Class I applications (low risk): ~60 days
- Class II/III applications (high risk): 180 - 210 days

3.1.3. Unique Features (8):

- Canada is among the strictest regulators for nutraceuticals globally.
- It allows traditional evidence (e.g., Ayurvedic texts) for certain claims, making it accessible for cultural medicines.
- Clear labeling requirements ensure consumer safety and transparency.

3.1.4. Challenges (1):

- Lengthy approval process can delay market entry.
- Requirement for evidence may be difficult for small manufacturers without research facilities.
- High compliance costs make it harder for SMEs to compete.

3.2 India Food Safety and Standards Authority of India (FSSAI)

The Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016 (2, 1) and the Food Safety and Standards Act, 2006 govern nutraceuticals in India.

3.2.1. Classification

FSSAI classifies nutraceuticals as Health Supplements/Nutraceuticals under the food category, not as pharmaceuticals. (2)

3.2.2. Approval Pathway (2):

- Product Approval: Submission of formulation, intended use, safety studies and proof of ingredient safety.
- License Requirement: Manufacturers must obtain an FSSAI license for production.
- Ingredients: Only ingredients listed in Schedule VI of the 2016 regulations are permitted. Any new ingredient requires additional approval.
- Labeling: Must include the FSSAI logo and license number, list of ingredients, nutritional information, recommended usage and warnings.
- Post-Market: FSSAI conducts surveillance, inspections and random sampling to ensure compliance.

3.2.3. Timelines

- Product approval and licensing typically take 6 - 12 months. (1)

3.2.4. Unique Features

- India follows a food-based regulatory approach (not medicine-based).
- Only limited health claims are permitted; disease prevention or cure claims are prohibited.
- Affordable regulatory pathway encourages wider domestic manufacturing. (1, 2)

3.2.5. Challenges

- Ambiguity in classification of some products (e.g., borderline between drugs and nutraceuticals). (1)
- Enforcement is inconsistent across states. (1)
- Lack of requirement for clinical trials reduces scientific rigor. (13)

3.3 Australia Therapeutic Goods Administration (TGA)

The Therapeutic Goods Administration (TGA) oversees the regulation of nutraceuticals in Australia as

Complementary Medicines under the Therapeutic Goods Act, 1989. (9)

3.3.1. Classification:

Products are divided into (9):

- Listed Medicines (AUST L): Low-risk products using pre-approved ingredients.
- Registered Medicines (AUST R): Higher-risk products requiring scientific evaluation.

3.3.2. Approval Pathway (9):

- Fast-track approval, sponsor self-certifies compliance with TGA standards.
- Evidence of safety is kept by the sponsor (not submitted upfront).
- Must use permitted ingredients list.
- Registered Medicines (AUST R).
- Require submission of clinical trial data for safety and efficacy.
- TGA conducts full evaluation.
- Labeling must display AUST L or AUST R number on packaging.
- Post market adverse events must be reported and then TGA conducts audits.

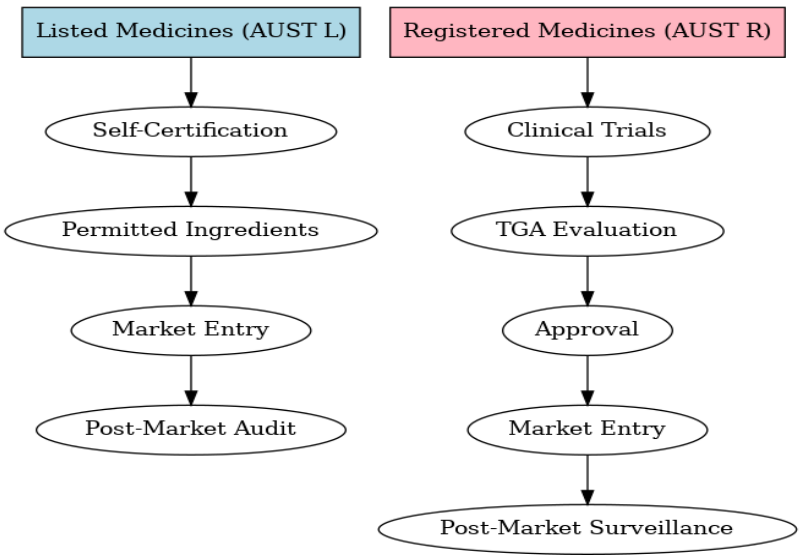

Figure 1. Distinguish regulatory pathway between Australian registered & listed medicine

3.3.3. Timelines (9):

- Listed Medicines: Approval within 48 hours - 2 weeks.
- Registered Medicines: 12 - 18 months.

3.3.4. Unique Features (9):

- Dual system allows rapid market entry for low-risk products while ensuring rigorous checks for high-risk claims.
- Strong GMP compliance ensures product safety.

3.3.5. Challenges (13):

- Sponsors may misuse the self-certification system.
- Consumers sometimes misinterpret AUST L as an efficacy guarantee.

3.4 Japan - Foods for Specified Health Uses (FOSHU) & Foods with Functional Claims (FFC)

Japan has one of the most structured systems, where nutraceuticals are regulated by the Consumer Affairs Agency (CAA) under the Food Labeling Act. (10, 14)

3.4.1. Classification

3.4.1.1 FOSHU (Foods for Specified Health Uses) (10):

- Requires government evaluation and approval.
- Clinical trials are mandatory.
- Approved products carry the FOSHU seal.

3.4.1.2 FFC (Foods with Functional Claims) (14):

- Less strict, only requires notification to CAA.
- Manufacturer submits scientific evidence but no pre-market approval.

3.4.2. Labeling:

- FOSHU products can display specific health claims (e.g., "reduces cholesterol"). (10)
- FFC products can display only functional claims with scientific support. (14)

3.4.3. Post-Market:

- Regular monitoring by CAA for FOSHU. (10)
- Self-monitoring for FFC products. (14)

3.4.4. Unique Features:

- Japan pioneered the functional foods concept in the 1990s. (10)
- Two-tier system balances consumer protection and market growth. (14)

3.4.5. Challenges:

- Clinical trial requirement for FOSHU makes the process expensive and time-consuming. (1)
- Many companies prefer FFC due to faster approval. (14)

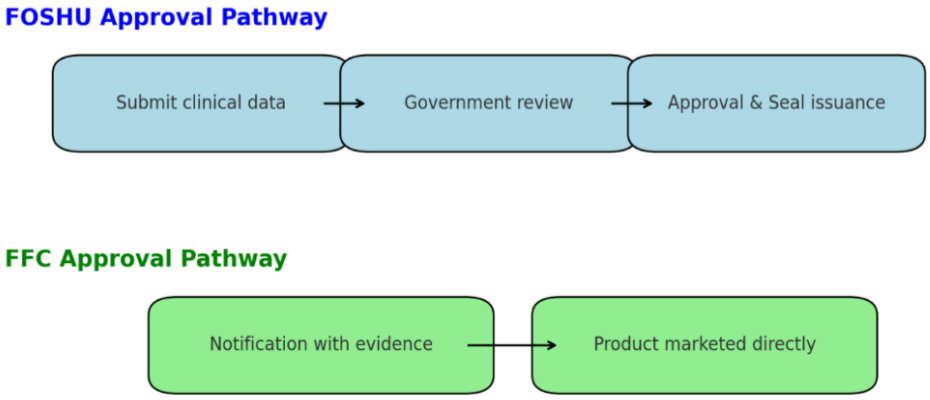

Figure 2. Approval pathway of FOSHU and FFC

3.5 South Korea - Health Functional Foods (HFF)

South Korea regulates nutraceuticals under the Health Functional Foods Act, 2004, administered by the Ministry of Food and Drug Safety (MFDS). (11, 6)

3.5.1. Classification:

Products are categorized as Health Functional Foods (HFF). (11)

3.5.2. Approval Pathway (11):

- Pre-Market Approval: Manufacturers must submit safety and functionality data, which may include clinical trials if the ingredient is new.
- Certification: MFDS issues an HFF certification number after evaluation.
- GMP Compliance: Mandatory for all facilities.
- Labeling: Must display HFF certification number and only approved health claims.
- Post-Market: Periodic inspections and safety monitoring by MFDS.

3.5.3. Timelines:

- Typically 9 -12 months depending on data submission. (1)

3.5.4. Unique Features (11):

- Emphasizes scientific validation of claims.
- Strong post-market surveillance ensures consumer safety.

3.5.5. Challenges (1):

- Stringent requirements may limit entry of small businesses.
- Complex documentation delays approvals.

4. Comparative Analysis of Regulatory Pathways

The regulatory frameworks for nutraceuticals across Canada, India, Australia, Japan and South Korea reveal significant variations in classification, approval requirements and post-market controls. (1, 15)

Table 1. Comparative analysis of nutraceutical regulatory pathway across various regions in the globe

Aspect	Canada	India	Australia	Japan	South Korea
Regulatory Pathway	Product Licence (NPN)	FSSAI Approval + License	Listed (AUST L) vs. Registered (AUST R)	FFC (Notification) vs. FOSHU (Approval)	Pre-Market HFF Certification
Evidence Required	Traditional/ Scientific	Safety/ Formulation	Listed: Minimal; Registered: Clinical Trials	FFC: Scientific Basis; FOSHU: Clinical Trials	Safety/Functionality Data (Clinical Trials if new ingredient)
GMP	Required	Required	Required	Required for FOSHU	Required
Labeling	NPN	FSSAI Logo	AUST L/R Number	FOSHU Seal/Claims	HFF Certification
Post-Market	Adverse Reporting	Surveillance	Adverse Reporting	Monitoring	Inspections

4.1 Evidence and Approval Requirements

- **Canada:** Accepts both traditional knowledge and scientific evidence, depending on claims. (8)
- **India:** Relies on ingredient safety lists; limited requirement for efficacy data. (2, 13)
- **Australia** (9):
- Listed medicines (AUST L): Low evidence requirement, sponsor-certified.
- Registered medicines (AUST R): Requires clinical trial data.
- **Japan:**

A. FFC: Notification-based; self-certified evidence. (14)
B. FOSHU: Government-reviewed clinical trial data. (10)

- **South Korea:** Requires safety and functional data, often clinical trials, especially for new ingredients. (11)

Thus, the strictest frameworks are seen in Japan (FOSHU) and South Korea, while India is the most flexible. (1)

4.2 GMP and Quality Controls

All five countries mandate Good Manufacturing Practice (GMP) compliance, but the stringency varies. (1)

- Canada, Australia and South Korea have robust inspection-based GMP frameworks. (8, 9, 11)
- India mandates GMP but enforcement varies regionally. (2, 1)
- Japan applies strict GMP for FOSHU products but lighter control for FFC. (10, 14)

4.3 Labeling and Claims

- Canada: Requires NPN on labels. (8)
- India: Mandatory FSSAI logo & license number. (2)
- Australia: Packaging must show AUST L or AUST R. (9)
- Japan: FOSHU products may display the FOSHU seal; FFC can only carry functional claims (10, 14)
- South Korea: Products must display HFF certification number. (11)

Across all jurisdictions, disease-prevention or treatment claims are highly restricted, with most regulators only allowing structure/function claims (e.g., "supports immunity") rather than medical claims (e.g., "treats arthritis"). (13, 1)

5. Key Challenges in Global Nutraceutical Regulation

Despite regulatory progress, several challenges persist (13, 1):

- Lack of Harmonization
- No universally accepted definition of "nutraceutical". (3, 4)
- Varying classification systems (food vs. medicine) complicate global trade. (1)
- Scientific Validation Gaps
- India and Australia's listed products often lack clinical trial evidence. (2, 9, 13)
- Many health claims are not rigorously tested. (13)
- Consumer Misinterpretation
- Terms like "natural" and "herbal" are often seen as "safe" without scientific basis (13)
- Labels may confuse consumers (e.g., AUST L in Australia is mistaken as efficacy approval) (13)
- **Cost and Time Barriers**
    A. FOSHU (Japan) and HFF (South Korea) require costly clinical trials. (10, 11, 1)
    B. Smaller manufacturers struggle to meet these standards. (1)
- Post-Market Surveillance Weaknesses Systems are in place, but reporting rates of adverse effects are low worldwide. Many adverse reactions remain undocumented.

6. Future Perspectives

To improve safety, efficacy and consumer trust, the following strategies are recommended (15, 4):

- **International Harmonization:** Organizations like WHO, Codex Alimentarius and ICH could help develop unified definitions and guidelines for nutraceuticals, similar to pharmaceutical harmonization efforts.
- **Tiered Evidence-Based Regulation:** A global tiered model could balance innovation and safety:
    - Low-risk supplements → notification system.
    - High-risk claims (e.g., disease-related) → clinical trial data required.
- **Strengthened Post-Market Systems:** Enhanced digital pharmacovigilance and consumer awareness campaigns could improve reporting of adverse effects.
- **Encouraging Clinical Research:** Governments could incentivize nutraceutical clinical trials through grants, tax benefits, or public-private partnerships.
- **Smart Labeling:** The adoption of QR codes linking to product dossiers could ensure transparency and enhance consumer trust.

Global & Asia-Pacific Context: The global nutraceutical market is projected to expand from USD 500.6 billion in 2025 to USD 986.8 billion by 2032, reflecting a robust CAGR of 10.18%. (16) In the Asia-Pacific region, demand is even stronger-with 39.84% of global share in 2024. (17) Another estimate pegs APAC's nutraceutical market at USD 115.0 billion in 2025, growing to USD 230.5 billion by 2033, at a CAGR of 9.1%. (18)

7. Country-Specific Market Highlights

Canada:

- In North America, Canada is projected to command around USD 12.74 billion in 2025, with growth at a 9.1% CAGR. (16)
- Consumer preference leans toward immune support, digestive health and fiber-enriched formulations. (19)

India:

- India is one of Asia's fastest-growing nutraceutical markets estimated at USD 41.16 billion in 2025, holding ~29.7% of the APAC market and growing at a CAGR of 11.3%. (17)
- Drivers include rising middle-class disposable income, increased health consciousness and a strong preference for Ayurvedic and herbal supplements. (20)

Australia:

- Forecasts estimate Australia's market at USD 5.49 billion in 2025 (~4% of APAC) with around 8.8% CAGR, fueled by demand for plant-based dietary supplements. (18)
- Consumers place high value on quality, regulation and trusted domestic brands. (19)

Japan:

- Anticipated market size of USD 24.89 billion in 2025, comprising nearly 18% of APAC-driven by the aging population and high consumer demand for quality, science-backed products; CAGR ~8.6%. (17)
- Long-standing preventive healthcare culture (e.g., FOSHU/FFC products) supports stable, premium demand. (20)

South Korea:

- Estimated at USD 8.27 billion in 2025 (~6% of APAC share), growing at ~9.3% CAGR, driven by strong interest in beauty, immune and health supplements. (18)
- Consumers favor personalized, premium wellness solutions. (20)

7.1 Comparative analysis of market size

Country Market Size (2025 est.)

Table 2. Comparative analysis of market size in 5 respective countries

Country	Market Size (2025 est.)	CAGR	Key Drivers
India	USD 41.2 billion	~11–12%	Rising income, herbal demand, middle class
Japan	USD 24.9 billion	~8.6%	Aging population, preventive wellness
South Korea	USD 8.3 billion	~9.3%	Beauty, immunity, K-wellness trends
Australia	USD 5.5 billion	~8.8%	Health-conscious consumers, plant-based
Canada	USD 12.7 billion	~9.1%	Digestive health, immunity and aging health

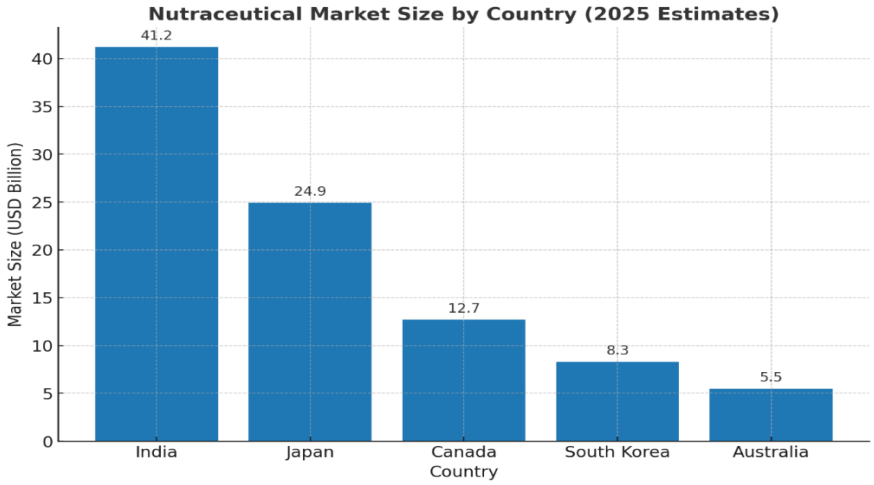

Figure 3. Country-wise nutraceutical market size

7.2 Demand Insights

- Preventive healthcare is the dominant theme across all markets especially in Asia, where traditional medicine and preventive habits are deeply embedded.
- Immunity, beauty, digestion and senior health are the top categories driving consumer interest.
- E-commerce and D2C growth: Particularly in India, South Korea and Australia, online retail is a key channel, supported by digital-savvy consumers.
- Premium and personalized products especially in Japan and South Korea command higher revenue per user.

7.3 Strategy Implications

- India: Massive opportunity focus on accessible herbal blends, affordability and e-commerce reach.
- Japan and South Korea: High-value innovation wins invest in clinical registration (FFC/FOSHU) and premium formats (e.g., functional gummies, sachets).
- Australia and Canada: Trusted wellness staples thrive products emphasizing "clean," regulated formulations appeal strongly.
- All Markets: Tailor formats and channels sachets/gummies in Asia, capsules/tablets in Canada Australia; emphasized science/claim credibility everywhere.

8. Conclusion

The regulation of nutraceuticals remains fragmented, with countries adopting diverse frameworks based on cultural, economic and healthcare philosophies. Canada and Australia combine traditional knowledge and scientific data, India follows a food-based licensing system, while Japan and South Korea impose rigorous evidence requirements. This comparative analysis reveals that the most stringent systems (Japan FOSHU, South Korea HFF) offer strong consumer protection but pose high barriers to market entry. In contrast, flexible systems (India, Australia, Listed Medicines) allow rapid commercialization but may compromise scientific rigor. To ensure both consumer safety and industry growth, international harmonization of nutraceutical regulations,

improved clinical evidence standards and robust post-market surveillance are urgently needed.

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Conflict of Interest

The authors declare that they have no competing interests related to this work.

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