REVIEW ARTICLE

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Exploring Regulatory Frameworks and Consumer Protection for Herbal and Dietary Supplement Safety: A Scoping Review

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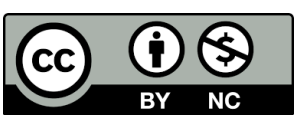


ABSTRACT

Background: Herbal and dietary supplements are being increasingly used for health promotion and disease prevention. However, differences in regulation may affect consumer safety and create challenges for nurses involved in patient education and monitoring. This scoping review examined herbal and dietary supplements regulatory frameworks and consumer safety guidelines across selected countries to identify gaps in regulation and safety monitoring.

Methods: A scoping review was conducted following the Arksey and O'Malley framework and reported in accordance with the PRISMA Extension for Scoping Reviews (PRISMA-ScR). ProQuest, Scopus, ScienceDirect, ClinicalKey Nursing, and the Malaysian Ministry of Health website were searched for relevant literature published between 2018 and 2025. Two independent reviewers conducted study screening and eligibility assessment. Data were charted using a structured extraction form and synthesised descriptively and thematically.

Results: Thirteen studies across seven countries met the inclusion criteria. Five major thematic domains related to consumer safety were identified: (1) regulatory compliance and product verification, (2) practitioner consultation and professional oversight, (3) consumer education and awareness, (4) adverse event monitoring and pharmacovigilance, and (5) safe use practices and risk mitigation. Considerable variation was observed in regulatory oversight, pharmacovigilance, and public education across countries.

Conclusion: The findings highlight the need to strengthen safety monitoring, improve public education, and enhance regulatory awareness among healthcare providers to promote the safe use of herbal and dietary supplements globally.

Keywords: Herbal and dietary supplements; Pharmacovigilance; Regulatory framework; Consumer protection; Nursing practice

INTRODUCTION

Herbal and dietary supplements (HDS) represent one of the fastest-growing sectors of the global healthcare market, driven by rising consumer interest in wellness, self-care, and preventive medicine. In 2023, the global HDS market was valued at around USD 92.84 billion, with forecasts suggesting a compound annual growth rate (CAGR) of 7.81% from 2025 to 2032 (1,2). This expansion signifies economic growth and a broader transition towards natural and integrative health approaches, underscoring the importance of HDS in holistic and person-centered nursing practice. Nurses involved in holistic care frequently regard HDS products as supportive tools that correspond with person-centered and wellness-focused strategies for health promotion.

Despite their widespread global use, the safety of HDS remains a persistent concern, hindered by fragmented regulatory frameworks, variable product quality, and limited pharmacovigilance mechanisms that lead to contamination, adulteration, and product misbranding. The regulatory complexity surrounding HDS is further exacerbated by widespread consumer misconceptions of safety associated with ‘‘natural’’ products, despite mounting evidence of contamination risks involving heavy metals, pesticide residues, as well as prescription drugs such as steroids and thyroid hormones, phosphodiesterase inhibitors and others (3). Unlike prescription medications, HDS are not stringently monitored by the US Food and Drug Administration (FDA), with some countries classifying HDS as food products rather than therapeutic agents. Indeed, under present legal frameworks, the FDA may not take action to limit distribution of HDS until after they have been proved to cause adverse reactions (4). These deficiencies pose a growing challenge to healthcare systems, as supplement-related adverse events remain underdiagnosed or underreported. Data from the Drug-Induced Liver Injury Network (DILIN) reveal that HDS collectively represent the second leading cause of drug-induced liver injury, emphasising the growing clinical significance of supplement-associated hepatotoxicity (5).

Holistic nurses play a crucial role in addressing these challenges by providing education, advocacy, and evidence-based guidance. Nevertheless, their capacity to guarantee safe supplement utilisation is contingent upon access to dependable regulatory information and uniform safety frameworks. This scoping review aims to examine the variations in consumer safety guidelines and regulatory frameworks for HDS across seven countries to identify critical gaps in pharmacovigilance, practitioner involvement, and public education. Specifically, this review sought to answer the following question: What regulatory frameworks and consumer safety guidelines are currently available for HDS, and what gaps exist in their implementation across different countries? By synthesising regulatory approaches from various countries, this review provides insights that can inform holistic nursing education, practice, and advocacy, emphasising the need for nurses to be actively involved in promoting safe, culturally competent, and evidence-informed use of natural health products.

METHODS

This scoping review followed the methodological framework established by Arksey and O’Malley and complied with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist to ensure transparency and reproducibility.

Information Sources

Four electronic databases, ProQuest, Scopus, ScienceDirect, and ClinicalKey Nursing, were systematically searched for literature published between 2018 and 2025, supplemented by grey literature from the Ministry of Health (MOH) Malaysia. The literature search was conducted between January and April 2025.

Search Strategy

Search terms were developed using Boolean operators (AND/OR) and keyword mapping based on Medical Subject Headings (MeSH) and related terminology, combining concepts of "Herbal Products" OR "Herbal Medicine" OR "Medicinal Herb" OR "Dietary Supplement" OR "Food Supplement" OR "Nutraceutical" AND "Policy" OR "Guideline" OR "Protocol" OR "Safe Practice" OR "Consumer Safety" OR "Framework" OR "Regulation". Search filters were applied to narrow the search results by publication years, text availability, article type and article language.

Operational Definition

This review defines a 'consumer safety guideline' as any peer-reviewed or policy document that delineates principles, standards, or recommendations intended to ensure safe consumption, regulation, monitoring, or public communication concerning herbal and dietary supplements (HDS). Herbal and dietary supplements refer to orally consumed products containing herbal or botanical ingredients, vitamins, minerals, amino acids, or other dietary substances used to supplement the diet or support health and well-being. The term encompasses products that may be classified differently across regulatory jurisdictions, including dietary supplements, herbal medicines, natural health products, and food supplements. This operational definition was applied to determine study eligibility and ensure conceptual consistency across various national and institutional sources.

Eligibility Criteria

The eligibility criteria were established to ensure that the included sources were relevant to the regulatory oversight, safety, and consumer protection aspects of HDS. Sources were eligible for inclusion if they focused on HDS intended for consumer use and addressed regulatory frameworks, consumer safety guidelines, pharmacovigilance, or public education mechanisms related to HDS. Global- and national-level policies, regulations, and institutional guidelines concerning HDS safety and oversight were also considered. Eligible sources included peer-reviewed articles, official government publications, and institutional reports published between 2018 and 2025. Earlier publications were also considered when they provided meaningful insights and remained relevant to current regulatory frameworks and practices. Only sources published in the English language were included.

Sources were excluded if they focused solely on the clinical efficacy or pharmacological testing of HDS, or on traditional healing practices without addressing regulatory, safety, or consumer protection issues. Local-level community practices, anecdotal evidence, and information obtained from unverified online sources were not considered eligible. In addition, non-scholarly sources, conference abstracts without available full texts, and unpublished dissertations were excluded.

Study Selection and Data Collection Process

All retrieved references were imported into Microsoft Excel for deduplication and screening. Two independent reviewers screened all titles and abstracts, followed by full-text reviews against the inclusion/exclusion criteria. Any disagreements were resolved through discussion or consultation with a third reviewer. The overall agreement rate between the two reviewers was 86%. The selection process was illustrated in a PRISMA-ScR flow diagram (**Figure** 1).

Data Items

Data were charted using a structured extraction form capturing: (i) Country, (ii) Regulatory authority, (iii) Characteristics of safety regulations, (iv) Pharmacovigilance mechanisms, and (v) Public education or awareness initiatives. Thematic analysis was conducted using an inductive approach following Braun and Clarke's framework. Two reviewers independently coded the extracted data. The reviewers subsequently compared their codes and discussed areas of agreement and disagreement. Coding discrepancies were resolved through discussion and consensus. Related codes were grouped into preliminary themes based on recurring patterns, conceptual similarity, and relevance to the review objectives. The preliminary themes were then reviewed against the extracted data and collaboratively refined to ensure that they accurately represented the recurring regulatory and consumer safety issues identified across the included sources.

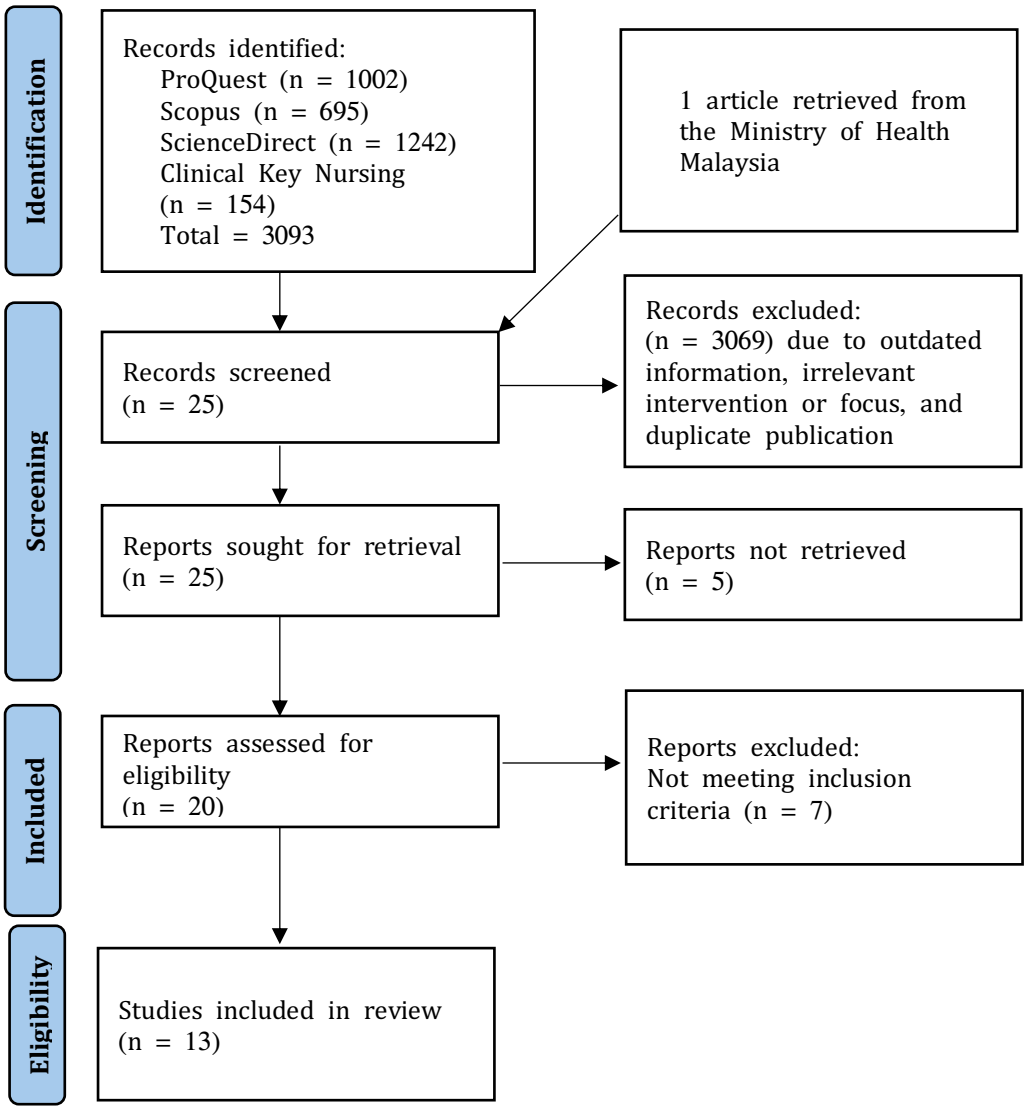
Synthesis and Reporting

The extracted data were summarised descriptively and synthesised through a narrative approach, incorporating comparative analysis.

RESULT

From an initial 3,093 records retrieved across databases, 25 articles were screened in full. Following eligibility assessment, 7 studies were excluded because they constituted secondary analyses or did not meet the inclusion criteria. In total, 13 studies met all inclusion criteria and were incorporated into the final synthesis.

Figure 1: Flow Chart of the Study Selection Process



Study Characteristics

The review synthesised findings from 13 sources, comprising 12 research studies and one report conducted across seven countries, representing diverse regulatory and cultural contexts in herbal and dietary supplements (HDS) governance. The studies collectively span the United States (n = 4), Malaysia (n = 3), India (n = 1), Canada (n = 1), Malawi/Nigeria (n = 1), the European Union (n = 1), and Romania (n = 2), highlighting both developed and emerging regulatory systems.

Comparative Evaluation of Consumer Safety Frameworks of Herbal and Dietary Supplement (HDS) Across Countries

A comparative synthesis of regulatory frameworks across seven countries, emphasising key mechanisms that govern the safety of herbal and dietary supplements. **Table** 1 delineates regulatory bodies, pre-market controls, post-market surveillance, pharmacovigilance systems, and public education mandates, highlighting structural differences in global governance and the varying levels of maturity in consumer protection systems.

Herbal and dietary supplement (HDS) regulation varies significantly across countries in terms of scope, rigor, and enforcement. A synthesis of seven national frameworks identifies two primary regulatory philosophies: (i) proactive pre-market assurance, as seen in India, Malaysia, the EU, and Canada, and (ii)

reactive post-market surveillance, exemplified by the United States, Nigeria, Malawi, and Romania. The differing approaches indicate distinct levels of institutional maturity, integration of pharmacovigilance, and emphasis on consumer education.

Table 1: Cross-National Regulatory Comparison of Herbal and Dietary Supplement Safety Frameworks

Author, Year and Country	Primary Regulatory Body	Pre-Market Controls	Post-Market Surveillance	Pharmacovigilance Mechanism	Public Education Mandate
Bansal and Dhiman 2019 (6) India	Food Safety and Standards Authority of India FSSAI), established under the Food Safety and Standards FSS) Act, 2006.	• Mandatory safety and ingredient verification. • Product registration required.	• Food Safety Officers can inspect facilities, take samples for analysis, and seize violating items. • Non-compliance might result in license suspension or termination.	• Health claims for food must be supported by sufficient documentation and provided for Food Authority evaluation. • Third-party and internal audits follow food safety rules.	• Promotes nutrition-related campaigns. • Dissemination of safety standards to consumers and food business operators. • Training programs in food safety.
Ismail et al. 2020 (7); Ministry of Health 2019 (8); Roziman et al. 2024 (9) Malaysia	National Pharmaceutical Control Bureau (NPCB), under the Malaysian Health Ministry's Drug Control Authority (DCA) regulates herbal and traditional medicine safety, quality, and registration.	• Comprehensive product registration (MAL number, hologram, halal certification). • Manufacturers must adhere to Good Manufacturing Practices (GMP).	• DCA post-market surveillance comprises sample testing of registered items. • Quality-related product recalls are crucial to surveillance.	• No formal herbal medicine pharmacovigilance program. • Monitor health outcomes and report any adverse effects to healthcare professionals.	• Structured awareness programs under MOH. • Consult qualified practitioners registered under the TCM Act 2016 (Act 775) before starting treatment.
Schmitz et al. 2020 (16); Enioutina et al. 2020 (17); Thakkar et al. 2020 (11); Williams 2020 (23) United States	Food and Drug Administration (FDA) under Dietary Supplement Health and Education Act DSHEA (1994)	• Dietary supplement pre-market restrictions are limited in the U.S. Dietary supplements are not FDA-approved like pharmaceuticals. • Manufacturers must ensure product safety and FDA-compliant claims. • Unless excluded, new dietary additives introduced after 1994 must pass New Dietary Ingredients	• MedWatch program, where adverse events related to dietary supplements can be reported.	• FDA MedWatch lets consumers and healthcare providers report adverse events and defects in products.	• No dedicated public education program. • Ensure product labels accurately reflect ingredients, uses, and risks. • The agency warns about harmful supplements based on safety data.

		Notification (NDIN).			
Ng & Luong 2020 (10) Canada	Natural and Non-prescription Health Products Directorate under Health Canada	• Each Natural Health Product (NHP) must be licensed by Health Canada before sale. • Products are approved based on modern health claims (requiring scientific evidence) or traditional use (with a history of safety). • NHPs must meet labeling, safety, and production standards.	• Monitoring adverse reactions and maintaining safety standards. • Limited resources for site inspections, which usually occur after product complaints.	• Mandatory reporting for licensed natural products by manufacturers, distributors, and retailers.	• Public education about NHPs usage and safety, risks and benefits, efficacy and side effects. • Regulatory measures to ensure proper labeling and public awareness.
Gatt et al. 2024 (13) European Union	European Medicines Agency (EMA)	• Full marketing authorisation (like pharmaceutical drugs), • Well-established use (WEU) for clinically used products, • Traditional Herbal Medicinal Products (THMP) for those with 30 years of use, including 15 years in the EU. • For registration, products must meet safety, quality, and efficacy standards with monographs and quality documentation.	• Companies report any adverse reactions associated with their products.	• Manufacturers and member states to ensure herbal product safety. • Report adverse reactions and monitor herbal product safety continuously.	• The regulatory system provides accurate herbal product information to the public (proper use, potential risks, safe practices), enabling informed decision-making and reducing misuse.
Mponda et al. 2025 (12) Nigeria/ Malawi	Malawi: The Pharmacy and Medicines Regulatory Authority (PMRA). Nigeria: The National Agency for Food and Drug Administration and Control (NAFDAC).	• Malawi: No comprehensive regulatory framework exists for herbal medicine pre-market registration. • Nigeria: NAFDAC regulates herbal medicine registration, production, and marketing. It inspects and evaluates products before	• Malawi: Product mix raw material variability, unknown stability and quality variables, lack of information due to non-registration • Nigeria: Poor labeling, advertisement, unwillingness to be	• Malawi: Safety, quality, and efficacy unknown, insufficient public and practitioner understanding of TCM ADR reporting, non-standardisation, missing product names and quantities. • Nigeria: Poor reporting, under-reporting, lack of standard safety profile of	• Substantial gaps in public education about traditional medicine use.

		they enter the market to ensure safety.	monitored, mixture of conventional and herbal medicines.	products to verify safety claims.	
Nyulas et al. 2024 (15); Barbulescu & Harel 2015 (14) Romania	National Agency for Medicines and Medical Devices (NAMMD).	• Medicinal product clinical trials require NAMMD ethics committee approval.	• A standard reporting system for possible herb-drug interactions is mentioned. • Voluntary reporting of adverse events. • The authority monitors for adverse effects and ensures compliance with safety standards through inspections and audits.	• Pharmaco-vigilance reporting and monitoring is coordinated by the NAMMD with the European Medicines Agency (EMA) and other international authorities. • Collection of data on adverse drug reactions (ADR).	• The NAMMD promotes pharmaceutical product safety and risk awareness. • Healthcare professionals may collaborate to guarantee public safety through open commu-nication.

Structured pre-market regulatory mechanisms were identified in India, Malaysia, the European Union, and Canada. The Food Safety and Standards Authority of India (FSSAI) mandates ingredient verification and safety documentation (6), similar to the Drug Control Authority of Malaysia (DCA), which necessitates comprehensive product registration, compliance with Good Manufacturing Practices (GMP), and traceability via unique identifiers like holograms and halal certification (7–9). Health Canada's Natural and Non-prescription Health Products Directorate requires pre-sale licensing to ensure that natural health products comply with labeling and safety standards, which must be substantiated by clinical or traditional evidence (10). The U.S. FDA permits dietary supplements to avoid pre-market authorisation, thereby assigning full responsibility for safety to manufacturers (11).

Regulatory challenges were more pronounced in the evidence from Nigeria and Malawi. In Malawi, the reviewed evidence indicated the absence of a comprehensive regulatory framework for pre-market registration of herbal medicines, together with challenges related to non-registration, variability in raw materials, limited product information, and inadequate mechanisms for monitoring safety and adverse reactions. In Nigeria, herbal medicines are regulated by the National Agency for Food and Drug Administration and Control (NAFDAC), which oversees product registration, production, and marketing. However, challenges remain in relation to product labelling, advertising, monitoring of informal supply chains, and underreporting of adverse events (12). These findings highlight important differences in regulatory and pharmacovigilance capacity across the settings included in this review.

The robustness of post-market monitoring mechanisms varies significantly. Centralised regulatory agencies in countries such as the EU (13) and Malaysia implement organised market surveillance programs that include regular sampling, testing, and product recalls. Canada mandates the monitoring of adverse reactions; however, limited resources restrict proactive inspections (10). In contrast, the U.S. FDA's MedWatch system represents a consumer-driven surveillance model that depends on voluntary reporting instead of systematic inspection (11). Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) perform regular inspections and recalls; however, it encounters difficulties in enforcing compliance within informal supply chains. The Pharmacy and Medicines Regulatory Authority (PMRA) in Malawi demonstrates a lack of consistent monitoring infrastructure, highlighting disparities in regulatory enforcement capacity (12). The lack of uniformity in post-market vigilance leads to inconsistent consumer protection and

diminished accountability for adverse outcomes in developing contexts.

Pharmacovigilance systems are globally underdeveloped, exhibiting varying levels of institutionalisation. The EU and Romania (14,15), via the European Medicines Agency (EMA) and the National Agency for Medicines and Medical Devices (NAMMD), uphold integrated databases for adverse reactions that facilitate cross-border safety evaluations. Malaysia and Canada have initiated the formalisation of reporting mechanisms; however, herbal pharmacovigilance continues to be fragmented due to inconsistent data collection and limited participation from practitioners. The United States, despite possessing an advanced reporting system, does not implement mandatory tracking of adverse events for supplements, thereby constraining real-time safety assessments. Nigeria and Malawi demonstrate systemic underreporting and a lack of standardised adverse drug reaction (ADR) registries. The findings indicate that pharmacovigilance capacity is associated with economic and institutional development; however, no country has established a fully comprehensive and harmonised system for monitoring herbal products.

Public education mandates are inconsistently integrated into regulatory frameworks. Malaysia's Ministry of Health implements organised consumer campaigns and professional consultation in accordance with the TCM Act 2016, exemplifying effective community-level engagement. Canada's public communication strategies emphasise safe product usage and labeling literacy, whereas India's FSSAI utilises nutrition campaigns to enhance regulatory awareness. In contrast, the U.S. FDA adopts an informational approach, focusing primarily on label transparency and warning notices rather than educational initiatives. The EU facilitates public access to reliable information on herbal medicine via guidance from the EMA, despite ongoing national discrepancies. In Nigeria and Malawi, the lack of public education initiatives renders consumers susceptible to misinformation and hazardous self-medication practices. This gap illustrates that regulatory rigor is inadequate without proactive public risk communication.

Consumer Safety Guidelines

Based on **Table 2**, the extracted safety guidelines were clustered into five major thematic domains; (i) regulatory compliance and product verification, (ii) practitioner consultation and professional oversight, (iii) consumer education and awareness, (iv) adverse event monitoring and pharmacovigilance, and (v) safe use practices and risk mitigation. Each theme captures recurring principles and regulatory patterns observed across the reviewed studies.

Regulatory Compliance and Product Verification

This theme encompasses guidelines emphasising product registration, certification, and adherence to established regulatory standards. Studies from India, Malaysia, Canada, and Nigeria underscored the importance of verifying official product approval through agencies such as the FSSAI, MOH Malaysia, Health Canada, and the National Agency for Food and Drug Administration and Control (NAFDAC). Consumers are advised to confirm product authenticity via registration numbers, holograms, or halal certification, and to avoid unregulated market items. This reflects an overarching need for enforcement-driven consumer protection and transparent labeling standards.

Practitioner Consultation and Professional Oversight

Guidelines within this theme advocate for consultation with qualified healthcare or traditional medicine practitioners before initiating supplement use. Several studies (8,9,12,13) highlighted that professional oversight is essential to mitigate risks such as misdiagnosis and herb-drug interactions. These recommendations align with the Traditional and Complementary Medicine Act 2016 (Malaysia) and global clinical standards promoting practitioner-guided usage to enhance safety and accountability.

Consumer Education and Awareness

Education-oriented recommendations appear consistently across studies from the United States, Canada, Europe, and Malaysia (7,10,13,16,17). These sources emphasised the need for continuous education on pharmacology, toxicology, and risk perception, countering the misconception that "natural" equals "safe", and encouraged the use of verified resources. Strategies such as clinical seminars, public awareness campaigns, and

accessible online databases (e.g., Epocrates and Natural Medicines) are advocated to improve consumer decision-making and promote evidence-based supplement use.

Table 2: Thematic Clusters of Consumer Safety Guidelines for Herbal and Dietary Supplements (Hds)

Theme/Cluster	Core Focus	Representative Studies
Regulatory Compliance and Product Verification	Verification of product legitimacy, adherence to national regulatory standards, and authenticity of labelling.	Bansal & Dhiman 2019 (6); Ministry of Health 2019 (8); Ismail et al. 2020 (7); Mponda et al. 2025 (12); Roziman et al. 2024 (9); Ng & Luong 2020 (10)
Practitioner Consultation and Professional Oversight	Role of licensed healthcare providers or traditional medicine practitioners in guiding safe supplement use and ensure practitioners are registered under national legislation.	Ministry of Health 2019 (8); Williams 2020 (23); Gatt et al. 2024 (13); Roziman et al. 2024 (9); Mponda et al. 2025 (12)
Consumer Knowledge and Awareness	Education on risks, benefits, and misconceptions surrounding herbal and dietary supplements, encourage use of verified resources, and promote continuous pharmacological education and literacy.	Schmitz et al. 2020 (16); Enioutina et al. 2020 (17); Ismail et al. 2020 (7); Ng & Luong 2020 (10); Gatt et al. 2024 (13)
Adverse Event Monitoring and Pharmacovigilance	Establishing systematic reporting mechanisms for supplement-related adverse effects, and develop standardised pharmacovigilance and post-market surveillance systems.	Schmitz et al. 2020 (16); Ng & Luong 2020 (10); Nyulas et al. 2024 (15)
Safe Use Practices and Risk Mitigation	Promoting responsible self-care and monitoring of supplement consumption.	Williams 2020 (23); Roziman et al. 2024 (9); Mponda et al. 2025 (12)

Adverse Event Monitoring and Pharmacovigilance

Multiple studies underscored a critical deficiency in adverse event reporting systems governing HDS use. Evidence from (10,15,16) collectively emphasised the need for robust pharmacovigilance frameworks that mandate adverse event reporting, systematic product labeling, and adherence to preoperative cessation protocols for high-risk herbs such as ginkgo, ginseng, garlic, ginger, and green tea. These authors advocated for standardised reporting mechanisms and strengthened post-market surveillance to ensure timely detection and management of supplement-related complications. Notably, improved monitoring is vital for identifying cardiovascular and hepatic adverse effects, which remain among the most frequently underreported outcomes. The integration of structured pharmacovigilance systems into national regulatory policies would therefore represent a pivotal step toward enhancing transparency, accountability, and consumer safety in the rapidly expanding global supplement market.

Safe Use Practices and Risk Mitigation

This theme integrates guidelines promoting safe consumption behaviors, such as avoiding multiple concurrent herbal products, verifying active ingredients, and monitoring personal health outcomes. Several studies (9,12,18) highlighted the importance of reading product labels, adhering to recommended dosages, and discontinuing supplements before surgical procedures or when adverse symptoms occur. Collectively, these practices support risk mitigation through proactive self-monitoring and responsible consumer behavior.

DISCUSSION

The expanding use of HDS continues to challenge existing regulatory and clinical paradigms. As their popularity grows globally, ensuring product safety, quality, and consumer protection has become a critical

public health priority. This scoping review contextualises studies within the broader discourse concerning regulatory governance, pharmacovigilance, and evidence-based consumer protection, highlighting opportunities for harmonisation and policy advancement across diverse healthcare systems.

Regulatory Divergence

This review highlights significant regulatory divergence in the governance of HDS across the reviewed studies. Countries that have established structured pre-market verification systems exhibit enhanced regulatory coherence and mechanisms for consumer protection, while various countries that predominantly depend on post-market surveillance and voluntary compliance result in a reactive rather than a preventive safety framework. The disparities highlight the influence of institutional capacity, resource allocation, and political commitment on regulatory maturity. Loosely enforced frameworks result in inconsistent consumer safety protections, variable labelling requirements, and limited market surveillance, allowing the circulation of substandard or adulterated products. Product adulteration typically involves the addition of cheaper or toxic substances, dilution or removal of active ingredients, or substitution with inferior materials to reduce production costs or conceal product defects (18). Such practices critically undermine product integrity and pose significant public health risks, including carcinogenic effects, hepatotoxicity, cardiovascular complications, renal impairment, and neurotoxicity. The absence of harmonised quality assurance and enforcement mechanisms therefore perpetuates a cycle of consumer vulnerability and regulatory inefficacy in the global supplement market. To mitigate these disparities, there is an urgent need for a globally harmonised regulatory framework supported by international bodies such as the World Health Organisation (WHO). Such a framework should standardise product registration, pharmacovigilance, and adverse event reporting protocols, thereby strengthening cross-border collaboration and ensuring equitable consumer safety standards worldwide.

Cultural and Economic Influences on Regulatory Approaches

Regulatory approaches to HDS should also be interpreted within their broader cultural and economic contexts. Cultural traditions influence how herbal products are perceived, used, and incorporated into healthcare systems, which may subsequently shape regulatory priorities. In settings where traditional medicine is widely used and culturally embedded, regulatory systems must balance the recognition of traditional practices with requirements for product quality, safety, and consumer protection. Differences in the classification of HDS as foods, supplements, traditional medicines, or therapeutic products further contribute to variations in regulatory approaches across countries (1,6,7,8).

Economic and institutional capacity may also influence the maturity of HDS regulatory systems. The findings of this review suggest that countries with more established regulatory infrastructures, such as Canada, the European Union, and Malaysia, generally demonstrate more structured mechanisms for pre-market assessment, product registration, post-market surveillance, and adverse-event reporting (7,10,13). In contrast, resource-constrained settings may experience challenges in implementing comprehensive regulatory systems because of limited surveillance infrastructure, enforcement capacity, and pharmacovigilance resources. For example, the evidence reviewed from Malawi and Nigeria highlighted challenges related to registration, monitoring, adverse-event reporting, and informal supply chains (12). However, these patterns should be interpreted cautiously, as this scoping review did not formally assess or statistically examine the relationship between national economic development and regulatory maturity.

These findings indicate that regulatory harmonisation should not necessarily imply the adoption of an identical regulatory model across countries. Rather, international guidance should accommodate differences in cultural practices, healthcare systems, economic resources, and institutional capacity while establishing minimum standards for product quality, pharmacovigilance, consumer education, and safety monitoring.

Gaps in the Pharmacovigilance System

This review identifies a significant limitation in the pharmacovigilance infrastructure present in the majority of regulatory systems. A limited number of countries have established structured mechanisms for adverse event reporting that facilitate cross-border data sharing. Conversely, countries such as Nigeria and Malawi exhibit deficiencies in formal reporting systems or depend on inadequate frameworks that are susceptible to underreporting. The existing gaps impede the timely identification of supplement-related risks and obscure the actual burden of adverse events in real-world contexts. Unlike conventional pharmaceuticals, most HDS products enter the market without premarket safety evaluation or systematic post-market monitoring, creating substantial blind spots in detecting product-related risks. The current reliance on voluntary reporting mechanisms limits the traceability of adverse outcomes, particularly in cases of hepatotoxicity, cardiotoxicity, or herb-drug interactions (19). Integrating technologies such as digitalised pharmacovigilance tools could revolutionise supplement monitoring, enabling the early identification of emerging risks and supporting evidence-based regulatory interventions (20).

Consumer Education

Evidence suggests a persistent lack of education among consumers concerning the safe utilisation of HDS. A pervasive misconception that "natural" equates to "safe" continues to shape consumer attitudes toward HDS, driving self-prescription and unsafe consumption practices. A content analysis conducted by previous study (21) reveals that articles primarily depict positive media influence on dietary supplements, without substantial scientific evidence. This false perception often leads individuals to underestimate potential toxicities, herb-drug interactions, and product adulteration risks, especially when using unregulated or internet-sourced supplements. The COVID-19 pandemic further intensified global reliance on HDS for immune support, underscoring the growing emphasis on preventive health (22). Several countries in this review have implemented public awareness programs and established professional training requirements; however, these instances are exceptions rather than standard practice.

Strengthening consumer education, labeling transparency, and healthcare practitioner engagement is imperative to mitigate misinformation and promote safe use. Public awareness initiatives should emphasise that the natural origin of a substance does not guarantee safety or efficacy. Moreover, integrating consumer safety and pharmacognosy modules into medical, nursing, and pharmacy curricula, as well as embedding HDS risk communication campaigns into national public health programs, would enhance both professional competence and public literacy. Such multidisciplinary education efforts are crucial for fostering responsible supplement use and reducing preventable adverse outcomes linked to misinformation.

Policy Implications for Nursing Practice

Regulatory inconsistencies, insufficient pharmacovigilance systems, and lack of consumer education highlight the necessity for nursing leadership in the development of evidence-based policy and clinical governance. Holistic nurses play a distinctive role in connecting regulatory frameworks with patient care practices. Their active participation in patient education, recognition of adverse events, and informed consent processes offers essential insights for the formulation of practical, patient-centered safety policies. In clinical practice, nurses can routinely assess HDS use during medication history-taking and health assessments, document the types and frequency of supplements used, identify potential herb–drug interactions, and encourage patients to disclose HDS use to their healthcare providers. Nurses can also educate patients on verifying product registration and labelling, adhering to recommended dosages, and recognising symptoms that may require discontinuation of a supplement or further medical assessment.

Nurses can promote the implementation of standardised systems for reporting adverse events, thereby ensuring that incidents related to supplements are systematically documented and communicated throughout healthcare environments. For example, suspected HDS-related adverse events can be documented and reported through established institutional or national pharmacovigilance systems. Incorporating regulatory literacy and pharmacovigilance principles into nursing curricula and continuing education programs would enhance nurses' capabilities in safety

monitoring and policy discussions. At the institutional level, nurse leaders and educators can facilitate the integration of HDS safety protocols into clinical guidelines, thereby encouraging interdisciplinary collaboration with pharmacists and physicians. Nursing organisations can collaborate with regulatory agencies to develop unified frameworks that balance consumer autonomy with professional accountability. Integrating safety advocacy into holistic nursing practice enables nurses to impact policy development and public education, thereby strengthening their essential role in promoting health through the use of herbal and dietary supplements while maintaining patient safety.

CONCLUSION

This scoping review identified considerable regulatory variability and differing enforcement capacity across seven countries regulating HDS. These disparities affect both consumer protection and nursing practice in holistic care settings, where patient confidence and safety rely on the quality and transparency of natural health products. The findings highlight the necessity for holistic nurses to incorporate a thorough evaluation of supplement safety, understanding of regulatory discrepancies, and patient education into clinical decision-making. Deficiencies in pharmacovigilance and consumer literacy underscore the necessity for nurses to serve as educators, advocates, and collaborators in interdisciplinary safety initiatives. Integrating evidence-based guidelines on HDS into holistic nursing courses and ongoing professional education can improve clinical competence and ethical practice. While worldwide harmonisation of HDS regulation is still a goal, the nursing profession may significantly contribute to the enhancement of regional and institutional frameworks that emphasise transparency, education, and patient empowerment. Through promoting informed dialogue and advocating equal safety standards, holistic nurses can help ensure that integrative health practices are both therapeutically efficacious and ethically compliant.

LIMITATIONS AND RECOMMENDATIONS

This review was conducted based on the Arksey and O'Malley scoping framework, which ensured methodological rigor and transparency, while the inclusion of studies from multiple regions provided a comparative perspective on regulatory maturity and enforcement diversity. This review also identifies critical policy and research gaps, offering actionable insights for harmonising international HDS safety standards.

This review presents several limitations that must be considered when interpreting its findings. The synthesis was derived from a limited number of included studies (n = 13), which restricts the scope of global representation. The restriction to English publications may have led to the exclusion of pertinent regulatory frameworks or policy documents published in other languages, especially from non-English-speaking regions with developing herbal and dietary supplement markets. The review predominantly utilised policy and guideline documents, which constrained the evaluation of the practical implementation and effectiveness of consumer safety measures due to the lack of empirical data.

Given the qualitative and document-based nature of the evidence, the findings should be considered as preliminary mappings that delineate regulatory patterns and thematic domains rather than conclusive global generalisations. Furthermore, the predominance of high- and middle-income country sources may overrepresent structured and well-established regulatory systems, potentially underestimating the challenges faced in low-resource settings.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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AUTHOR CONTRIBUTIONS

NAM: Conceived and designed the study, supervised the research, interpreted the data, critically revised the manuscript and approved the final version.
MZRMZB: Contributed to the study conception, data collection, data analysis, and manuscript drafting.
WHWM: Contributed to the critical revision of the manuscript and final approval of the submitted version.
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DECLARATION OF GENERATIVE AI USE

The authors declare that artificial intelligence (AI) tools were used solely to assist with language editing, grammar correction, and improving the clarity and readability of the manuscript. All intellectual input, data analysis, interpretation of findings, and final decisions regarding the content remain the sole responsibility of the authors. The authors have carefully reviewed and verified the accuracy of all AI-assisted outputs and accept full responsibility for the integrity and originality of this work.

REFERENCES

1. Bhilare P. Herbal Supplements Market Share, Size, Trends, & Industry Analysis Report 2025 - 2034. 2025.
2. Surwase A. Herbal Supplements Market Size, Share, and Growth Forecast, 2025 - 2032. 2025.
3. Luo L, Wang B, Jiang J, Fitzgerald M, Huang Q, Yu Z, et al. Heavy Metal Contaminations in Herbal Medicines: Determination, Comprehensive Risk Assessments, and Solutions. Front Pharmacol. 2021;11(January):1–14. doi:10.3389/fphar.2020.595335
4. Blaj SB, Marius C, Miron R, Valea DC, Muntean DL. Regulation of Food Supplements and Pharmacists ' Responsibility in Professional Practice : A Review. Pharmacy. 2026;14(25):1–29.
5. Halegoua-DeMarzio D, Navarro V. Challenges in herbal-induced liver injury identification and prevention. Liver International. 2025;45(3):1–6. doi:10.1111/liv.16071 PubMed PMID: 39136211.
6. Bansal R, Dhiman A. Line of Progression: Indian Regulatory Framework for Nutraceuticals and Dietary Supplements. Applied Clinical Research, Clinical Trials and Regulatory Affairs. 2019;6(1):46–61. doi:10.2174/2213476x06666190128150415
7. Ismail SF, Madieha Abd Ghani Azmi I, Daud M, Abd Jalil J, Safuan S. Regulatory Control of Herbal and Traditional Medicines in Malaysia: Issues and Concerns. International Journal of Business and Society. 2020;21(1):192–204.
8. Ministry of Health. Consumer guideline for proper use of traditional and complementary medicine services in Malaysia. 2019.
9. Roziman NSM, Mustafa Din W, Mahadi Z, Islahudin F, Said MM. Safe use elements of finished herbal products: insights from consumers and practitioners in Malaysia. BMC Complement Med Ther. 2024;24(1):1–12. doi:10.1186/s12906-024-04546-7 PubMed PMID: 38961355.
10. Ng JY, Luong M. Evaluation of the Canadian natural health product regulatory framework in academic research: A scoping review. Eur J Integr Med. 2020;37:101159. doi:10.1016/j.eujim.2020.101159
11. Thakkar S, Anklam E, Xu A, Ulberth F, Li J, Li B, et al. Regulatory landscape of dietary supplements and herbal medicines from a global perspective. Regulatory Toxicology and Pharmacology. 2020;114(April). doi:10.1016/j.yrtph.2020.104647 PubMed PMID: 32305367.
12. Mponda JS, Muula AS, Choko A, Ajuwon AJ, Moody JO. Traditional medicine regulation status and challenges in Malawi and Nigeria. BMC Complement Med Ther. 2025;25(1). doi:10.1186/s12906-025-04812-2 PubMed PMID: 39953523.
13. Gatt AR, Vella Bonanno P, Zammit R. Ethical considerations in the regulation and use of herbal medicines in the European Union. Front Med Technol. 2024;6(June):1–14. doi:10.3389/fmedt.2024.1358956
14. Barbulescu G, Harel C. Market Report Romania ' s Regulatory Framework for

Clinical Trials. Journal for Clinical Studies. 2015;7(2):7–9.
15. Nyulas KI, Simon-Szabó Z, Pál S, Fodor MA, Dénes L, Cseh MJ, et al. Cardiovascular Effects of Herbal Products and Their Interaction with Antihypertensive Drugs—Comprehensive Review. Int J Mol Sci. 2024;25(12). doi:10.3390/ijms25126388 PubMed PMID: 38928095.
16. Schmitz SM, Lopez HL, Mackay D, Nguyen H, Miller PE. Serious Adverse Events Reported with Dietary Supplement Use in the United States: A 2.5 Year Experience. J Diet Suppl. 2020;17(2):227–48. doi:10.1080/19390211.2018.1513109 PubMed PMID: 30513022.
17. Enioutina EY, Job KM, Krepkova L V., Reed MD, Sherwin CM. How can we improve the safe use of herbal medicine and other natural products? A clinical pharmacologist mission. Expert Rev Clin Pharmacol. 2020;13(9):935–44. doi:10.1080/17512433.2020.1803739 PubMed PMID: 32730191.
18. Anagaw YK, Ayenew W, Limenh LW, Geremew DT, Worku MC, Tessema TA, et al. Food adulteration: Causes, risks, and detection techniques—review. SAGE Open Med. 2024;12. doi:10.1177/20503121241250184
19. Binns CW, Lee MK, Lee AH. Problems and Prospects: Public Health Regulation of Dietary Supplements. Annu Rev Public Health. 2018;39:403–20. doi:10.1146/annurev-publhealth-040617-013638 PubMed PMID: 29272167.
20. Anthony OC. AI Driven Pharmacovigilance Systems for Real-Time Detection of Adverse Drug Events in Multi-Center Health Networks. International Journal of Research Publication and Reviews. 2025;6(4):303–18. doi:10.55248/gengpi.6.0425.1309
21. Melero-Bolaños R, Gutiérrez-Villar B, Montero-Simo MJ, Araque-Padilla RA, Olarte-Sánchez CM. Media Influence on the Perceived Safety of Dietary Supplements for Children: A Content Analysis of Spanish News Outlets. Nutrients. 2025;17(6):1–14. doi:10.3390/nu17060951 PubMed PMID: 40289933.
22. Ababneh MA, Halloush S, Altawalbeh S, Mardini A. Knowledge and attitudes towards herbal and dietary products use during the COVID-19 pandemic. Clinical Nutrition Open Science. 2023;49(January):118–29. doi:10.1016/j.nutos.2023.05.003
23. Williams CT. Herbal Supplements: Precautions and Safe Use. Nursing Clinics of North America. 2020;56(1): 1–21. https://doi.org/10.1016/j.cnur.2020.10.001