Pharmacovigilance in Nutraceuticals and Dietary Supplements

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Abstract: The concept of "Nutrivigilance," a synthesis of "nutrition" and "pharmaceutical," emphasizes the need for monitoring adverse drug reactions (ADRs) in nutraceuticals and dietary supplements. Defined by Dr. Stephen De Felice, Nutrivigilance involves systematic tracking, evaluation, and prevention of adverse effects, including interactions and safety concerns stemming from varying quality and regulatory oversight in nutraceutical products. With rising consumer reliance on these products, effective monitoring and reporting systems are critical to public health. Nutraceuticals, offering vital nutrients and therapeutic benefits, play a significant role in preventing or managing health conditions like obesity, diabetes, and heart diseases. The regulatory landscape varies globally, with structured systems in place for dietary supplements in the U. S. under the DSHEA and in the EU through various safety regulations. However, challenges remain, particularly in countries like India, where Nutrivigilance is still developing, lacking comprehensive post-market surveillance. The Pharmaco-vigilance Programme of India is in place to enhance drug safety monitoring, but further measures are needed to establish robust systems for nutraceuticals. The overall goal of these initiatives is to ensure public safety and confidence in the efficacy of nutraceutical products while facilitating research into their benefits and potential hazards.

Key Words: Nutrivigilance, Nutraceuticals, ADRs, Safety, Surveillance, Regulation, Interactions, Quality, Public health.

I. INTRODUCTION

The term “Nutrivigilance” by combining the terms “Nutrition” and “Pharmaceutical” in 1989 by Chairman of the foundation for innovation in medicine, Dr. Stephen De Felice.[1]. The tasks associated with gathering, identifying, evaluating, tracking, and preventing adverse drug reactions (ADR) are referred to as "pharmacovigilance." An unpleasant and unexpected reaction to a medication, including ineffectiveness, is referred to as an adverse drug reaction. The Pharmakon, which means “Drug” in Greek, and Vigilare, which means “Keep an eye on/monitor” in Latin, are the roots of the phrase “Pharmacovigilance”. This kind of “Vigilance” has recently expanded to cover the safety of Nutraceuticals, cosmetics and herbal goods [2]. Nutrivigilance involves monitoring the safety of nutraceuticals and dietary supplement. Essential elements like carbs, proteins, fats, vitamins and minerals are found in nutraceuticals, which include dietary supplements, herbal products, probiotics and prebiotic. Pharmacovigilance in nutraceuticals helps detect adverse reactions, interactions with medicines and safety issues arising from variable quality and lack of standard regulation. With increasing consumer use, effective monitoring and reporting systems are necessary to protect public health and ensure product reliability. Hippocrates, some 2000 years ago, properly stated, “Let food be your medicine, and medicine be your food.” The recognition that “nutraceuticals” play a vital role in health enhancement has sparked a surge in global interest.[3]

II. NUTRIVIGILANCE IN NUTRACEUTICAL

“The discovery, assessment, understanding and prevention of adverse goods of nutraceuticals or any other possible functional food, and salutary affiliated problems” is the definition of Nutrivigilance. According to WHO guidelines, this description clearly covers the goals of the Pharmacovigilance in modern medicine and its supplements, as well as the AYUSH program and its content area [4]. A meal with therapeutic benefits for human health is called a “nutraceutical". Stephen De Felice first used the term "nutraceutical" in 1979. It is defined as “A food or

food components that offer health or medical benefits, such as illness prevention and treatment." [5]. Nutritional therapy uses nutraceuticals as complementary treatment, where food acts as both nutrition and medicine to support detoxification and digestion. Nutraceuticals are now acknowledged to offer health benefits due to mounting scientific evidence containing diet to lifestyle disease. Conditions like cancer, heart disease, hypertension, diabetes, obesity, osteoporosis and various age-related, digestive can be prevented or managed with their help [6-12].

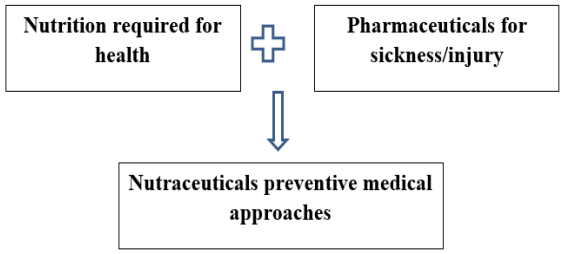

Fig No. 01: Concept of Nutraceuticals

The concept of nutraceuticals has started to be acknowledged as one of the approaches for preventing such disorders.

III. CONCEPT OF DIETARY SUPPLEMENTS

Products that are consumed in addition to a regular diet to supply extra nutrients that promotes health are known as dietary supplements. The dietary supplement Health and Education Act (DSHEA) of 1994 defines and regulates dietary supplements in the United States. A dietary supplement is defined by the DSHEA as a product that is meant to be consumed as a pill, capsule, tablet or liquid contains dietary ingredients like vitamins, minerals, amino acids, herbs and botanicals and is labeled as such. Dietary supplements are governed by the Food and Drug Administration (FDA) in a very different manner than conventional medications. The intake of dietary supplements is generally safe, but not totally without risk. Dietary supplements can be brought to the market without the support of clinical trials; there is a paucity of systematic studies of adverse effect [13].

Classification of Nutraceuticals [14]

1. Traditional
- Chemical constituents Nutrients, Herbals, Phytochemicals.
- Probiotic organisms
- Nutraceutical enzyme

2. Non Traditional
- Fortified nutraceuticals
- Recombinant nutraceuticals

3. Substance with established nutritional function
- Vitamins, Minerals, Amino acids, Fatty acids

4. Herbs or Botanical products

5. Reagents derived from other sources
- Pyruvate, Chondroitin sulphate, Steroid hormone precursors

6. Functional foods

7. Probiotics and Prebiotics
8. Polyunsaturated fatty acids

9. Antioxidant vitamin

10. Polyphenols

11. Spices

Need of Nutrivigilance:
- Due to contamination, interaction or misuse, dietary supplements can have negative effects.
- Long-term use of protein supplements can damage the kidneys and bones.
- Interactions between calcium and vitamin D3 can lead to muscular and gastrointestinal problems.
- Antibiotic efficacy and absorption may be decreased by supplements.
- In India, a lot of protein supplements have false labels and are tainted.
- No amount of lead is safe and heavy metals like lead and arsenic present major health risks.
- FSSAI does not approve dietary supplements, but it does regulate manufacturing practices.
- Teaches consumers and medical professionals about safe usage and potential hazards.

IV. ROLE OF NUTRACEUTICALS

- Increased trust in the efficacy and quality of the product.
- The market for nutraceutical products has improved.
- A greater level of public awareness.
- A greater understanding of the healthcare sector.
- The creation of a self-governing agenda boosts the diets health value.
- Contribute to a longer life.
- Benefit psychologically from taking care of oneself.
- Special foods for people with special needs.
- Aid in preventing specific medical conditions.

Global Perspectives on Nutrivigilance:
The increasing use of nutraceuticals and dietary supplements emphasizes the need for efficient nutrivigilance, with regional and regulatory variations.

United States:
Dietary supplements are governed by the USFDA under the DSHEA of 1994. Pre-market approval is not necessary for dietary supplements; manufactures are in charge of product safety and accurate labelling. Under section 522 of the FD and C Act, the FDA promoted post-market surveillance and adverse event reporting in 2022 [15]. There are numerous databases available to find negative effects related to dietary supplements, including herbal products. FDA spontaneous report databases include the CFSAN Adverse Event Reporting System (CAERS) and the FDA Adverse Event Reporting System (FAERS) [16]. Over 1,000 Garcinia cambogia-related adverse events, including gastrointestinal symptoms, liver damage and kidney problems, were reported to CAERS between 2004 and 2021. Additionally, Joy Luck Brand Lily Flowers were recalled by U.S. [17]. Trading Company on March 3, 2025, because of unreported sulfites, which can cause severe allergic responses in sensitive people [18].

European Union (EU):
The General Food Law Regulation (Reg. (EC) 178/2002) serves as the foundation for all EU food safety regulations. The Food Supplement Directive (Directive 2002/46/EC) governs the EU food supplement industry [19]. Although EFSA and the European Commission oversee the EU's centralized food safety system, post-market surveillance of food supplements is not required throughout the EU. General food safety reporting is supported by systems such as EREN and RASFF [20]. National nutrivigilance systems have been established in a few nations, most notably France. Founded in 2009, France's ANSES-led system gathers voluntary adverse-event reports and has demonstrated an increasing trend in serious cases [21]. The EHPM released nutrivigilance guidelines in 2024 in response to growing safety concerns. These guidelines encourage food business operators to use post-market surveillance and gather adverse-event data in order to enhance consumer safety [22].

Table No. 01: Some of the EU countries and their Nutrivigilance systems.

EU Country	Established year	Nutrivigilance System	Responsible Authority	Current Status
France	2009	National Pharmacovigilance network co-ordinated with EU system	ANSM-Agence Nationale de Sécurité du Médicament et des Produits de Santé	EU EudraVigilance and active monitoring of a national photovoltaic system with regional centers.
Italy	2012	National Pharmacovigilance Network	AIFA-Agenzia Italiana del Farmaco	Active national PV network with EU-wide reporting and designated regional centers.
Denmark	2013	Danish pharmacovigilance within EU framework	Danish Medicines Agency (DKMA)	The Danish medicines agency has a fully operational PV system with an advisory council and EudraVigilance integration.

Portugal	2014	Portuguese PV system as per EU regulations	INFARMED- National Authority of Medicines and Health Products	Active national pharmacovigilance body for EU is reporting and safety monitoring.
Czech Republic	2015	Czech national PV system aligned with EU requirements	State Institute for Drug Control (SUKL)	Fully functional national PV authority for EU reporting, safety evaluation and ADR collection.
Slovenia	2016	Slovenian PV system within EU context	JAZMP-Agency for Medicinal products and Medical Devices of the Republic of Slovenia	PV operations that are currently underway with EU network reporting (JAZMP).
Croatia	2020	Croatian PV system integrated with EU PV	HALMED- Agency for Medicinal products and Medical Devices	MAHs are needed to maintain PV systems and contacts; national PV systems are operating with EU reporting.

Japan:

There is no official legal definition for dietary supplements, Japan's framework for functional foods and dietary supplements, which has been gradually developed since the FOSHU was introduced in 1991, is both structurally complex and scientifically sound [23]. FOSHU and Foods with Nutritional Function Claims (FNFC) were incorporated into the Food with Health Claims (FHC) system in 2001, which improved consumer protection and regulatory oversight. Though there was less premarket scrutiny, the introduction of the more adaptable Foods with Function Claims (FFC) system in 2015 signaled a change toward innovation and quicker market access [24]. This shift has led to a greater reliance on post-market surveillance systems, especially PIO-NET, which since FY2008 has gathered almost 900,000 consumer inquiries per year. The high percentage of complaints from senior citizens, as seen in FY2022 and FY2023, emphasizes persistent issues with communication and safety. Overall, even though Japan's system has changed dramatically over time, public health protection in the context of an aging population and growing functional food market requires ongoing strengthening of adverse event reporting, transparency, and Consumer education. In japan, more than half of the adult population uses dietary supplements. These products have been linked to adverse occurrence as their use has grown [25]. There are three basic ways to report adverse occurrences related to dietary supplements; a) Manufactures or retail establishments b) PIO-NET system c) Local government public health clinics [26].

India:

The Food Safety and Standards Authority of India (FSSAI) is the primary regulatory body in charge of food safety in India. Dietary supplements and other food products are governed by the Food Safety and Standards Act (FSS Act), 2006, which also gives the FSSAI the authority to set food safety supplements and other food products are governed by the Food Safety and Standards Act (FSS Act), 2006, which also gives the FSSAI the authority to set food safety standards and guarantee compliance through a number of regulations. The Food Safety and Standards Regulations, 2016, which specify product categories, labelling specifications, and acceptable health claims, regulate dietary supplements in India. The FSSAI must approve the use of dietary supplements before they are introduced to the market. Compared to introduced to the market. Compared to pharmacovigilance, which is well-established for tracking medication side effects through a specific national pharmacovigilance program, nutrivigilance is a relatively new idea in India. However, there are currently no official laws in India that deal with dietary monitoring in particular, including organized post-market surveillance programs for dietary supplements [27].

V. PHARMACOVIGILANCE PROGRAMME OF INDIA

The Ministry of Health and Family Welfare (MoHFW), Government of India, launched the Pharmacovigilance Programme of India (PVPI) in July 2010 with the goal of lowering the risks related to medication use among Indians. In December 1961, W. McBride, an Australian physician who initially suspected a connection between thalidomide, a medication used during pregnancy, and severe fetal deformities (phocomelia), published a letter (case report) in the Lancet, officially introducing pharmacovigilance (PV): Pregnant women were given thalidomide as a sedative and antiemetic. In order to centralize global data on adverse drug reactions (ADRs), the World Health Organization (WHO) launched the "Programme for International Drug Monitoring" in 1968. In order to identify safety risks and stop patient harm, pharmacovigilance (PV) entails tracking and assessing the side effects of medications and related products. Pharmaceutical companies must actively manage drug safety throughout the whole product lifecycle, from development to post-marketing use, due to growing complexity of healthcare [28].

Vision: To monitor medication safety and lower the risk associated with its use in order to improve patient safety and the welfare of the Indian population.

Mission: To safeguard the health of Indian population by ensuring that the benefits of use of medicine outweigh the risks associated with its use.

VI. SCOPE AND OBJECTIVES

- To create a nation-wide system for medicines safety reporting and monitoring.
- To find and examine fresh signals from the cases that have been reported.
- To support the National drug regulators in the decision-making process on use of medicine.
- To generate evidence-based information on safety of medicine.
- To promote quality and safe use of medicines.
- To emerge as a centre of excellence for pharmacovigilance.

Nutraceuticals safety through Pharmacovigilance Programme of India:

The World Health Organization's (WHO) definition of an adverse drug reaction (ADR) as "An unpleasant and unwanted reaction that happens at doses typically used in humans for disease prevention, diagnosis, or treatment, or for altering physiological function"[29]

Who can Report?

ADRs can be reported by non-healthcare professionals, such as patients or consumers, as well as by all healthcare professionals, including clinicians, dentists, pharmacists, and nurses. The ADRs report for their products can also be sent to NCC by pharmaceutical companies.

What to Report?

- Regardless of causality, all suspected ADRs known or unknown, serious or non-serious, common or uncommon must be reported.
- Included are adverse drug reactions associated with medications, vaccines, herbal products, medical devices, contrast media and diagnostics.
- It is possible to report problems with pharmaceutical quality and ineffectiveness.

Whom to Report?

The required forms found on the IPC and CDSCO websites can be used to report ADRs. Forms can be sent to NCC, the closest AMC, or via email at pvpi@ipcindia.net or pvpi.ipcindia@gmail.com. They are available in ten vernacular languages (Hindi, Tamil, Telugu, Kannada, Bengali, Gujarati, Assamese, Marathi, Oriya and Malayalam.)

Why to Report?

- To guarantee patients safety when taking medications.
- To assist regulatory bodies in making crucial policy choices pertaining to the safe use of medications.

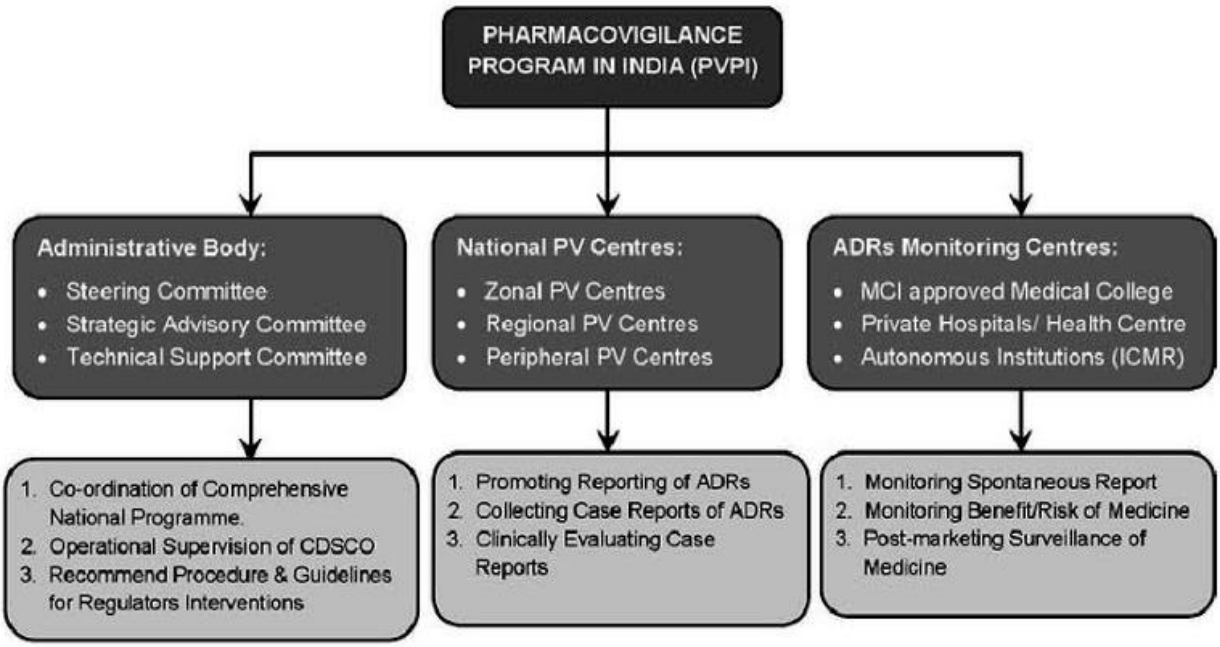

Fig No. 02: Pharmacovigilance program in India and responsibilities

Pharmacovigilance Program Timeline

Traditional drugs the World Health Organization is accredited by its member states "To develop, establish, and promote transnational norms with respect to food, natural, pharmaceutical and analogous products," as stated in composition-2 of its constitution. Additionally, regulations pertaining to "norms with respect to the safety, chastity and energy of natural, pharmaceutical and analogous products moving in transnational commerce" may be borrowed under article 21. The 1961 Thalidomide tragedy served as the impetus foe WHO to launch a program that would fully cover all designated medications. Resolution WHA1636 of the sixteenth World Health Assembly in 1963 highlighted the necessity of quickly disseminating information about ADRs [30].

1980: The start of adverse drug reaction (ADR) monitoring in India, which was overseen by the ADR monitoring centers of the Indian council of medical research (ICMR).

1986: The establishment of a formal ADR monitoring system with 12 regional centers, each serves a population of roughly 50 million.

India signed international agreements on pharmacovigilance and drug safety in 1997 and 2002. These agreements served as the foundation for a national program that complied with international standards [31].

2002: India committed to reporting all adverse drug reaction associated with conventional medications to the WHO ADR monitoring center in Uppsala, Sweden. Reports entered into the global database using MedDRA and WHO-ART terminology [32].

2004: The Central Drugs Standard Control Organization (CDSCO) established a nationwide network of pharmacovigilance centers.

From 2004 onward patients are required to report adverse drug reactions. Periodic Safety Update reports (PSURs) based on post-marketing surveillance must be submitted by pharmaceutical companies. Gaps in the 2004 system were identified by stakeholders, who felt that restructuring was necessary to address unmet goals.

In April 2010, CSCO reopened the Pharmacovigilance programme of India (PvPI) as the new National Coordination Center in partnership with the Department of Pharmacology, AIIMS and New Delhi. After 2010 over forty medical school have been designated as pharmacovigilance centers. Policy intended to cover all Indian medical colleges. A redesigned system was put in place to guarantee a strong and reliable framework for drug safety monitoring [32, 33].

Approaches to Improve Nutrivigilance India

- Strengthening Regulations: Create precise nutrivigilance guidelines akin to the RASFF system used by the EU.
- Interagency Co-ordination: Make sure that regulators, healthcare system and food authorities regularly coordinate.
- Public Education and Awareness: Run national awareness campaigns via print, radio, television and social media.
- Food Safety Risk Communication (FSRC): Use contemporary platforms to enhance communication between risk assessors and risk managers [34].
- Simple Reporting Systems: Develop multilingual, user-friendly mobile apps and web portals.
- Consumer-Centric Digital Tools: Give users access to previous reports, free-text reporting and submission confirmation.
- Centralized Database: Create a national database for early signal detection and monitoring.
- Industry Engagement: Encourage the food industry to adhere to internal monitoring and nutrivigilance standards.
- Adoption of International Best Practices: Take a cue from the US FDA CAERS and EU RASFF systems.
- International Cooperation: Exchange information and knowledge with international food safety organizations.
- Continuous Feedback Loop: Regularly update policies based on field data and public input.
- Research and Innovation: Encourage risk analysis, safety evaluation and sophisticated food testing.
- Public Feedback Integration: To increase system efficacy and trust, actively incorporate customer feedback [35].

VII. CHALLENGES IN NUTRIVIGILANCE

1. Under-reporting of adverse events: under reporting of negative incidents many adverse reactions linked to foods and supplements go unreported because of ignorance, a fear of being held accountable, or the lack of simple reporting mechanisms.
2. Low awareness: Nutrivigilance programs and the significance of reporting adverse food reactions are frequently unknown to consumers and medical professionals.
3. Weak regulatory framework: Compared to pharmacovigilance regulations, nutrivigilance guidelines are less explicit and less rigorously enforced.
4. Poor surveillance systems: Monitoring, signal detection and risk analysis are challenging in the absence of a robust, centralized database.
5. Difficulty in causality assessment: Due to the numerous ingredients in food and nutraceuticals, it can be challenging to associate a particular ingredient with a negative outcome.
6. Lack of Unified Regulations: Globally, dietary supplements are regulated inconsistently. While the U.S. FDA requires serious adverse event reporting under the Dietary Supplements and Non-prescription Drug Consumer Protection Act (DSNDCPA), other regions have varied or voluntary framework. This results in poor data interoperability and reporting compliance.

VIII. FUTURE PERSPECTIVE OF NUTRIVIGILANCE

It is anticipated that the quick development of functional foods, nutraceuticals and bioactive compounds derived from oilseeds will significantly improve human health, especially in the prevention of chronic inflammatory diseases. However, significant safety concerns about long-term consumption, metabolic interactions and cumulative effects are raised by the growing dietary exposure to complex lipid mixtures, phenolic-rich extracts, and oilseed-derived by products. The scope of nutrivigilance needs to go beyond traditional dietary supplements as oilseeds are increasingly utilized in everyday diets, food additives, pharmaceuticals and industrial applications within a circular economy framework. To guarantee the safe and long-term application of oilseed-based innovations for public health, future nutrivigilance systems should concentrate on systematic safety assessments, post-market surveillance and risk communication.

IX. CONCLUSION

Nutrivigilance is an essential component of public health safety due to the growing use of nutraceuticals and dietary supplements. Although considered safe, these products can cause adverse effects, interactions, and toxicity if improperly used or poorly regulated. Global systems for nutrivigilance exist but vary widely, while in India it remains underdeveloped compared to pharmacovigilance. Strengthening regulations, improving adverse event reporting, increasing awareness, and adopting international best practices are necessary. An effective nutrivigilance system will ensure consumer safety, enhance product quality, and support the sustainable growth of the nutraceutical industry.

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