

## THE PHARMA INNOVATION

# Nutraceutical –A Bright Scope and Opportunity of Indian Healthcare Market

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Neutraceutical is regarded as the bio active substance and the constituents are either of known therapeutic activity or are chemically defined substance generally accepted to contribute substantially to the therapeutic activity of the drug. Phytochemical screening involves botanical identification, extraction with suitable solvents, purification and characterization of the bioactive constituents of pharmaceutical importance. Quality control for the officiality and safety of herbal product is essential. The quality control of phytochemical may be defined as the status of a drug which is determined either by identity, purity, constant and other chemical physical biological properties or by manufacturing process. Compound with synthetic drug. The critical and approach for herbal drug are much more complex. Nutraceutical, a portmanteau of the words "nutrition" and "pharmaceutical", is a food or food product that reportedly provides health and medical benefits, including the prevention and treatment of disease. A product isolated or purified from foods that is generally sold in medicinal forms not usually associated with food. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease. The dietary and advanced analytical techniques for the determination and quantification of various nutraceuticals. Supplements and nutraceutical market is projected to achieve a global market size of about Rs.90 billion in 2013 at a CAGR of 20.24%. There has been resurgence in the area of nutraceutical development in past few years especially because of the development of highly sophisticated.

*Keyword:* - Neutraceutical, Dietary Supplement, Market Developments

**INTRODUCTION:** The term nutraceutical was originally defined by Dr. Stephen L. DeFelice, founder and chairman of the Foundation of Innovation Medicine (FIM), Crawford, New Jersey. Since the term was coined by Dr. DeFelice, its meaning has been modified by Health Canada which defines nutraceutical as: a product isolated or purified from foods, and generally sold in medicinal forms not usually associated with food and demonstrated to have a

physiological benefit or provide protection against chronic disease. Examples are beta-carotene and lycopene. Dr Stephen DeFelice coined the term "Nutraceutical" from "Nutrition" and "Pharmaceutical" in 1989. The term nutraceutical is being commonly used in marketing but has no regulatory definition. An attempt to re-define nutraceuticals and functional foods is made in this article. The proposed definitions can help distinguish between functional foods,

nutraceuticals, and dietary supplements. The advantages and disadvantages of nutraceuticals are also briefly discussed. Many nutraceuticals, functional foods and naturally occurring compounds that have been investigated and reported in various studies revealed that these products are extremely active, have profound effect on cell metabolism and often have little adverse effect. It is natural that people's focus is shifting to positive approach for prevention of diseases to stay healthy. Nutraceuticals is scientific area generated all over the world. In many cases nutraceuticals offer advantage over the synthetic drugs under development by the pharmaceuticals industry. It is novel pharmacological activity that are become interesting in their possible clinical use and thus helping in prevention and therapeutic in several diseases. Most of the pharmaceuticals companies often lack motivation on pursue these difficulties in obtaining the patents. It is hope that government agencies and research centers will give support for further research in nutraceuticals. The Indian nutraceutical industry has great prospects. Over the last decade a wide range of products have been available, giving an insight into the tremendous growth. On one hand a booming economy has resulted in overall increase in disposable income of population. Added to this unhealthy, eating habits coupled with sedentary lifestyle have led to increase incidence of diet and its related health issues. On the other hand, there is a growing awareness on the importance of nutrition and diet for long term good health. These have contributed to a favorable market conditions for Nutraceutical industry in India. India has a lot of advantages like qualified human resources, world class R & D facilities and varied raw material-aspects that give our country a leading edge. Nutraceuticals are currently receiving recognition as being beneficial in coronary heart disease, obesity, diabetes, cancer, osteoporosis and other chronic and degenerative diseases such as Parkinson's and Alzheimer's diseases. Evidences indicate that the mechanistic actions of natural compounds involve a wide array of biological processes, including activation of antioxidant defenses, signal transduction

pathways, cell survival-associated gene expression, cell proliferation and differentiation and preservation of mitochondrial integrity. It appears that these properties play a crucial role in the protection against the pathologies of numerous age-related or chronic diseases. It is very imperative that the nutrients found in many foods, fruits and vegetables are responsible for the well documented health benefits. For example, lutein and zeaxanthin prevent cataracts and macular degeneration; beta-carotene and lycopene protect the skin from ultraviolet radiation damage; lutein and lycopene may benefit cardiovascular health, and lycopene may help prevent prostate cancer. Because of these and other marked health benefits of these, it must be taken regularly and to reduce the risk factors like high cholesterol, high blood pressure and diabetes. Some of the most popular nutraceutical products marketed today are botanicals such as St. John'swort, echinacea, ginkgo biloba, saw palmetto, and ginseng. Many industries manufacture and market the nutraceuticals, where the side effects (especially consumed in large quantities) of these nutraceuticals not reported or often not proven. In order to have scientific knowledge about the nutraceuticals, public should be educated, where recommended daily doses of these nutraceuticals should be known by each consumer. With the rapidly increasing interest in the nutraceutical revolution, we need to establish a vibrant nutraceutical research community which is absolutely necessary to convert the majority of potential nutraceuticals to established ones thereby truly delivering their enormous benefits to all of us. The list of nutraceuticals being studied is changing continually and reflects ongoing research, market developments and consumer interest. **"The nutraceutical market in India is estimated to grow to US\$2,731 million in 2016 at a CAGR of 13%"** Biospectrum Asia Edition, 16 March 2012.

#### DIETARY SUPPLEMENT<sup>1,3,4</sup>

The DSHEA formally defined "dietary supplement" using several criteria. A dietary supplement:

- Is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vita-min, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.
- Is intended for ingestion in pill, capsule, tablet, or liquid form.
- Is not represented for use as a conventional food or as the sole item of a meal or diet.
- Is labeled as a "dietary supplement."
- Includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).

Thus, nutraceuticals (as per the proposed definition) differ from dietary supplements in the following aspects:

- Nutraceuticals must not only supplement the diet but should also aid in the prevention and/or treatment of disease and/or disorder.

A ray of "cure preference" in the mind of common patients revolves around nutraceuticals because of their false perception that "all natural medicines are good." Also, the high cost of prescription pharmaceuticals and reluctance of some insurance companies to cover the costs of drugs helps nutraceuticals solidify their presence in the global market of therapies and therapeutic agents.

### Food As Medicin <sup>5,6,8</sup>

Considered a father of Western medicine, Hippocrates advocated the healing effects of food. The Indians, Egyptians, Chinese, and

Sumerians are just a few civilizations that have provided evidence suggesting that foods can be effectively used as medicine to treat and prevent disease. Ayurveda, the 5,000 year old ancient Indian health science, have mentioned benefits of food for therapeutic purpose. Documents hint that the medicinal benefits of food have been explored for thousands of years. Hippocrates, considered by some to be the father of Western medicine, said that people should "Let food be thy medicine." The modern nutraceutical market began to develop in Japan during the 1980s. In contrast to the natural herbs and spices used as folk medicine for centuries throughout Asia, the nutraceutical industry has grown alongside the expansion and exploration of modern technology. New research conducted among food scientists show that there is more to food science than what was understood just a couple decades ago. Until just recently, analysis of food was limited to the flavor of food (sensory taste and texture) and its nutritional value (composition of carbohydrates, fats, proteins, water, vitamins and minerals). However, there is growing evidence that other components of food may play an integral role in the link between food and health. These chemical components are derived from plant, food, and microbial sources, and provide medicinal benefits valuable to long-term health. Examples of these nutraceutical chemicals include probiotics, antioxidants, and phytochemicals. Nutraceutical products were considered alternative medicine for many years. Nutraceuticals have become a more mainstream supplement to the diet, now that research has begun to show evidence that these chemicals found in food are often effective when processed effectively and marketed correctly.

### Classification of Nutraceuticals <sup>9,10,12,18</sup>

Nutraceuticals is a broad umbrella term used to describe any product derived from food sources that provides extra health benefits in addition to the basic nutritional value found in foods. Products typically claim to There is minimal regulation over which products are allowed to display the nutraceutical term on their labels. Because of this, the term is often used to market products with varying uses and effectiveness. The

definition of nutraceuticals and related products often depend on the source. Members of the medical community desire that the nutraceutical term be more clearly established in order to distinguish between the wide varieties of products out there. There are multiple different types of products that may fall under the category of nutraceuticals.

### **Dietary supplements**

Dietary supplements, such as the vitamin B supplement show above, are typically sold in pill form. A dietary supplement is a product that contains nutrients derived from food products that are concentrated in liquid or capsule form. The Dietary Supplement Health and Education Act (DSHEA) of 1994 defined generally what constitutes a dietary supplement. “A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gencaps, liquids, or powders.” Dietary supplements do not have to be approved by the U.S. Food and Drug Administration (FDA) before marketing. Although supplements claim to provide health benefits, products usually include a label that says: “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”

### **Functional foods**

Functional foods are designed to allow consumers to eat enriched foods close to their natural state, rather than by taking dietary supplements manufactured in liquid or capsule form. Functional foods have been either enriched or fortified, a process called nutrification. This practice restores the nutrient content in a food back to similar levels from before the food was processed. Sometimes, additional complementary nutrients are added, such as vitamin D to

milk. Health Canada defines functional foods as “ordinary food that has components or ingredients added to give it a specific medical or physiological benefit, other than a purely nutritional effect.” In Japan, all functional foods must meet three established requirements: foods should be

- (1) present in their naturally-occurring form, rather than a capsule, tablet, or powder;
- (2) consumed in the diet as often as daily; and
- (3) should regulate a biological process in hopes of preventing or controlling disease.

### **Medical foods**

Medical foods aren't available as an over-the-counter product to consumers. The FDA considers medical foods to be “formulated to be consumed or administered internally under the supervision of a physician, and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, on the basis of recognized scientific principles, are established by medical evaluation.” Nutraceuticals and supplements do not meet these requirements and are not classified as Medical Foods. Medical foods can be ingested through the mouth or through tube feeding. Medical foods are always designed to meet certain nutritional requirements for people diagnosed with specific illnesses. Medical foods are regulated by the FDA and will be prescribed/monitored by medical supervision.

### **FARMACEUTICALS** <sup>6,11,16,17</sup>

According to a report written for the United States Congress entitled "Agriculture: A Glossary of Terms, Programs, and Laws", “(Farmaceuticals) is a melding of the words farm and pharmaceuticals. It refers to medically valuable compounds produced from modified agricultural crops or animals (usually through biotechnology). Proponents believe that using crops and possibly even animals as pharmaceutical factories could be much more cost effective than conventional methods .

Examples:

Broccoli may help in the prevention of cancer. The following is an incomplete list of foods with reported medicinal value:

- Antioxidants: resveratrol from red grape products; flavonoids inside citrus, tea, wine, and dark chocolate foods; anthocyanins found in berries, Vitamin C
- Reducing hypercholesterolemia:<sup>[16]</sup> soluble dietary fiber products, such as psyllium seed husk
- Cancer prevention: broccoli (sulforaphane) fiddleheads (Matteuccia Struthiopteus)
- Improved arterial health: soy or clover (isoflavonoids)
- Lowered risk of cardiovascular disease: alpha-linolenic acid from flax or chia seeds, Omega 3 fatty acids in fish oil.

In addition, many botanical and herbal extracts such as ginseng, garlic oil, etc. have been developed as nutraceuticals. Nutraceuticals are often used in nutrient premixes or nutrient systems in the food and pharmaceutical industries.

### SCOPE AND OPPORTUNITY INDIAN NUTRACEUTICAL MARKETS<sup>22,25,27</sup>

The Indian nutraceutical market valued at \$ 1,480 million in 2011 could grow to \$ 2,731 million in 2016, a report said today. According to the report by business research and consulting firm Frost & Sullivan, functional foods will be the quickest growing category followed by dietary supplements until 2015. However, dietary supplements specifically herbal and dietetic supplements, will form the greatest opportunity areas for nutraceutical manufacturers, it added. Nutraceutical a portmanteau of the words 'nutrition' and 'pharmaceutical', is a food or food product that reportedly provides health and medical benefits, including the prevention and treatment of diseases. The report said that at present the dietary supplements were the largest category accounting for 64 per cent of the

nutraceuticals market. This market is driven primarily by the pharmaceutical sector in the form of vitamin and mineral supplements, it added. As per the study the global nutraceutical market was estimated to be \$ 149.5 billion in 2011 with US, Europe and Japan being the largest regional markets, accounting for nearly 93 per cent of the global nutraceutical demand. As these markets are nearing maturity, with exceedingly high per capita spends on nutraceutical products nutraceutical manufacturers are looking at developing countries such as India and China as key growth regions, it added. Apart from the current low per capita spend on these products in India, other factors that could support the growth of nutraceuticals in India are increasing obesity in the population and rising instances of diabetes and cardiovascular diseases, the report said. The government is also chipping in by funding vitamin fortification initiatives due to increasing food security concerns in India and need for additional nutrition. With increasing sophistication among nutraceuticals, consumer demand for products with specific health benefits has been on the rise, the study said. Globalisation of the nutraceutical and functional food industries present significant challenges to stakeholders, not the least of which is the regulatory variance between countries active in the marketplace. Nutraceuticals are playing an important role in the development of future therapeutics but it depends on the control of purity, efficacy and safety. Hence, when any new entrant wants to enter the Indian nutraceutical market, it is very important to comply with the regulatory framework, so that the business is run smoothly. The focus areas should be product evaluation for each active ingredient in the context of permissibility, standards and dosage of vitamins/minerals allowed, product classification as per various Indian healthcare laws (legal definition of the product), India-specific label claims and advertising. Excerpts from a white paper published by Interlink, a business performance consultancy, which gives an overview of the Indian nutraceuticals market, latest happenings on its regulatory front and the requirements to be met by new entrants before

entering it. Globally, the nutraceutical market was estimated to be \$140.1 billion in 2010. Of this, US and Europe formed the largest markets accounting to 36 per cent and 25 per cent respectively. In 2010, the Indian nutraceutical industry was estimated at \$2 billion, roughly 1.5 per cent of the global nutraceutical industry. Broad segments of Indian nutraceutical industry include dietary supplement (40 per cent) and functional food and beverage market (60 per cent). The total Indian nutraceuticals market is expected to be approximately \$5 billion in 2015.

### **Rationale For Use Of Nutraceuticals** <sup>6,7,8,9</sup>

Dietary factors play an important role in premature chronic disease appearance, disease progression, morbidity and mortality. Approximately 40-50% proportion in cardiovascular disorders, 35-50% proportion in cancers, and 20% proportion in osteoporosis is attributable to dietary factors. Use of food as medicine for treatment and prevention of various disorders is not a recent development. Fortification of table salt with iodine and wheat flour with iron/folic acid has been used with specific aims of prevention of iodine deficiency goiter and anemia for long. Similarly, food fortified with vitamin A has been found to be a feasible and cost-effective approach to reduce vitamin A deficiency. A growing interest in relationship between diet and health has added impetus to the demand for information on nutraceuticals. This increased interest has been aided by advances in science and technology, increasing health care costs, changes in food laws affecting label, and product claims and aging population in various countries. Along with offering treatment, use of nutraceuticals favours a preventive treatment model as well.

### **Regulation Of Nutraceutical Industry In India** <sup>11,12,15,17,19</sup>

Nutraceutical is a new buzzword in Indian healthcare market. This promising term reflects lucrative market opportunities for domestic as well as international pharmaceutical and Nutraceutical companies. Nutraceuticals has a spectacular annual growth rate of 25 % in Indian

healthcare market. It is estimated that, by end of 2007 global Nutraceutical market may cross USD 80 bn. Though several scholars have given different definitions for Nutraceuticals, essence remains same, and it means “food as medicine”. Still ambiguity exists in interpreting differences between Nutraceuticals and different related terminologies like Functional food, Dietary supplements, and Designer food. Absence of regulatory guidelines for Nutraceuticals in India results in mushrooming of Nutraceutical manufacturers. In the process of cut-throat competition, for their survival they may compromise with the quality of product. This study suggests framing a harmonised definition for Nutraceuticals and proper regulatory guidelines to control the excessive mushrooming of Nutraceutical manufacturers.

### **Indian scenario**

Nutrition is a poorly understood concept in India. The percentage of people who are properly nourished is very small. The imbalances of nourishment patterns give rise to three categories of people: Over-nourished (about 80 million); Under-nourished (about 380 million) and Nourished with calories but not nutrients (about 570 million). The entire population below the poverty line have been considered as under-nourished; irrespective of their calorie intake. Similarly, the people who consume less than 175 gm of fruits and vegetables in a day have been considered deficient in micronutrients. Thus the pressing need of the consumer is to supplement food with external nutrients to avert disease conditions.

### **Varying guidelines**

Nutraceuticals is an evolving concept with varying definitions across the globe. Some of developed countries have implemented legislations as early as in 2004. In Canada, nutraceuticals are named ‘Natural Health Products’. They are known as “Dietary Supplements” in the US and Japan calls them ‘Foods for Special Health Use’ (FOSHU). In US, Canada and in EU there are distinct definitions and guidelines for dietary supplements and

functional foods where as in Japan they are governed under same set of rules. Traditional and herbal medicines are part of the definition of dietary supplements in Canada, but not the case in Japan. Herbs and botanicals find place in nutraceuticals in US.

The Indian definition (as per Food Safety and Security Act passed in 2006, yet to be implemented) lists down the ingredients a nutraceutical product must have and its general properties. A traditional medicine is not a part of nutraceuticals. Foods for special dietary use are specifically processed or formulated to satisfy particular dietary requirements which exist because of a physical or physiological condition or specific disease and disorder. These are presented as such, where in the compositions of these foodstuffs must differ significantly from the Indian Standard (IS) composition of ordinary foods of comparable nature, if such ordinary food exists and may contain one or more of the following ingredients, namely:-

- Plants or botanicals or their parts in the form of powder, concentrate or extract in water, ethyl alcohol or hydro alcoholic extract, single or combination.
- Minerals or vitamins or proteins or metals or their compounds or amino acids (in amounts not exceeding the Recommended Daily Allowance (RDA) for Indians) or enzymes with permissible limits
- Substances of animal origin
- Dietary substances for use by human beings to supplement the diet by increasing the total dietary intake

### **FSSAI: The new ray of hope!**

Food Safety and Security (FSS) Act was passed by the parliament in 2006. In 2008, Food Safety and Standard Authority of India (FSSAI) came into existence. The FSSAI has prepared the draft rules and regulations for implementation of FSS Act 2006 which is going through process of pre-publication consultation. It is expected that by the end of this month (September 2010) the draft regulation would be sent for notification.

1. The FSSAI will make rules and frame standards to regulate nutraceuticals as outlined in the Food Safety Act, 2006.

2. Food Safety and Standard Act 2006 consists of 12 chapters and chapter IV article 22 of the Act addresses nutraceutical, functional food, dietary supplements and need to regulate these products such that anyone can manufacture, sell or distribute or import these products. These products include novel foods, genetically modified article of food, irradiated food, organic food, and food for special dietary uses, functional food, nutraceuticals and health supplements.

3. Article 23 and 24 address the packaging and labeling of food and restriction of advertisement regarding foods.

4. A product that is labeled as “food for special dietary uses” functional food or nutraceutical dietary supplements which is not represented for use as conventional food and whereby such products may be formulated in the form of powders, granules, tablets, capsules, liquids, jelly and other dosage forms but not parenterals, and are meant for oral administration.

5. Nutraceutical products do not claim to cure or mitigate any specific disease, disorder or condition (except for certain health benefit or such promotion claims) as may be permitted by the regulations made under this Act;

6. It does not include a narcotic drug or a psychotropic substance as defined in the Schedule of the Narcotic Drugs and Psychotropic Substances Act, 1985 and rules made there under and substances listed in Schedules E and EI of the Drugs and Cosmetics Rules, 1945;

7. It also includes "genetically engineered or modified food which means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified or engineered organisms obtained through modern biotechnology; "organic food" means food products that have been produced in accordance with specified organic production standards; "proprietary and novel food" means an article of food for which

standards have not been specified but is not unsafe.

8. With the draft guidelines, there may be provisions of testing and tracing the origin of the food products right back up to farm level.

9. The Authority would also have to grapple with the gigantic task of putting in place the minimum levels of compliance of food laws, administrative efficiency, transparency and an independent audit system.

10. Under the new rule each state will have a food safety commissioner who would be the implementing agency.

Rules and regulation under the new regime will be exhaustive to control quality and claims and their implementation should be expedited.

- The industry is waiting for revised RDA levels to make them applicable for Indian population’s current lifestyle.
- Recognise list of nutritional ingredients with proven health benefits.
- Define the list of permitted health claims and specify the quantity of ingredients required to make such claims.
- Formation of a Regulatory Framework
- Increased collaboration among Indian manufacturers on R&D
- Standardizing the Manufacturing Process, Validation and Intellectual property protection
- Active involvement of Government and Private Agencies in educating consumers on the benefits of nutraceuticals.

The Indian nutraceuticals market is a mere 0.9 percent of the total global market size of \$ 117 billion. At \$ 1 billion, the Indian market is growing fast at a CAGR of 18 percent; while globally CAGR is seven percent. The FSSAI has a formidable task ahead to ensure that effective regulations and guidelines are evolved and implemented to enable the Indian nutraceutical industry to gain further momentum. Effective implementation of the FSS Act 2006 has the potential to open up tremendous opportunity for the nutraceutical industry in India and this would

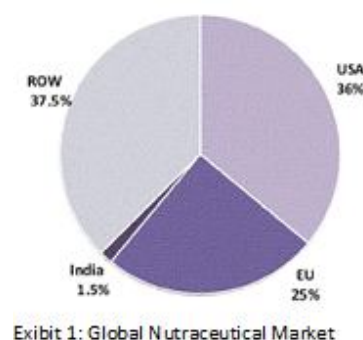
require a co-ordinated and sincere effort from all the stake holders.

## REGULATORY PERSPECTIVE OF NUTRACEUTICALS IN INDIA<sup>22,23,24,28</sup>

### Regulatory guidelines

Since nutraceuticals are not a part of pharma and drugs formulation, rules and regulations also tend to be different for this segment. Indian government has recently implemented the new law FSSAI (Food Safety and Standards Authority of India). As a result, there is some confusion in the minds of new entrants about the do's and dont's of the Indian regulatory system.

Transition perspective - The Ideal Scenario



The Food Safety and Standards Act, 2006 consolidates eight laws governing the food sector and establishes the Food Safety and Standards Authority of India (FSSAI) and its other allied committees to regulate the sector. The FSSAI comprises a chairperson and 22 members. The chairperson is either an eminent food scientist or a civil servant not below the rank of secretary. Seven of the members would be ex-officio, not below the post of joint secretary, from various ministries. Five members would be appointed by rotation every three years from the States and Union Territories. The authority would have two representatives each from the food industry and consumer organisations, three food technologists and two members from a farmers' organisation and one from retail organisation. FSSAI will be aided by several scientific panels and a Central Advisory Committee to lay down standards for food



safety. These standards will include specifications for ingredients, contaminants, pesticide, biological hazards, labels and others. Everyone in the food sector is required to get a license or a registration that would be issued by the local authorities. Temporary stall holders are exempted from the license but need to get their businesses registered with the local municipality or panchayat.

The law will be enforced through state commissioners of food safety and local level officials. The Act empowers the FSSAI and state food safety authorities to monitor and regulate the food business operators. The commissioner of food safety of each state appoints a designated officer (DO), not below the level of sub-divisional officer, for a specific district. His duties include issuing or cancelling licenses, prohibiting sale of food articles that violate specified standards, receiving report and samples of food articles from food safety officers and getting them analysed. The state commissioner, on the recommendation of the designated officer, decides whether a case of violation would be referred to a court of ordinary jurisdiction or to a Special Court. The Act provides for a graded penalty structure where the punishment depends on the severity of the violation. Offences such as manufacturing, selling, storing or importing sub-standard or misbranded food could incur a fine. Offences such as manufacturing, distributing, selling or importing unsafe food, which result in injury, could incur a prison sentence. The sentence could extend to life imprisonment in case the violation causes death. Petty manufacturers who make their own food, hawkers, and vendors or temporary stall holders could be fined up to Rs 25000 if they violate the specified standards.

### Current scenario

The Food Safety and Standard Rules, 2011 have been issued, effective from 5th May, 2011. The Food Safety and Standard Authority has also issued regulations about licensing and registration of food business, packing and labelling, food products standard and additive

etc. These acts, rules and regulations have been implemented from 5th August, 2011. Thus, now there is one single legislation and specified authorities to regulate manufacture, sale and distribution of nutraceuticals, functional food and dietary supplement in India. However, due to lack of clarity of specific regulations for registration of nutraceuticals and permitted additives, entrepreneurs intending to launch nutraceuticals in India is still facing the following challenges.

i. Drugs defined under Section 3(b)(i) of the Drugs and Cosmetics Act, 1940 and also ayurvedic, siddha and unani drugs are specifically excluded from the scope of the definition of nutraceutical, health supplement etc. under Section 22 of the Act. The definition of drug under Drugs Act is very exhaustive. Taking recourse to the definition of drug, regulatory officers are categorizing nutraceuticals, especially manufactured and marketed in tablet, capsule or liquid oral dosages form containing vitamin and minerals as drugs on the basis of even structure function claims.

ii. The regulatory officers also take a view that as empty gelatin capsule itself is covered by the definition of drug, any product marketed in capsule form will also be considered as drug.

iii. Some commonly used colours and additives such as binding agents, granulating agents used in formulating tablets do not find place in the list of permitted food additives under the regulations.

iv. Though the structure function claims are permitted, there is no clarity as to the permitted structure function claims for nutraceuticals and dietary supplements.

To overcome these difficulties, it would be necessary to amend Schedule K of the Drugs and Cosmetics Rules, 1945 to provide for specific exemption to nutraceuticals, dietary supplements, health supplements from the scope of Drugs and Cosmetics Act, 1940 and Rules, 1945.

It is also necessary to have specific regulations for product approval, approval of claims, permitted additives, quantity of vitamins and

minerals etc. for nutraceuticals as it is necessary to treat this segment as an independent and unique entity under the Food Safety Standard Act, 2006.

### Regulatory requirements for India entry

As nutraceutical regulations are evolving in India, it is a possibility that some of the content is conflicting / confusing. Yet, for the Indian industry to take shape, these have to be streamlined. In order to enter the Indian nutraceutical market, some of the very important areas of focus include product evaluation, actual product analysis, procuring licenses and developing India specific health and label claims.

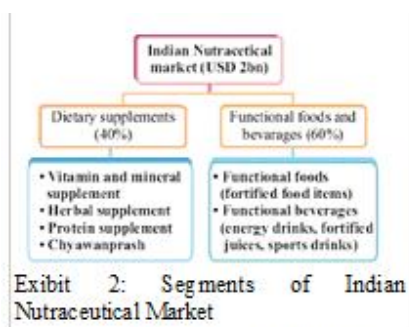


Exhibit 2: Segments of Indian Nutraceutical Market

Exhibit 1: Global Nutraceutical Market

1. Product evaluation: In Indian conditions, the classification of formulations is very complex. Hence, due diligence in terms of carving a specific amount for each ingredient and the combination of ingredients becomes very crucial.

In order to assess a product as per the Indian regulations, it is very important to examine each active ingredient and additive in the context of permissibility, standards and dosage of vitamins/minerals allowed as per the therapeutic, prophylactic or recommended daily allowance for Indians. Manufacturers are also unclear whether their products will be classified as food or food supplement or drug in the context of the Prevention of Food Adulteration Act, 1954 and Rules, 1955, Food Safety and Standards Act,

2006 and Drugs and Cosmetics Act, 1940 and Rules, 1945.

The Food Safety and Standards Rules, 2011 highlights the regulatory enforcement structure and procedures which the Central Government proposes to create. The structure has a hierarchy beginning from the commissioner of food Safety to a number of officers like designated officer, food safety officer, food analyst, etc. who will be involved in the product analysis process at different points.

Various steps in the product analysis include

- Developing extracts of documents and authenticating the same by the concerned authority
- Sample collection (in the presence of witnesses)
- Sample dispatch to the concerned authority (different processes for bulk package and single package)
- Food analysis
- If analysis is not complete within the stipulated period of time, further action plan by the designated officer
- Adjudication proceedings (holding enquiry, appeal procedure, hearing, etc.)

2. Licenses: Though the new FSSAI promises to simplify the licensing and registration processes for nutraceuticals, the actual process varies as per the number of parameters. To get a product registered in India, number of licenses (almost 4 - 5) might be required, depending on the actual product status like

Number of documents will have to be furnished by the food importer to the government authority alongwith registration application dossiers. Interlink, through its regulatory product portfolio, provides regulatory support related to these licensing procedures for

- Import licensing
- Manufacturing licensing
- Marketing licensing and
- Other state and national level clearances/licenses required from the regulatory

side, which need to be taken care of before launching these products in India.

3. Health and label claims: Developing health and label claims, specific to Indian regulatory guidelines, is a major element to be considered while entering the Indian market. International as well as national clients have number of questions about

- India specific labelling and packaging requirements
- Packaging of the consignment composition of the consignment and approach to market the same
- Need for sample material and declaration for registration
- Label content and claim
- Structure - function claim

Based on the regulatory assessment of the product, India-specific label content and claims needs to be developed. New entrant should also consider the requirements to be met, to make specific product claims

### Nutraceuticals And Diseases 12,13,14,15,16

Nutraceuticals are currently receiving recognition as being beneficial in coronary heart disease, obesity, diabetes, cancer, osteoporosis and other chronic and degenerative diseases such as Parkinson's and Alzheimer's diseases. Evidences indicate that the mechanistic actions of natural compounds involve a wide array of biological processes, including activation of antioxidant defenses, signal transduction pathways, cell survival-associated gene expression, cell proliferation and differentiation and preservation of mitochondrial integrity. It appears that these properties play a crucial role in the protection against the pathologies of numerous age-related or chronic disease. It is very imperative that the nutrients found in many foods, fruits and vegetables are responsible for the well documented health benefits. For example, lutein and zeaxanthin prevent cataracts and macular degeneration; beta-carotene and lycopene protect

the skin from ultraviolet radiation damage; lutein and lycopene may benefit cardiovascular health, and lycopene may help prevent prostate cancer. Because of these and other marked health benefits of these, it must be taken regularly and to reduce the risk factors like high cholesterol, high blood pressure and diabetes. Some of the most popular nutraceutical products marketed today are botanicals such as St. John's wort, echinacea, ginkgo biloba, saw palmetto, and ginseng. Many industries manufacture and market the nutraceuticals, where the side effects (especially consumed in large quantities) of these nutraceuticals not reported or often unproven. In order to have scientific knowledge about the nutraceuticals, publics should be educated, where recommended daily doses of these nutraceuticals should be known by each consumer. With the rapidly increasing interest in the nutraceutical revolution, we need to establish a vibrant nutraceutical research community which is absolutely necessary to convert the majority of potential nutraceuticals to established ones thereby truly delivering their enormous benefits to all of us.

### Cardiovascular diseases

Because of the extremely long history of CVD, the causal relationship of nutrition/physical exercise on major CVD events is still difficult to assess prospectively. The relationship between calcium and risk of hypertension is inconsistent and inconclusive, and the relationship between calcium and risk of pregnancy-induced hypertension. Treatment with beta carotene, vitamin A, and vitamin E may increase mortality. There are possibilities to develop nutraceuticals to prevent and manage thrombosis risk in women with thrombophilic gene mutation.

### Obesity

A blend of glucomannan, chitosan, fenugreek, *G. sylvestre*, and vitamin C in the dietary supplement significantly reduced body weight and promoted fat loss in obese individuals. Further studies are needed to establish a long term efficacy and adverse effect potential. There is a very high prevalence of obesity globally and hence nutrition

and exercise play a key role in its prevention and treatment. Nutraceutical interventions are currently being investigated on a large-scale basis as potential treatments for obesity and weight management. Nutraceuticals like conjugated linoleic acid (CLA), capsaicin, *Momordica Charantia* (MC) and Psyllium fiber possess potential antiobese properties.

### Diabetes

Diet therapy is the cornerstone for the management of gestational diabetes mellitus. Although there is wide spread use of herbal dietary supplements that are believed to benefit type 2 diabetes mellitus, few have been proven to do so in properly designed randomized trials. Isoflavones are Phytoestrogens; they have a structural/functional similarity to human estrogen and have been consumed by humans world-wide. Of all phytoestrogens, soy isoflavones have been studied most. A high isoflavone intake (20–100 mg/day) is associated with lower incidence and mortality rate of type II diabetes, heart disease, osteoporosis and certain cancers. Omega-3 fatty acids have been suggested to reduce glucose tolerance in patients predisposed to diabetes. For the synthesis of the long chain n-3 fatty acids, insulin is required; the heart may thus be particularly susceptible to their depletion in diabetes. Ethyl esters of n-3 fatty acids may be potential beneficial in diabetic patients. Docosahexaenoic acid modulates insulin resistance and is also vital for neurovascular development. This is especially important in women with gestational diabetes mellitus which foster the recommendation for essential fatty acids during pregnancy<sup>50</sup>. Lipoic acid is a universal antioxidant, now used in Germany for the treatment of diabetic neuropathy. It is possible that lipoic acid may be more effective as a long-term dietary supplement aimed at the prophylactic protection of diabetics. Dietary fibers from psyllium have been used extensively both as pharmacological supplements, food ingredients, in processed food to aid weight reduction, for glucose control in diabetic patients and to reduce lipid levels in hyperlipidemia. Good magnesium status reduces diabetes risk and

improves insulin sensitivity; chromium picolinate, calcium and vitamin D appear to promote insulin sensitivity and improve glycemic control in some diabetics; extracts of bitter melon and of cinnamon have the potential to treat and possibly prevent diabetes. However it has been suggested that nutraceuticals with meaningful doses of combinations may substantially prevent and presumably could be marketed other uses-

- Cancer
- Immune boosters and anti-inflammatory agents
- Immune boosters
- Inflammatory disorders
- Osteoarthritis
- Allergy
- Degenerative diseases
- Macular degeneration
- Vision improving agents
- Alzheimer's disease
- Parkinson's disease

### CONCLUSION:

Nutraceuticals are available in the form of isolated nutrients, dietary supplements and specific diets to genetically engineered foods, herbal products and processed foods such as cereals, soups and beverages. Nutraceuticals provide all the essential substances that should be present in a healthy diet for the human. Nutraceuticals provides energy and nutrient supplements to body, which are required for maintaining optimal health. Nutraceuticals are widely used in the food and pharmaceutical industries. Some Nutraceuticals are useful in maintaining healthy prostate function, remedy for restlessness and insomnia. Nutraceuticals, such as glucosamine and chondroitin sulfate, offer possible chondro-protective effects against joint injury.

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