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## Neutraceuticals and Nutrivigilance-Present Scenario in India

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#### **Abstract**

Neutraceutical, is a food or part of a food that supposedly provide medicinal or health benefits, including the prevention or treatment of the disease by acting on the root cause of the disease or problem. The word "nutraceutical" consolidates two words - "nutrient", which is health-giving, beneficial dietary constituent and "pharmaceutical", which means medicinal remedy. At specific time in the past, traditional Indian homemade food played a pivotal role on immunity, inflammation, brain function and people were healthy. Now, the scenario across the globe has changed and India has also become a part of it. Increasing health awareness, drift in population disease demographics, where younger people are furthermore affected, lifestyle alterations, escalated purchasers opulence and elevated life expectancy are responsible for increasing market for nutraceuticals in India. Wide range of nutraceuticals are targeted right from the birth in the form of formula milk, dietary supplements, protein health drinks to meet one's need. People presume that these supplements are thoroughly safe as they are natural and vended over the counter. The use of processed and prepacked food, lack of standardization and awareness of effective dose and its safety, excessive pricing, marketing and distribution is questionable and controversial. The need, scope, and importance of this article is to give an overview of inappropriate use of nutraceuticals and valiant challenges for government to impose stringent guidelines and regulations over the active ingredients, identity, purity and bioavailability for the rationale use of nutraceuticals and to strengthen nutrivigilance in India.

**Keywords:** Neutraceuticals, Nutrivigilance, Dietary supplements, Functional food, Guidelines, Approaches.

#### Introduction

Nature is the treasure trove of infinite and inexhaustible agglomera tion or cluster of molecular entities. It perches as an enormous capital and resource for the drug development, novel pharmacophore and chemotypes to intensify the evolution of effective and beneficial drugs for several diseases. It has been well documented that natural products had remarkable role in modern drug development. Many natural products and powerful drugs used in modern medicine originated from roots, leaves, flowers or seeds of plants. Since the earliest times, mankind has treasured and gathered these substances to create medicines to treat certain diseases.

Thomas Edison quoted that -"The doctor of the future will no longer treat the human frame with drugs, but rather will cure and prevent disease with nutrition." Linus Pauling said that "Optimum nutrition is the medicine of tomorrow."

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Hippocrates, a Greek physician who is considered as the "Father of Medicine" for his outstanding figures in the history of medicine said "Let food be thy medicine", which explained that the people eating fresh, plant-based diet developed fewer diseases and recognised that, people who are constitutionally obese are more prone to expire early than those who are thin built. His primary form of treatment was usually improving a patient's diet. The relation between food and health is lined with epigenetics, which is the study of changes in organisms caused by modification of gene expression rather than alteration of the genetic code itself. Processed foods which contain sugar, saturated fats, trans fats, and artificial chemicals initiate disease-causing genes, which might be inactive otherwise. Processed food has paucity of healthy nutrients that activate protective genes [1].

Since last few years, food supplements manifested an upsurge throughout the world including India. The ingestion and availability of these food supplements and few special food items like energy drinks, are in persistent progression. The transition in the healthcare system from treatment to prevention encouraged the physicians and patients to think diversely about health and disease, thus launching momentum for nutraceuticals, creating opportunity for pharma and food companies to work together in disease management.

The word "nutraceutical" consolidates two words -"nutrient", which is health-giving, beneficial dietary constituent and "pharmaceutical", which means medicinal remedy. Stephen De Felice, Founder and Chairman of the Foundation for Innovation in Medicine (FIM), located in Cranford, New Jersey, coined the term "nutraceuticals" for the first time in 1989 [2]. Nutraceutical, is a food or part of a food that supposedly provide medicinal or health benefits, including the prevention or treatment of the disease [3]. A nutraceutical may be naturally nutrient-rich or medicinally active food, like soya beans or garlic, or it may be specific component of a food, such as the omega-3 fish oil that can be extracted from salmon and other cold-water fish. The comparison between nutraceuticals and pharmaceuticals is given in table 1 [4].

#### **Categorization of Nutraceuticals**

Nutraceuticals is an extensive appellation or word used to represent the products acquired from food sources that contribute notable well-being in addition to nutrition [5-7].

Nutraceuticals are classified based on the source, chemical construction and pharmacological conditions into following categories:

- 1) Dietary supplements
- 2) Nutrients
- 3) Herbals
- 4) Functional food
- 4) Medical food
- 5) Farmaceuticals

### **Dietary supplements**

The Dietary Supplement Health and Education Act (DSHEA) of 1994 elucidated what constitutes a dietary supplement. There are more than 50,000 dietary supplements available which comprise vitamins, minerals, amino acids, herbs, and enzymes that are dispensed in the form of tablets, capsules, powders, liquids, gel caps, and soft gels. These supplements reassure to furnish essential components involved in the regular activities of our body, and may also ameliorate the risk of disease. Dietary supplement is not the substitute for the healthful diet, must be taken besides complete meals. Unlike drugs, dietary supplements are not authorised to be sold with the intention to treat, diagnose, prevent or cure diseases. Thus, supplements should not make disease claims, such as "cures heart disease" or "reduces high cholesterol". Such claims are legally not accepted for dietary supplements. Many supplements hold active components which show extensive biological effects, thus making them unsafe in few situations and impair health. Dietary supplements perhaps beneficial but can also embrace health risks. The U.S. Food and Drug Administration (FDA) do not have the authority to evaluate dietary supplement products for effectiveness and safety analysis before marketing.

For example, the following deeds could lead to deleterious - even fatal outcome.

- · Taking multiple combinations of supplements
- Combining supplements with medicines (prescribed or over-the-counter drugs)
- · Replacing the supplements with prescribed drugs
- Consuming excess of supplements, such as vitamin A, vitamin D or iron

Table 1: The comparison between nutraceuticals and pharmaceuticals.

Nutraceuticals	Pharmaceuticals
Nutraceuticals are predominantly concerned with prevention and securing well-being.	Pharmaceuticals are primarily focused on ailment, illness and therapy.
Nutraceuticals need no mandatory medical supervision and approval from the Food and Drug Administration (FDA).	Pharmaceuticals need mandatory medical supervision and approval from Food and Drug Administration (FDA).
Nutraceuticals act on the root cause of the disease or problem.	Pharmaceuticals work on manifestations & symptoms in a specific part or entire body.
Nutraceuticals takes prolonged duration to show its results.	Pharmaceuticals mostly provide instantaneous results or in short time.
Nutraceuticals are marketed without any prescription at drug stores, health food stores, supermarkets, online stores, internet, etc.	Prescription is mandatory to dispense Pharmaceuticals from a qualified doctor for marketing (except OTC).
Neutraceuticals have minimal or no side-effects.	Pharmaceuticals mostly have side-effects.

Table 2: Common dietary supplements.

Vitamins
Minerals
Coenzyme Q
Calcium
Fish oil
Vitamin D

To prevent such consequences healthcare provider and pharmacist should be informed about the present medications or supplements being used. The common dietary supplements are mentioned in table 2.

**Nutrients:** Currently, India inclining towards western tradition, taking food which are high in calories, added sugar, sodium (salt), saturated fats, trans fats and low in micronutrients, leading to increasing health issues such as diabetes and heart diseases. Nutrients are the substances that provide nutriment that nurtures one's health. The most commonly known nutrients are antioxidant, water and fat-soluble vitamins. Antioxidants may be useful in prevention of cerebro-vascular diseases and cancer. Agus *et al.*, determined that the oxidized form of vitamin C, dehydroascorbic acid, readily crosses the blood brain barrier [8]. Vitamin E intake may prevent Parkinson's disease. Their potential health benefits have been associated with dietary intake of nutrients.

Herbals: Medicinal herbs contain numerous nutraceuticals as key [9]. Echinacea may be helpful in the treatment or prevention of cold and flu, but the trial data is not quite answerable [10]. Ernst suggested that St John's wort is effective for depression, but potential adverse consequences are seen as it interacts with prescription drugs. Though herbal medicines are complete storehouse of remedies to cure diseases, their safety is questionable, as none of these herbal medicines are free of adverse effects. Eg., Ginkgo, green tea, garlic, ginseng etc.

Functional food: Mankind accredited diet and food has a notable role on health for centuries. Conceptualization of "functional food" evolved in Japan in early 1980s and got established as "Food for Specified Health Use" (FOSHU) in 1991. Functional foods comprise processed or fortified food which ameliorates health and minimize the probability of long-standing and persistent diseases, e.g. cereals, breads, beverages that are fortified with vitamins, vitamin D as a complementary nutrient added to milk. Functional food is defined as "any food or component that has a productive influence on the health, physical performance, or state of mind, in addition to its nutritive value on an individual". Functional foods are formulated to allow buyer to eat enriched foods close to their natural form, rather than by taking dietary supplements manufactured in liquid or capsule-form.

Examples: Oats, bran, psyllium, and lignin's for heart disease and colon cancer, omega-3 milk for prevention of heart disease, canola oil with lowered triglycerides for cholesterol reduction, stanols (Benecol) for reduction of cholesterol adsorption, table salt fortified with iodine.

Medical food: A medical food is defined as a foodformulated to be consumed or administered enterally under supervision of a physician, which is intended for the specific dietary management of a disease or condition, for which distinctive nutritional requirements, based on recognised scientific principles, have been established by medical evaluation. Medical foods do not undergo premarket review or approval by FDA. Medical foods aren't available as an over-the counter product to consumers. Medical foods can be ingested through the mouth or through tube feeding. Eg., Axona (Accera) was developed by Accera (USA) as a medical food to provide the necessary nutrients for patients with Alzheimer's Disease (AD). AD is the leading cause of dementia, a neurodegenerative disease characterized by a decline in the ability of the brain to metabolize glucose, even in its early stages. Limbrel is a medical food developed for the nutritional management of the metabolic processes associated with osteoarthritis.

Examples: Slowly digested carbohydrates for diabetes mellitus, lactoferrin for immune enhancement, transgenic plants for oral vaccination against infectious diseases, health bars with added medications.

**Farmaceuticals:** The term "Farmaceuticals" is a blend of farm and pharmaceutical. They are medically valuable compound produced from modified agricultural crops or animals, usually through biotechnology.

### Examples:

- · Broccoli: in prevention of cancer.
- Lowered risk of cardiovascular disease: alpha-linolenic acid from flax or chia seeds, Omega 3 fatty acids in fish oil.
- Reducing hypercholesterolemia: soluble dietary fiber products, such as psyllium seed husk [11].
- Improved arterial health: soy or clover (isoflavonoids).

### **Increasing use of nutraceuticals in India:**

At specific time in the past, traditional Indian homemade food was not only healthy, but also owned incredible health benefits. Indian food played a pivotal role on immunity, inflammation, brain function and people were healthy. Now, the scenario across the globe has changed and India has also become a part of it. Nutraceutical market is flourishing predominantly in United States, India and European countries. Increasing health awareness, drift in population disease demographics, where younger people furthermore affected, lifestyle alterations, escalated purchasers opulence and elevated life expectancy are responsible for increasing market for nutraceuticals in India. Wide range of nutraceuticals are targeted right from the birth in the form of formula milk, dietary supplements in reproductive and geriatric section of people, protein health drinks to increase muscle mass, improve overall body composition and to meet their protein needs. In India, multivitamins, multi- minerals, proteins, health drinks, herbs are the common dietary supplements sold in the form of tablets, liquids, powders, capsules, soft gels to improve one's well-being.

Table 3.	Comparison	of Indian	Nutraceutical	Market	hetween	2015-2022	121
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	2015	2022	CAGR
1) Share of India in Global Nutraceutical market (%)	2%	3%	
2) Nutraceutical market (Billion US \$)	2.8%	8.5%	17%
3) Dietary supplements market (Billion US \$)	1.8%	5.2%	16%
4) Vitamin & mineral supplements market (Billion US \$)	0.7%	2.1%	16.8%
5) Herbal supplements market (Billion US \$)	0.6%	1.7%	16.9%
6) Protein & amino acids supplements market (Billion US \$)	0.40%	1.09%	15.5%
7) Other dietary supplements market (Billion US \$)	0.11%	0.23%	11.6%
8) Functional food market (Billion US \$)	0.7%	2.1%	17.1%
9) Functional beverage market (Billion US \$)	0.30%	1.09%	20.3%
10) Neutraceutical market for nutritional deficiency (Billion US \$)	1.4%	4.4%	17.7%
11) Nutraceuticals Market for Muscle Building (Billion US \$)	0.8%	2.6%	17.6%
12) Nutraceuticals Market for Weight Management (Billion US \$)	0.4%	1.3%	17.4%
CAGR-Compound Annual Growth Rate			

The critical situation is due to surge in the price, and also due to dwindling or diminished demand of present-time modern medical therapy. This lead to impetus and gained momentum for establishment of multiple nutraceutical companies, who invested tremendously and laboriously in Research and Development (R&D) division.

The Article published by ASSOCHAM under the title of "Indian Nutraceuticals market study on the current scenario and Future trends", present the following data of comparison of Indian Nutraceutical market between 2015 and 2022 in table 3 [12].

It is observed from the data given in table 3 that by 2022 there would be an escalation in utilization of nutraceuticals.

### Inappropriate use of nutraceuticals

Nutrition is incompletely understood notion in India. The proportion of people who are adequately nourished are precisely mere. The population can be categorized into three nourished groups: Under-nourished, over-nourished and nourished with calories but not with nutrients. The deprived population are pondered to be under-nourished. Likewise, people eating limited fruits and vegetables are deficient in micronutrients. Thus, increasing the consumption of nutraceuticals in India to avert these deficiencies and diseases.

In a research analysis by Preeta K. Chugh et al, observed that there was outrageous quantity of nutrients in nutraceuticals than the recommended dietary allowance. Common supplements like vitamins, minerals and herbal products are available without a prescription in pill, powder or liquid form. Unrestrictedly administered nutraceuticals by oneself can cause deleterious effects in predisposed population. The dosage and composition of each ingredient should be rightly labelled for a specific compound. They suggested the necessity to impose strict implementation on availability of enormous preparations with undefined ingredients and dosage as over-the-counter agents to defend and prevent the adverse effects caused by the inappropriate use of nutraceuticals [13].

A study called Selenium and Vitamin E Cancer Prevention Trial (SELECT) which included 35,000 men, found unanticipated evidence about vitamin E supplements. Earlier, research suggested that men who took vitamin E supplements had lower risk of developing prostate cancer, but found that men who took 400 IU (international units) of vitamin E daily had more prostate cancer than men who took placebo. The researchers estimated the amount of vitamin E, selenium and other nutrients in the blood of all the participants to see if the effect of supplements and looked for single nucleotide polymorphisms (SNPs) to check for genetic differences that increased the risk of developing prostate cancer while taking vitamin E [14].

Unlike medicines, nutraceuticals cannot claim to cure, prevent or treat a disease. Though evidence suggests that few nutraceuticals enhance the health in different ways, few nutraceuticals have mild adverse effects too. Women need folic acid 400 micrograms and iron supplements daily in pregnancy, breastfed infants need vitamin D supplements, which enhance one's wellbeing, while other nutraceuticals like vitamin K and Ginkgo reduced and increase the effect of blood thinners respectively due to drug interactions. The herbs kava and comfrey cause serious damage to liver.

Nutraceuticals can cause problems in certain health conditions or when taken along with other medications. It is important to talk to the healthcare provider for advice on whether one needs a nutraceutical in first place, the dosage and possible drug interactions when taken with other prescribed drugs. It is important to check the intake of the amount of nutraceuticals is within the % daily value (%DV) as too much of certain nutraceuticals as they can be harmful. Effects of many supplements have not been tested in children, pregnant and lactating women, geriatric and on population with diseases, thus the safety of nutraceuticals is questionable. It is important to conduct clinical trials of nutraceuticals to confirm their beneficial and harmful effects.

As the nutraceuticals are considered as supplements and not as drugs, the FDA does not assess the standard or their effects on humans. Once the product is found to be unsafe or harmful after it is out in the market, the FDA can ban or

disallow its use. The manufacturers of nutraceuticals are responsible and answerable about the product's purity, safety and should specifically list out all the ingredients and their quantities as there is chance of receiving less or more amount of ingredients than the required % daily value.

### **Nutrivigilance**

People presume that these supplements are thoroughly safe as they are natural and vended over the counter. Nutraceuticals are marketed without prescription at drug stores, health food stores, supermarkets, online stores, internet, etc., as there is no mandatory medical supervision and approval from the Food and Drug Administration (FDA) required. The use of processed and pre-packaged food, lack of standardization and awareness of dose-safety, excessive pricing, marketing and distribution is questionable and controversial. There is a crucial need to impose stringent guidelines and regulations over the active ingredients of nutraceuticals, identity, purity and bioavailability for the rationale use of nutraceuticals.

In the last few decades, the range of availability of nutraceuticals has significantly expanded, with new products characterised by personalised nutraceuticals which includes nutrigenomics, newer ingredients in nutraceuticals like food supplements, fortified foods and beverages, products vended out of proportion, especially on internet, can expose the buyer and consumers to new risks which are in need of identification. The objective of nutrivigilance is to incorporate monitoring schemes to discern or identify the adverse effects caused by nutraceuticals for the consumer safety.

The products that are covered by nutrivigilance scheme are-food supplements, food or beverages fortified with vitamins, minerals, amino acids, plants extract, foods intended for certain population such as infants, elderly etc.

# Need to incorporate stringent guidelines in regulatory aspects

The Dietary Supplement Health and Education Act was passed in 1946, set rules to govern nutraceutical market. The Food Safety and Standard Act (FSSA) was effective from August 2011. Food Safety and Standard Authority issued rules and regulations regarding registration and licensing of nutraceuticals manufacturing companies, manufacturing, labelling, packing, storage, distribution, sale and import of nutraceuticals in India.

According to this act, the manufacturer:

- Is accountable for product analysis, development, authentication of extracts and safety of the nutraceuticals it makes and supplies.
- Must not print any false or misleading information on the label of the nutraceuticals that may lead to mass consumption of the nutraceuticals by the population.
- Must not claim that the product will diagnose, treat or prevent the disease.
- Must guarantee the purity, identity, composition of their nutraceuticals.

The manufacturing, packaging, labelling and marketing of nutraceuticals are regulated by government regulatory body in developed countries. In developing country like India, it is difficult to implement stringent guidelines and regulations for manufacturing, labelling and marketing of nutraceuticals. Lately, USFDA warned India about unlawful marketing of recalled products (the product that is brought back or summoned back after discovery of safety issues that might endanger public health and put manufacturer at risk of legal action) of nutraceuticals in US market through internet. There is no authority which controls the false advertising regarding few nutraceuticals. As 22% of Indians fall below the poverty line and as more than half of the nation's population lacks basic literacy skills, any misleading information claiming miracle cure of the disease may lead to mass consumption of the nutraceuticals by the consumers. There is a need for strict implementation to maintain the standard of the nutraceuticals to safeguard the health of the population [15].

# Approaches to improve nutrivigilance in India by

### Encouraging reporting by healthcare provider:

- Healthcare providers play a vital role by actively observing and reporting cases of adverse effects that they suspect of being associated with intake of nutraceuticals.
- Providing nutrivigilance leaflets to inform and guide the side effects caused by few products of nutraceuticals.
- Prescribing medications after taking complete history of on-going treatment and other nutraceuticals, to avoid drug interactions which may harm one's wellbeing.

The objective of nutrivigilance will be achieved with feedback in the form of reporting sheets and valuable responses from professionals [16,17].

# Educating everyone about the chances of adverse effects due to nutraceuticals by:

- Avoiding intake of nutraceuticals on a repeated, prolonged basis without taking an advice from healthcare professional.
- Not taking nutraceuticals to treat a health condition that is self-diagnosed by a person himself, without consulting a healthcare professional.
- Not consuming nutraceuticals in combination with, or in place of prescribed medication without approval by healthcare provider.
- Consulting healthcare professional about the supplements that a person is taking when scheduled for surgical procedure.
- Practicing utmost caution while using the products claiming to have miracle diagnosing, preventing and treating properties.
- Abstaining use of nutraceuticals sold through improper channels, especially through internet.

### Demanding the proper nutraceutical standards by:

- Providing product evaluation, product analysis, purity, identity, composition, licence and development of the nutraceuticals.
- Providing factors like accurate dosage and permissibility according to daily requirements in Indian context on the label.

### Providing information to nutravigilance on:

- The known side effects, contraindications, unsafe drug interactions caused by nutraceuticals.
- Creating newsletters to share the information at a larger scale.

### **Conclusion**

The global market is currently experiencing growth in marketing nutraceuticals throughout the world. Indian companies are now supplying nutraceuticals both locally and globally. The adverse effects caused by consuming high amount of nutraceuticals are not generally reported and documented. The safety of nutraceuticals remains a priority for health authorities in India. Product analysis, development and authentication of extracts can be identified by utilizing scientific methodology and collective expertise and implementation of stringent guidelines in manufacturing, marketing and availability of nutraceuticals are required. Nutraceutical companies must be legally prosecuted which do not follow the laid regulations. The standardization of these products is one of the valiant challenges for any government that lead to the initiation of Nutrivigilance, which has to be strengthened in India. It is recommended to get all nutrients one need by eating variety of traditional home-made healthy foods, instead of depending on nutraceuticals, whose safety is questionable, as there is absence of strong evidence of benefit from clinical trials. Awareness among the population is to be created to minimise the use of nutraceuticals and to be used whenever essential. The need, scope, and importance of Nutrivigilance is to improve the process of adverse events reporting in the country due to recent surge in the growth of nutraceuticals.

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No economic interest or any conflict of interest exists for the authors.

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