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Nutrivigilance in India: A global comparative analysis of dietary supplement safety monitoring

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ABSTRACT

Nutrivigilance, a new term to define, is a system to monitor adverse effects associated with food and dietary supplements, is critical for safeguarding public health safety. As the dietary supplements (DS) business continues to change globally, continued collaboration and innovation become essential for ensuring consumer safety and maintaining high standards across all regions. Several countries have initiated to create frameworks to tackle the effectiveness and safety of nutritional supplements, determining the importance of scientific evidence, effective postmarket surveillance and harmonizing regulations globally. The major objective is to enhance regulatory oversight, promote safe product use and foster consumer confidence in nutritional products. This paper presents an insight into the Indian legislation governing food items, nutraceuticals and DS presently in place. Also, recent developments at the global level along with potential gaps and their future strategies to prepare a robust system are suggested.

KEYWORDS

Nutrivigilance; Dietary supplements; Nutritional supplements; Regulatory framework.

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Introduction

Nutrivigilance

Nutrivigilance is the systematic monitoring, collecting, analysis, and assessment of adverse events or responses caused by dietary supplements, functional foods, and other nutritional goods. Food safety is a critical public health concern. It serves as an important function in preserving public health by preventing food borne illnesses and ensuring the wellbeing of populations. Proper food handling, storage, and preparation practices help prevent the spread of harmful bacteria, viruses, and other contaminants that can cause serious health issues. These practices form a crucial part of nutrivigilance, which focuses on maintaining the safety of nutraceuticals and health supplements at every stage, from manufacturing to end use. Nutrivigilance is crucial in recognizing and mitigating negative effects related with food and dietary supplements. The term "nutrivigilance" was first defined by Schmitz et al. in 2013. They introduced it as “the science and activities related to evaluation, identification, consideration and prevention of adverse effects associated with use of health food, nutraceuticals or dietary supplements” [1]. Well-established pharmacovigilance ideas from the pharmaceuticals and biologics sectors serve as the foundation for the nutrivigilance methodology. The term "pharmacovigilance" refers to the practice of collecting, identifying, evaluating, tracking and preventing adverse reactions that arise from medications. The scope of this kind of "vigilance" has expanded recently to encompass the security of nutraceuticals, cosmetics, and herbal items. Furthermore, the prefixes nutri and nutra appear to indicate the same thing in different contexts. The term "nutria/nutra vigilance" refers to the detection of undesirable effects linked to the consumption of nutraceuticals, dietary supplements, and functional foods. It requires the methodical collecting, analyzing and evaluating data on the detrimental impacts of using these goods. The nutrivigilance system aims to explain the reason of the undesirable effects, advance scientific understanding, and enhance the safety of public health since the information gathered may cause the withdrawal of dangerous products from being marketed [2]. Matran et al., advocated for the use and adaptation of HACCP (Hazard Analysis and Critical Control Points) principles as a strategy to implement nutrivigilance during the research and development phase. The implementation of nutrivigilance within Romania's food supplement industry and healthcare system has proven to be a valuable approach for improving public health management by preventing adverse reactions and reducing the burden on the healthcare system [3]. France established the Nutrivigilance system in 2009, which is managed by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES). Koppe et al., emphasized that Nutrivigilance's alert effectiveness is hindered by underreporting. It is essential for healthcare providers to routinely ask patients about their dietary supplement (DS) usage and to report any suspected adverse reactions (AR). The expertise of nutrition professionals plays a crucial role in recognizing and analyzing adverse events related to DS [4]. Nutrivigilance provides several benefits, as presented in Figure 1 [5-7]. Table 1 presents some of the adverse events reported from the commonly used nutraceuticals/dietary supplements.

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Table 1. Some of the reported adverse effects from the commonly used Nutraceuticals

S. No.	Nutraceutical/Dietary supplement	Adverse effect	Optimum range	References
1.	Green tea extract	Hepatotoxicity: Multiple case reports have linked green tea extract supplements to liver damage, ranging from slight increases in hepatic enzymes to severe hepatitis that requires liver transplantation.	0.5-2 g/day	[8]
2.	Kava	Liver Toxicity: Kava supplements have been associated with severe liver injury, leading to restrictions or bans in several countries.	0.5-2 g/day	[9]
3.	St. John's Wort	Interactions with drugs: This herb may interfere with variety of drugs, including oral contraceptives and some antidepressants, decreasing their effectiveness.	3-6 g/day	[10]
4.	*Ginkgo biloba*	Bleeding Risk: Ginkgo may increase the risk of bleeding, particularly when used with blood thinning drugs.	120-240 mg/day	[11]
5.	Fish Oil Supplements	Gastrointestinal Issues: High dosages may result in diarrhea, nausea and "fishy" burps.	250-500 mg/day	[12]
		Increased Bleeding Risk: May raise the risk of bleeding, particularly when used with anticoagulant medicines.		[13]
6.	Vitamin D	Hypercalcemia: Abnormally high calcium levels from excessive consumption may result in weakness and renal issues.	0.11-0.16 µg/day	[14]
7.	Iron Supplements	Gastrointestinal Issues: Can cause constipation, nausea, and abdominal pain.	28-42.5 mg/Kg	[15]
		Overdose Risk: Accidental overdose, particularly in children, can lead to severe toxicity.		[16]
8.	Vitamin B6 (Pyridoxine)	Neuropathy: High doses over extended periods can cause sensory neuropathy.	1.5-2.5 mg/Kg	[17]

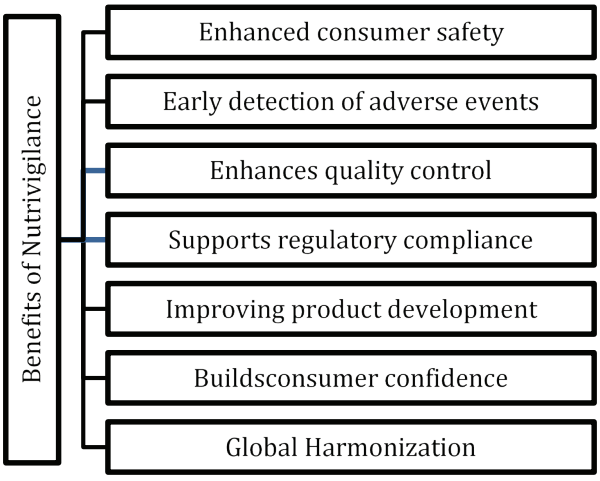

Figure 1. Benefits of nutrivigilance

Global Perspectives on Nutrivigilance

As the global usage of DS and nutraceuticals rises, the importance of efficient nutrivigilance (monitoring and ensuring the efficacy and safety of these products) becomes increasingly apparent. Different areas have developed various approaches to address these needs, reflecting diverse regulatory environments and cultural attitudes toward dietary supplements (DS).

United States

USFDA is regulatory agency for enforcing the rules and regulations that control DS. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the FDA oversees dietary components as well as completed dietary supplement products. The FDA oversees dietary supplements but does not require premarket approval. Rather, producers must guarantee that their products are both accurately labeled and safe. FDA published a paper in 2022 on "Post-market Surveillance under Section 522 of the FD&C Act, 1938" encouraging producers to set up mechanisms for tracking and reporting unfavorable incidents related to their goods [18].

Post-market monitoring is a crucial part of the overall safety assurance program for all goods, including dietary supplements, since it complements and reinforces the pre-market safety review procedure [19]. A variety of databases exist to identify adverse effects associated with dietary supplements, including herbal items. CFSAN Adverse Event Reporting System (CAERS) and FDA Adverse Event Reporting System (FAERS) are two FDA spontaneous report databases [20].

CAERS, post marketing surveillance system, that gathers data on unfavorable events involving products subject to CFSAN regulations. To make post-market monitoring and recording of adverse events (AEs) related to food, cosmetics and

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dietary supplements easier, the FDA created the CAERS database in 2003. It comprises information voluntarily submitted to the FDA by healthcare providers, consumers and government agencies. MedWatch, letters, emails, faxes, phone calls, electronic transfers from the Office of Regulatory Affairs (ORA) etc., are some of the ways that CAERS gets reports. To extract and examine individual case reports based on demographic information (gender and age), adverse event outcomes, symptoms and suspected product name, data files containing various tables are available for free viewing and download [21].

The Center for Food Safety and Applied Nutrition (CFSAN) has maintained an adverse event database system since 2004 that contains all adverse events and product complaint reports for dietary supplements that are filed with the FDA. The public may access this data via open FDA, CAERS Data Files, or by contacting the FDA with a Freedom of Information (FOI) request [19]. A product's adverse event reports and the total number of such reports in CAERS only list facts "AS REPORTED" and do not indicate the FDA's opinion on whether the product was responsible for adverse events [21]. FAERS is the largest publicly accessible database of adverse events, gathering US and non-US reports voluntarily submitted by consumers, healthcare providers and manufacturers. FAERS receives reports of post-marketing adverse events and medication errors related to therapeutic biologics and drugs. FAERS records adverse event reports related to dietary supplements that include drug adulterants or concurrent medicinal items [20].

Between 2004 and 2021, more than a thousand adverse events linked to *Garcinia cambogia* (commonly known as Malabar Tamarind) were reported by the CFSAN Adverse Event Reporting System (CAERS) (Figure 2). These incidents included symptoms such as headache, nausea, vomiting as well as liver damage or failure and renal issues [22].

On March 3, 2025, U.S. Trading Company, located in Hayward, California, recalled its Joy Luck Brand Lily Flowers due to the potential presence of undeclared sulfites. Individuals with sulfite allergies or high sensitivity could face serious allergic reactions if they consume these products [23].

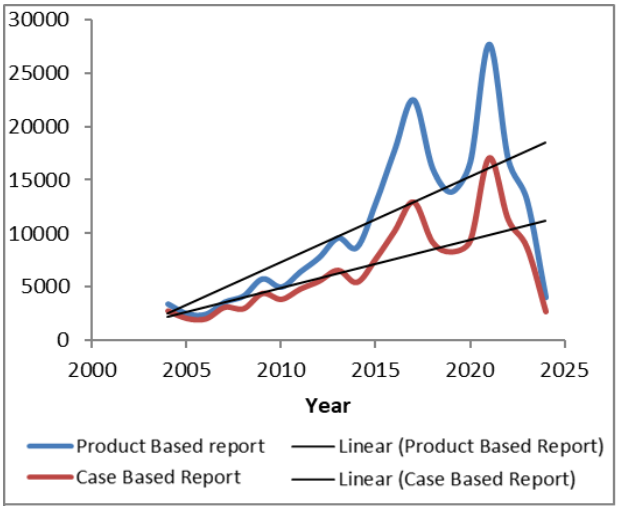

Figure 2. FDA received adverse event reports by year (CAERS 2004-2025) [24].

European Union (EU)

The entire EU food safety regulation framework is based on the General Food Law Regulation (Reg. (EC) 178/2002). The EU food supplement sector is governed by the Food Supplement Directive (Directive 2002/46/EC) [25].

The European Union's regulatory system is more centralized, with the European Food Safety Authority (EFSA) and European Commission (EC). Although, at present, there is no provision in European Union legislation to develop a specific surveillance system for food supplements (FSs). The Rapid Alert System for Food and Feed (RASFF) and the Emerging Risks Exchange Network (EREN) are systems for reporting food safety that are coordinated by the European Parliament and the European Commission [26]. A specific postmarket surveillance system has been established by few European countries for food supplements and other specific foodstuffs, even though no safety studies are required before a food supplement is placed on the market: Croatia (2020), Slovenia (2016), the Czech Republic (2015), Portugal (2014), Denmark (2013), Italy (2012), and France (2009) [27] (Table 2).

Table 2. Some of the EU countries and their Nutrivigilance systems.

Country	Established year	System Name	Managed by
France	2009	French Nutrivigilance System	French Agency for Food, Environmental and Occupational Health and Safety (ANSES)
Italy	2012	Italian Phytovigilance System	Italian National Institute of Health
Denmark	2013	Danish Nutrivigilance System	Danish Veterinary and Food Administration (DVFA)
Portugal	2014	Portuguese Nutrivigilance system	Directorate General for Food and Veterinary (DGAV)
Czech Republic	2015	Czech Nutrivigilance System	National Institute of Public Health-Center for Health, Nutrition and Food
Slovenia	2016	Slovenian Nutrivigilance System	National Institute of Public Health Solvenia (NIJZ)
Croatia	2020	Croatian Nutrivigilance System	Crotian Institute of Public Health (CIPH)

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A Nutrivigilance System was established in 2009 by France to detect potential undesirable effects of food for special dietary needs, fortified food and beverage (FFBs), novel foods, food supplements, as well as to strengthen customer safety. The Nutrivigilance System, which is based on voluntary reports from consumers, food supplement manufacturers, and medical professionals like doctors, pharmacists, and dieticians, is supervised by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES). Online reporting is possible through a website (www.nutrivigilance-anses.fr) [28]. The Agency received 7946 reports from November 13, 2009, when the nutrivigilance system was launched, and December 31, 2022. In 2022, there were 711 reported complaints, and 64% of these were investigated. Among the investigated cases, 7% were deemed serious, showing an increase from 5% reported during 2020–2021 [29].

Between October 2004 and December 2019, post-marketing data was gathered through a voluntary nutrivigilance system set up by the manufacturing company (Meda Pharma SpA, a Viatris enterprise, Monza, Italy). There were 542 notifications/cases in all, indicating 855 adverse events linked to the use of Armolipid Plus (enhanced) and Armolipid (standard). Twenty-six liver undesirable events and 148 musculoskeletal adverse events (17.3%) were reported [30]. Banach et al., conducted an updated study of undesirable events for the Red Yeast Rice (RYR) containing supplements Armolipid Plus (enhanced) and Armolipid (standard) up to December 31, 2023 (an extra four years). Up to 2023, a total of 1,186 reports related to these food supplements were received, an increase from 542 in 2019. Similarly, 1,904 adverse events were reported by 2023, compared to 855 in 2019 [31].

Recently, national and European authorities have emphasized a lack of post-market monitoring for FSs, raising safety concerns and distrust. The European Federation of Associations of Health Product Manufacturers (EHPM) created voluntary self-regulatory regulations to establish a strong system of food supplement vigilance. They act as an effective tool for food business operators (FBOs) to increase the safety of their products by assisting them in establishing and implementing efficient internal vigilance systems for processing reports logically and comprehensively. On February 29, 2024, the EHPM released its nutrivigilance guidelines for food supplement firms to manage adverse event reports [32]. The EHPM thinks that FBOs should develop a post-market surveillance strategy when launching goods in the EU. FBOs are required to gather any adverse events (AEs) which are reported by healthcare professionals, competent authorities and consumers related to use of their FSs alone or in conjugation with other products. It should be possible for consumers to contact the FBOs mentioned on the product label by phone, email, or the postal address provided on the label or leaflet, if relevant. Adverse event reports may be obtained directly from consumers, indirectly from their representatives, such as family, healthcare providers, legal representatives, friends, etc., or other sources like wholesalers, contract manufacturers, government agencies, distributors, retailers, etc. In all circumstances, fill out the AERs (Adverse Events Reports) Questionnaire (Annex I). Such AERs must be carefully examined by the Accountable Person (AP) assigned by the FBO. The FBO shall maintain a Central Records system for all received AERs. This might include specialized software, an electronic database system like Excel, or a paper file system [33].

Japan

In Japan, there is no legal definition for “dietary supplement,” and certain dairy or soybean products are sometimes classified as dietary supplements even though they are common foods. As a result, the interpretation of “dietary supplement” varies from person to person [34]. The Ministry of Health, Labor and Welfare (MHLW) divides foods into two groups: food with health claims (FHC) and general foods. Dietary supplements fall within the latter category, which is overseen by the Consumer Affairs Agency [35].

To allow label information about a food's impact on the human body, the Ministry of Health and Welfare established the Foods for Specified Health Use (FOSHU) program in 1991. Foods for Specified Health use were created under the Nutrition Improvement Law as a subset of "food for specified caloric use." Medical foods, milk powder for pregnant and nursing mothers, baby formula milk powder, and food for elderly people who have trouble chewing or swallowing are examples of foods for special dietary uses. FOSHU approval requires three key elements: analytical determination of the effective component, safety for consumption, and scientific proof of efficacy [36]. Originally passed as the Nutrition Improvement Law, FOSHU is now known as the Health Promotion Law [37].

In 2001, the Ministry of Health and Welfare unveiled the FHC regulation framework. FOSHU and foods with nutritional function claims (FNFC) are the two categories of foods with health claims. FNFC is the standard for two minerals (iron and calcium) and twelve vitamins i.e., vitamin B1, A, B6, B2, C, B12, D, E, Biotin, Pantothenic acid, Niacin, and Folic acid [36]. Furthermore, the FFC system was created in 2015 as a result of the Food Labeling Act. New health-related functional compounds that do not qualify for approval under the FOSHU category are included in the FFC group. Examples of compounds that aid memory include ceryl thyrosin obtained from soybeans, docosahexaenoic acid, eicosapentaenoic acid, and flavonoid glycosides found in ginkgo leaves [38,39].

FOSHU products require premarket approval based on scientific data, whereas FFC products must meet specific requirements for health claims but face less stringent premarket scrutiny [40]. Post-market surveillance is conducted by both local governments and Ministry of Health, Labor, and Welfare (MHLW). Companies are responsible for monitoring safety and reporting adverse events. Japan’s regulatory framework is considered effective, but challenges include maintaining rigorous standards for FFC products and addressing evolving consumer demands [41].

In Japan, more than half of the adult population uses dietary supplements. These products have been linked to adverse occurrences as their use has grown. There are three basic ways to report adverse occurrences related to dietary supplements: a) Manufacturers or retail establishments, b) PIO-NET system, c) Local government public health clinics [42].

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Consumers notify retailers or manufacturers about their negative experiences with DS. Manufacturers are exempt from reporting undesirable events related to DS usage to MHLW. Each manufacturer, therefore, handles the majority of concerns. Customers can also report negative incidents related to DS to the Practical Living Information Online Network System (PIO-NET), the operating system of Japan's National Consumer Affairs Center [34].

The PIO-NET (National Consumer Affairs Information Network System) system gathers consumer complaints and consultation data (also known as consumer affairs consultation data) about consumer life that consumers submit to consumer affairs centers. It does this by connecting the National Consumer Affairs Center of Japan to consumer affairs centers throughout the nation through a network. Since fiscal 2008, almost 900,000 instances have been reported yearly. The total number of consumer affairs inquiries collected by PIO-NET in fiscal year 2023 was 890,000, which is around 9,000 fewer than the 899,000 in fiscal year 2022. The largest age group is still those over 70, making up 24.2% of the total. The National Consumer Affairs Center of Japan (NCAC) has not yet published the summary of consumer affairs inquiries collected through PIO-NET (Practical Living Information Online Network System) for fiscal year 2024 (April 2024 to March 2025). Typically, such summaries will be released in August of the following fiscal year. For instance, the FY2023 summary was published in August 2024 [43].

Additionally, doctors, pharmacists, or consumers report severe adverse events associated with the use of nutritional supplements to public health institutions. These centers then forward the information to the MHLW. Though MHLW receives only twenty adverse event reports every year. Because of this, the Japanese government is unable to respond to negative incidents linked to the use of DS. It is still unknown why there were so few adverse effects reported to the MHLW. It is vital that patients, as well as physicians and pharmacists, insistently report of adverse effects associated with DS to public health organizations [34].

China

In China, dietary supplements are regulated as health foods under the Chinese Food Safety Law. The Chinese Food Safety Law 33 went into force in 2015. More transparency in the laws governing the production and distribution of dietary supplements was required before the new Chinese Food Safety Law in 2015 [44].

Following this, the China Food and Drug Administration (CFDA) made changes to its regulatory framework that addressed labeling, the creation of a catalog of health function claims, a catalog of ingredients for health foods, and the processes for registration and notification. The Chinese government is increasingly putting more emphasis on product safety and scientific evidence of efficacy, as seen by the requirement that all nutritional supplements obtain a Health Food Approval Certificate from the CFDA to be sold legally in China [35].

Chinese manufacturers are permitted to sell health foods that make therapeutic claims from a list of predetermined therapeutic claims. Consequently, before approval of these products, they must verify that they meet the standards of a rigorous testing and premarket clearance process, including toxicity testing [45]. According to the 2015 law, some supplements (vitamins and minerals) can avoid the China Food and Drug Administration's (CFDA) registration procedure by using a notification-based approach. The law allows the CFDA to regulate supplement ingredients and final products by implementing function and ingredient catalogs. Additionally, new regulations encourage producers to submit more thorough R&D reports, with an emphasis on product safety and scientific proof of efficacy. The blue hat system, which is named after the emblem found on authorized items, still applies to supplements other than vitamins and minerals. It requires businesses to conduct time-consuming and expensive review procedures for every final product [44].

China mandates all imported health supplements be approved by its State Administration for Market Regulation (SAMR) before being sold in the country. Once registered, products will be labelled with a 'blue hat' label, showing they can be sold as a health supplement legally. 'Blue hat' is also a government endorsement of the product quality [46].

The National Medical Products Administration (NMPA) is the regulatory authority for dietary supplements in China. Dietary supplements must be approved by the NMPA, which involves reviewing their safety, efficacy, and quality. Recent reforms have aimed to streamline the approval process and improve regulatory oversight [47]. Post-market surveillance includes adverse event reporting and market inspections. The NMPA has the authority to enforce recalls and regulatory actions based on safety findings. The rapid expansion of the dietary supplement market in China presents challenges related to maintaining regulatory oversight and ensuring product quality and safety [48].

Status of Nutrivigilance in India

The main regulatory agency in charge of food safety in India is the Food Safety and Standards Authority of India (FSSAI). The Food Safety and Standards Act (FSS Act) of 2006 regulates dietary supplements and other foods. The legislation empowers FSSAI to establish food safety standards and ensure compliance through various regulations. In India, dietary supplements are governed by the Food Safety and Standards Regulations, 2016. These regulations define product categories, labeling requirements, and permissible health claims. Before being introduced to the market, the usage of dietary supplements must be approved by the FSSAI. Nutrivigilance is a relatively new idea in India, in contrast to pharmacovigilance, which is used to record adverse effects of medicines. India created a specific pharmacovigilance program that enforced monitoring of adverse medication reactions. There are currently no formal Indian rules for dietary monitoring, including post-market surveillance programs for dietary supplements [27].

One of the Pharmacovigilance Programme of India (PvPI) participating centers for monitoring the safety of nutraceuticals is the Indian Council of Medical Research-National Institute of Nutrition (ICMR-NIN), Hyderabad; however, because of a lack of awareness among many stakeholders, they are not getting

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enough adverse drug reactions (ADRs). "To ensure patient safety, it is crucial to cultivate a culture of reporting adverse events related to the use of dietary supplements/nutraceuticals, as PvPI currently receives a very small number of adverse drug reactions (ADRs) related to their use." In light of this, PvPI encourages all parties involved, including physicians, pharmacists, nurses, and other allied health professionals, as well as the general public, to report any negative side effects related to dietary supplements and nutraceuticals [49, 50].

Robust nutrivigilance depends on the cooperation and information exchange among stakeholders like regulatory authorities, manufacturers, healthcare professionals and patients. The rapid dissemination of safety information and transparent communication about nutraceuticals related risks play a crucial role in ensuring patient protection and promoting public health [51]. An insufficient regulatory framework poses challenges to the effective surveillance and assessment the safety of dietary supplements. Recognizing exact ingredients in dietary supplements can be challenging, as they often comprise multiple compounds, and products with similar names may have differing ingredient profiles [52]. Unlike pharmaceutical drugs, most nutraceutical products are not evaluated through randomized controlled clinical trials [53]. Consequently, the development of a comprehensive and reliable nutrivigilance system in India is imperative (Table 3).

Table 3. Comparative analysis of adverse event reporting systems in India, the US, the EU, Japan, and China.

Feature	India	U.S.	EU	Japan	China
Primary Law/Regulation	FSS Act, 2006	DSHEA,1994	General Food Law,	Health Promotion Act	Chinese Food Safety Law
			Food supplements directive 2002/46/EC	Food Labeling Act	
Regulatory Authority	FSSAI	USFDA	EC	Ministry of Health, Labour and Welfare	CFDA
			EFSA	Consumer Affair Agency	NMPA
			National Authorities		SAMR
			In France (ANSES) for French nutrivigilance system		
Adverse event reporting system	Suspected ADR Reporting Form for healthcare professionals	CAERS	RASFF	PIO-NET	China Adverse Drug Reaction Monitoring System
	Medicines Side-effect Reporting Form for consumers	FAERS	Some member states have their own nutrivigilance system	Public health centres	
	Toll-Free Helpline No.1800-180-3024	MedWatch		Manufacturer	
	Through dedicated email (pvpi.ipc@gov.in)	Safety Reporting Portal		Or retailer stores	
Who can report	Pharmacist, Nurses, Physicians, Consumers	Consumers, Healthcare professionals and government agencies	consumers, healthcare experts, and/or competent authorities	Industry, Physicians, Pharmacists, Consumers etc.	Consumers Healthcare professionals and Manufactures

The Indian Council of Medical Research–National Institute of Nutrition (ICMR-NIN) released the updated Dietary Guidelines for Indians, 2024, offering science-backed recommendations to promote balanced nutrition and prevent diet-related diseases across all age groups. The guidelines highlight the significance of including a wide range of foods from all major food groups in the daily diet. Beyond dietary advice, they also cover key aspects such as regular physical activity, adequate water intake, healthy weight control, safe food practices, and interpreting food labels. As per Dietary Guidelines for Indians, 2024, given by ICMR-NIN, the estimated average protein requirement is 0.66 grams per kilogram of body weight per day, while the recommended dietary allowance (RDA) is 0.83 grams protein/ kilogram/day for healthy adult men and women [54].

Gaps in the Current Nutrivigilance Scenario for Dietary Supplements and Nutraceuticals in India

The regulatory framework for dietary supplements/ nutraceuticals in India faces several significant challenges that

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hinder effective nutrivigilance. At the core of these challenges is the lack of a comprehensive, dedicated regulation specifically tailored for these products. Instead, the oversight is fragmented across multiple regulatory bodies, including the Ministry of AYUSH, DCGI and FSSAI. This overlapping jurisdiction creates confusion and inconsistencies in how products are classified, regulated, and monitored. Many products fall into a gray area, straddling the definitions of food, drugs, and traditional medicines, making it difficult to apply appropriate safety standards and monitoring protocols.

Furthermore, the existing regulations suffer from inadequate enforcement due to limited resources and the vast, diverse market in India. This is compounded by the challenge of harmonizing Indian standards with international regulations, which is crucial in an increasingly global market. The ambiguity in product classification often leads to inconsistent quality control measures and safety assessments. For instance, a product might be regulated as a food supplement under FSSAI guidelines, but contain ingredients that would typically fall under AYUSH or drug regulations. This regulatory overlap not only creates confusion for manufacturers and consumers but also leaves gaps in safety monitoring and adverse event reporting. Additionally, the widespread growth of the nutraceutical/dietary supplement market in India has outpaced regulatory adaptations, leading to scenarios where novel products or formulations enter the market without adequate safety evaluations. These regulatory framework challenges collectively undermine the effectiveness of nutrivigilance efforts in India, potentially compromising consumer safety and hindering the growth of a responsible, well-regulated industry.

Insufficient post-market surveillance represents a critical gap in India's nutrivigilance system for dietary supplements and nutraceuticals. The cornerstone of this issue is the absence of a robust, centralized adverse event reporting system specifically designed for these products. This deficiency is exacerbated by a general lack of attentiveness among healthcare professionals about the importance of reporting adverse events related to supplements and nutraceuticals. Consequently, there is significant underreporting of side effects by both healthcare providers and consumers, leading to an incomplete picture of product safety profiles.

Quality control and standardization issues pose significant challenges in the Indian dietary supplement/nutraceutical market, undermining consumer safety and product efficacy. A primary concern is the inconsistent implementation of Good Manufacturing Practices (GMP) across the industry, leading to variability in product quality and safety. This is compounded by inadequate testing facilities, particularly for complex botanical products that are common in traditional Indian medicine. The prevalence of adulteration and contamination in the market further exacerbates these issues, with some products containing undeclared ingredients, heavy metals, or microbial contaminants.

There is a widespread lack of general public attentiveness about the problems connected with dietary supplements/nutraceuticals in India. Many consumers hold misconceptions about the safety and efficacy of "natural" products, often assuming they are inherently harmless. Product labeling often lacks adequate warning information or is not presented in a way that's easily understandable to the average consumer. Many consumers are unaware of the importance of consulting healthcare providers before starting any supplement regimen. There's a general lack of knowledge about proper dosage, timing, and duration of supplement use among consumers.

Moreover, there are challenges with novel ingredients and formulations as they are introduced without adequate safety data. There is a limited understanding of the impact of novel drug delivery systems in the Indian context. There is a lack of established protocols for evaluating synergistic effects in multi-ingredient products.

Need of nutrivigilance

Dietary supplements (DS), which are intended to enhance quality of life, can cause adverse effects. These may arise from improper use, the inherent characteristics of the active ingredients, interactions between drugs and supplements, or from contamination and adulteration [55]. For example, prolonged intake of protein powders or high-risk concentrates may cause potential health risks such as bone mineral loss and kidney damage. Interaction between Vitamin D3 and calcium phosphate may lead to symptoms like constipation, bloating, a metallic taste in the mouth, increased thirst, tiredness, weakness, loss of appetite, and muscle pain [54]. Moreover, when these supplements are taken alongside antibiotics such as quinolones and tetracycline, they can reduce the effectiveness of the antibiotics by decreasing their absorption [56]. Recent analysis of whey protein powders in India has shown that many whey protein powders are contaminated with heavy metals and inaccurately labeled in terms of protein content. Findings from the Citizens Protein Project indicated that a significant number of protein supplements failed to deliver the advertised protein amounts, while some surpassed the declared values, suggesting possible "protein/amino-spiking." The study also identified traces of mycotoxins, pesticide residues, and hazardous heavy metals like lead and arsenic in several brands. Soy products are naturally susceptible to mycotoxin contamination, while multi-herbal supplements are often associated with the presence of fungal toxins. Consumers need to be informed about the sources of protein they consume, particularly plant-based proteins like beans, which may naturally carry mycotoxins that can adversely affect health. The widespread presence of arsenic and lead in the protein products examined in the study is deeply concerning. Exposure to even low amounts of these heavy metals can significantly harm human health, leading to increased risks of cancer, blood abnormalities, digestive system issues, impaired brain function and development, and damage to the kidneys and liver. The World Health Organization emphasizes that no amount of lead exposure is considered safe [57]. Like the United States Food and Drug Administration (FDA), the Food Safety and Standards Authority of India (FSSAI) does not approve health and dietary supplements (HDS) but oversees and enforces good manufacturing practices for these products. To ensure the proper use of dietary supplements and nutraceuticals, stringent guidelines and regulations should be established concerning their active ingredients, authenticity, purity, labelling, health

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claims and bioavailability. FSSAI need to enforce nutrivigilance regulations for dietary supplements, just as pharmacovigilance rules are set for medicines and medical devices. The purpose of nutrivigilance is to set up surveillance mechanisms to identify and track adverse reactions caused by nutraceuticals, protecting consumer health.

Approaches to Improve Nutrivigilance in India

Enhancing nutrivigilance in India requires a comprehensive and multifaceted approach. By strengthening regulations, raising awareness, improving reporting systems, fostering research, engaging stakeholders, integrating technology, updating policies, and collaborating internationally, India can build a robust nutrivigilance system. These efforts will ensure better food safety and public health outcomes, protecting consumers from adverse effects related to food and dietary supplements. Drawing inspiration from the EU's comprehensive food safety regulations under RASFF, India should develop detailed guidelines for reporting adverse food reactions. This includes defining what constitutes an adverse reaction, outlining the responsibilities of food businesses and healthcare professionals, and specifying the reporting process. Regular interagency meetings and a shared database can facilitate better communication and data sharing. Research by Madsen et al. (2012) emphasized the importance of interagency coordination in managing food allergens [58].

To educate the public on the importance of reporting adverse reactions, nationwide campaigns through television, radio, print media, and social media can be launched. Studies have shown that public awareness campaigns can significantly improve reporting rates and public safety. As communication technologies rapidly evolve and audiences migrate to newer platforms, Food safety risk communication (FSRC) can significantly improve its outreach by creating specialized communication channels. To bolster FSRC, it is important to consistently enhance the cooperation and coordination between risk assessors and risk managers [59]. Online platforms and mobile apps can be developed and promoted that allow consumers and healthcare professionals to report adverse reactions easily. Consumers can submit reports of adverse drug reactions (ADRs) via phone, website, by email, or through a paper-based form. These platforms should be multilingual and accessible to people with disabilities. Research by Dedefo et al., found that consumers prefer digital methods for reporting ADRs and place extremely value on features like free-text fields for tracing ADRs, confirmation of report submission, and access to summaries of their earlier reports [60]. A centralized database should be created and maintained to collect and analyze reports of adverse food reactions. Research by Wirtz et al., emphasized the role of centralized databases in improving the monitoring and management of adverse drug reactions [61]. Food manufacturers, processors, and retailers should be encouraged to ensure that they understand and comply with nutrivigilance requirements. Guidelines and resources should be provided to help them establish internal monitoring and reporting systems. European Union's RASFF and FDA Adverse Event Reporting System (CAERS) for food safety should be adopted. International collaboration has been shown to enhance the effectiveness of nutrivigilance systems. Research by Kim et al., highlights the benefits of adopting global best practices in improving national food safety systems [62]. A feedback loop should be established where insights from the field inform policy and practice adjustments, similar to continuous improvement practices in Australia. Research supports the importance of continuous monitoring and feedback for effective nutrivigilance. Promoting research and innovation to develop advanced techniques for food testing, safety assessment, and risk analysis can significantly strengthen the performance and efficiency of nutrivigilance systems [63]. Public feedback has been shown to improve the effectiveness and acceptance of nutrivigilance systems. Research by Lee et al., highlights the role of public feedback in enhancing the responsiveness and effectiveness of public health policies [64].

Conclusions

In the context of dietary supplements and nutraceuticals, nutrivigilance has become a crucial paradigm for protecting public health. Diverse regulatory methods and procedures are evident when looking at nutrivigilance from an international perspective. Through the application of systematic and methodical techniques, nutrivigilance ensures a strict framework for the identification, assessment, comprehension, and avoidance of harmful effects connected with food items. Subsequent endeavors ought to concentrate on profoundly incorporating nutrivigilance methodologies into regulatory structures, promoting industry involvement, and capitalizing on technological progressions to enhance the efficacy of data gathering and examination. India can ensure improved food safety and public health by enhancing its nutrivigilance framework through some of the suggested measures.

Declaration of Interests

All authors declare no competing interests.

Author Contributions

Ritu Dhankhar: Extensive literatures search and preparing the original manuscript. Sonia Parashar: Investigation and validation at supporting degree. Sanju Dahiya: Guiding of the writing and data proof reading. Munish Garg: Perceived the manuscript's idea, guiding the writing and project administration.

Disclosure statement

No potential conflict of interest was reported by the authors.

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