NUTRACEUTICALS-ITS CURRENT SCENARIO AND CHALLENGES IN DIETARY SUPPLEMENTS


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ABSTRACT

Let food be the medicine and medicine be the food to predict the relationship between appropriate foods for health and there therapeutic benefits. Nowadays it’s very difficult to find a home which is healthy and free of illness. Many times it is seen that each member of family is suffering from one or other disease. Foreseeing the consequences, Nutraceutical started research for their remedies. Nutraceuticals has proven health benefits and their consumption will keep diseases at bay and allow humans to maintain an overall good health. The expanding neutraceuticals market indicates that end users are seeking minimally processed food with extra nutritional benefits and organoleptic value. This development, in turn is propelling expansion in the neutraceuticals markets globally. Thus, this review gives an idea about the current status and challenges in field of neutraceuticals which offers an incredible dietary supplements.

KEYWORDS- Neutraceuticals, Medicine, Disease, Health benefits.

1. INTRODUCTION

Nutraceutical, a term combining the words “Nutrition” and “Pharmaceutical”, is a food or food product that provides health and medical benefits, including the prevention and treatment of disease. Such products may range from isolated nutrients, dietary supplements and specific diets to genetically engineered foods, herbal products, and processed foods such as cereals, soups, and beverages. With recent developments in cellular-level nutraceutical agents, researchers, and medical practitioners are developing templates for integrating and
assessing information from clinical studies on complementary and alternative therapies into responsible medical practice.\textsuperscript{[1]}

The term nutraceutical was originally defined by Dr. Stephen L. DeFelice, founder and chairperson 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. Dr Stephen DeFelice coined the term "Nutraceutical" from "Nutrition" and "Pharmaceutical" in 1989.\textsuperscript{[1]}

The old proverb “an apple day keeps a doctor away” is now “a nutraceutical a day keeps the doctor away”. The idea behind the mode of action of nutraceutical is to provide functional benefits by increasing the supply of natural building blocker in body, replacement of this building blocker can work in two ways like to reduce disease sings or to improve performance.\textsuperscript{[2]}

The concept of nutraceuticals was started from the survey in UK, Germany and France which conclude or hereditary factors for achieving good health.\textsuperscript{[3,4]}

The nutraceutical industry is a dynamic, evolving industry that offers exciting opportunities to merge scientific discovery with growing consumer interest in health-enhancing foods. Nutraceuticals will continue to have great appeal because they are convenient for today’s lifestyle. The greatest challenge still remains in the public policy and regulatory areas, which will encourage research and development of products that provide health benefits and permit truthful, non-misleading communications of these products while protecting public health and maintaining public confidence.\textsuperscript{[4]}

2. COLLABORATION OF NUTRACEUTICALS
Nutraceuticals, foods or food components that help in prevention or treatment of disease, which is made from herbal/botanical raw materials. This is a rapidly growing industry (7-12% per year) with more than 100 million people using these natural products. With extensive anecdotal data on exciting health results, nutraceutical promise significant contributions to disease prevention. There are, however, barriers to the introduction of nutraceutical crops.\textsuperscript{[5,6]}
1. Common belief that only imported herbals/botanicals is effective.
2. Little data on the cultivation and adaptability of popular herbals/botanicals.
3. Little data on how to make nutraceutical a cash crop equal to more traditional crops.
4. Wide range of manufacturing processes with no attention to product extraction, effective "shelf life", storage, ingredient standards or contamination.
5. Pending federal regulations which could further restrict the supply of natural products.

3. NUTRACEUTICALS CATEGORIES: FOOD AS MEDICINES
Since the FDA does not formally screen and regulate nutraceuticals, the categories of nutraceutical can be somewhat wide-ranging.

3.1. Dietary Supplements: 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, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders which includes:
1. Probiotics and Prebiotic
2. Dietary fiber
3. Omega 3 fatty acid
4. Antioxidant

3.2. Functional Foods: Functional foods 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. Include oats, bran, cereals, and grains (known to prevent heart disease and colon cancer); yogurts and other probiotics (known to control intestinal flora); Omega-3-rich products like salmon (known to prevent heart disease); canola and other oils with lowered triglycerides (known to reduce cholesterol); plant stanols found in a variety of fruits, vegetables, and nuts (known to reduce cholesterol adsorption);

3.3. Botanicals: Includes ginseng, gingko biloba, saw palmetto, and other plant-based supplements;
3.4. Medicinal Foods: Includes transgenic plants (plants taken orally known to prevent infectious diseases); as well as food products enriched with medicines.[5,6]

4. NUTRACEUTICALS FOR RATIONALE USE
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, which has 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 favors a preventive treatment model as well.[7-10]

5. REGULATION OF NUTRACEUTICAL INDUSTRY IN INDIA
The Indian definition (as per Food Safety and Security Act passed in 2006, yet to implement). 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[10]. 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. [11]

A food stuff (as a fortified food or a dietary supplement) that provides health benefits, if indeed a claim was made that implied medicinal benefit regarding a nutraceutical product, the product would be required to comply with the regulatory requirements for medicinal products, in respect of safety, efficacy, and quality testing and marketing authorization procedures[12]. For decades, FDA regulated dietary supplements as foods to ensure that they were safe and that their labeling was truthful and not misleading. In 2006, the Indian government passed Food Safety and Standard Act to integrate and streamline the many regulations covering nutraceuticals, foods, and dietary supplements. The act calls for the creation of the Food Safety and Standards Authority (FSSA)
5.1. Food Safety and Standard Authority of India (FSSAI): Food Safety and Security (FSS) Act was passed by the parliament in 2006. In 2008, FSSAI came into existence. It has prepared the draft rules and regulations for implementation of FSS Act 2006 which is going through process of prepublication consultation. The FSSA has 12 chapters with 101 sections and two schedules. The FSSA incorporates the salient provisions of the Prevention of Food Adulteration Act 1954, and is based on international legislations, instrumentalities, and the Codex Alimentarius Commission.\[13\]

The aims to establish a single reference point for all matters relating to food safety and standards, by moving from multi-level, multi-departmental control to a single line of command. This unified Act, FSSA, will enable unidirectional compliance and address the need for a single regulatory body.

The FSSA establishes the Food Safety and Standards Authority of India (FSSAI) as an apex regulatory authority, consisting of a Chairperson and 22 members. In their endeavor to carry out the provisions of the FSSA, the FSSAI shall be assisted by a Central Advisory Committee (CAC), Scientific Panels (SPs), and a Scientific Committee (SC); each with specific responsibilities.

On September 5, 2008, the GOI notified the establishment of the FSSAI consisting of a chairman and members, who in turn will initiate the rule making process.\[14,15\] The implementation of the Act is reportedly in progress, and the FSSAI has notified its intention to the implementation of FSSA in a phased manner started from January, 2010.\[16\]

5.2. Nutrition Labeling and Education Act (NLEA): In 1990 (NLEA) defines how food is labeled, including nutrition labeling, in accordance with definitions established by FDA, and providing for the use of claims about the relationship between nutrients and diseases or health-related condition.

5.2.1. Benefits of Regulation

1. Allows greater legal security and more predictable environment.
2. Supports innovation (food and drink products).
3. Prevents unfair competition from manufactures using false or misleading claims.
4. If positive claims cannot be made, the regulation does not oblige anyone to make negative claims about the product.\[17,18\]
6. CURRENT SCENARIO
The Indian nutraceutical market valued at $1,480 million in 2011 could grow to $2,731 million in 2016, is expected. According to the report by business research and consulting firm, 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 that at present dietary supplements were the largest category accounting for 64 per cent of nutraceuticals market [19]. This market is driven primarily by the pharmaceutical sector in the form of vitamin and mineral supplements. 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 [20].

7. SCOPE AND OPPORTUNITY OF NUTRACEUTICAL MARKETS
Due to lack of clarity of specific regulations for registration of nutraceuticals and permitted additives, entrepreneurs intending to launch nutraceuticals in India are still facing the following scope and opportunity [20,21]

1. 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.

2. 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.

3. Some commonly used colors 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.
4. 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 for nutraceuticals, as it is necessary to treat this segment as an independent and unique entity under the Food Safety Standard Act, 2006. In 2012, the Indian Nutraceutical industry was estimated at US $ 2 Billion, roughly 1.5 percent of the global nutraceutical industry.\[22]\n
Currently the Indian market is trying to incorporate traditional herbal ingredients (usually ayurvedic) into the nutraceutical portfolio. Key example is the chyawanprash supplements market in India, which stood at US $74.5 Million in 2012. The existence of alternative medicine in India, and the Indian consumer’s belief in them, could provide a platform for the nutraceutical industry to capitalize on. The Indian consumer’s awareness about conventional nutraceutical ingredients such as omega-3 fatty acids or lutein is severely limited, and nutraceutical manufacturers need to take up the cause and spread awareness about their products to the Indian masses.\[23]\n
8. INDIAN NUTRACEUTICAL MARKET: TOWARDS SUCCESS

The nutraceutical market in India is growing at a compound annual growth rate (CAGR) of 18.46 per cent and is expected to be worth Rs 19,500 crore (US$ 3 billion) by the end of 2013-14, as per a recent research report. Divided into three segments dietary supplements functional foods and functional beverages, the Indian nutraceutical market is witnessing a shift in consumer buying behavior. Traditionally, Pharma dominated dietary supplement segment has been dominating the nutraceutical market but the changing consumer preferences has paved way for segments like functional food and functional beverages capturing a strong 67 per cent market share in India.\[23,24]\n
It is interesting to note that the domestic nutraceutical market is mainly concentrated in southern region of the country, followed by the eastern region with leading top three states being Andhra Pradesh, TamilNadu, and West Bengal. The urban-centric nutraceutical market
is gradually gaining ground in rural India with the rural market capturing almost 1/3rd of the total nutraceutical market in India. However, in terms of penetration, urban India still scores high at 22.51 per cent while it stands at 6.32 per cent in rural India. The Indian market currently holds a 2 per cent market share of the global nutraceutical market and is predictable to increase by manifold in the years to come.\textsuperscript{[22],[24]}

![Figure 1. Category of food supplements](image)

In India, market of nutraceutical over a broad spectrum of categories of food supplements which is shown in \textbf{fig 1}, which are approaching the higher degree of accuracy and growth through innovative approaches. A host of pharmaceutical and Fast Moving Consumer Goods (FMCG) companies are entering this market, other than Nutraceutical and Herbal/ Ayurvedic companies. Pharmaceutical companies consider nutraceuticals as an extension of the healthcare sector and lead the dietary supplement category. Meanwhile, FMCG companies are expanding by launching products in the functional food and beverage category. The domestic companies have a strong foothold with 55% of market share and international companies occupying 45%.\textsuperscript{[23]}

In India, functional foods are predictable to see increased consumption over the next five years resulting in functional foods and beverages garnering greater product share in the market as opposed to dietary supplements. The total Indian nutraceuticals market in 2015 is expected to be roughly US $ 5 billion\textsuperscript{[25]}. On the supply side, India will maintain a modest trade surplus in Nutraceutical ingredients as most of the country’s large pharmaceutical companies operate divisions that produce bulk medicinal and nutritional compounds. The distribution channels available for Nutraceutical shall play a vital role in the future growth of the business.\textsuperscript{[22]}
9. KEY GROWTH AREAS

9.1. Customization in India: It is currently not a prevalent trend, however is likely to pick up over the next few years. The potential for cultural customization and inclusion of natural ingredients is high in the region, given the high acceptance of alternative herbal medicines. Many of the natural products or their synthesized products used in various health issues, some of them are illustrated in fig 2. Moreover, India has emerged as a key sourcing destination for natural ingredients, thereby, allowing manufacturers easy access to their ingredients. [26],[27]

![Fig 2. Various nutrients used in various health issues.](image)

9.2. Innovative Delivery Formats: Nutraceutical ingredients have typically positioned as natural and healthy alternatives to traditional medicine. However one of the primary challenges being faced by these products is the difficulty in formulating these products into traditional food and beverage products. Consumers are also seeking more variety and benefits from delivery methods beyond those possible through traditional tablet and capsule technologies. Such challenges have caused for innovative product presentation to ensure ingredient viability and stability. Flavor masking has been one of the primary modes of supplying nutraceutical ingredients.

The prime examples as shown in fig 3 of innovative delivery of such masking have been for those of omega-3 and soy products, both increasing dynamic markets that were being hindered by the unpleasant taste of the ingredients as well as new formats of delivery such as electrolyte delivering strips and vitamin enhanced chewing gum. Manufacturers have cashed in on popular snacks and fortified them thereby allowing for a new lease of life for both the
nutraceutical as well as the convenience foods market. [27]

![Fig 3. Innovative Delivery Formats](image)

Food, beverages, and tobacco industry dominates the Indian retail industry and is anticipated to grow at a CAGR of nearly 8% during 2008-2012. Soft drinks market is anticipated to grow at a CAGR of nearly 12% from 2008 to 2012, and major demand will be seen in health & energy drinks, bottled water and fruit juices. Snack food market is estimated to grow at an annual rate of 18% to 20% in coming few years, albeit from a small base of consumers. With growing health awareness and concern, the functional food & drinks market is set to grow rapidly in India. Changing lifestyle coupled with growing middle class population and changing eating habits, is anticipated to fuel 7%-10% growth in the Indian food service sector annually. Low per capita consumption of alcoholic drinks makes the country highly lucrative to expand, with wine consumption projected to grow at a CAGR of nearly 23% in volume terms.[26]

10. MARKET GROWTH DRIVERS AND CHALLENGE

The increased awareness and preventive mind set with the rising ageing population, life style diseases and increased purchasing power will remain the key demand generators for nutraceuticals in India.

Lack of awareness coupled with lack of proper marketing and distribution, price skimming and low spending on food research are tough challenges hampering growth of Indian nutraceuticals market.[28]
Fig 4. Drivers leading to growth and key of challenges

The given fig 4 indicates that the drivers leading to growth in the market which includes increasing shift towards preventive therapies, increasing disposable income, increase in healthcare spending, increasing shift towards self-medication, changing demographics, growth in pharmacy and wellness related retail chains and favorable pricing environment. The key challenges to the market include lack of standardization, marketing and distribution challenges, high pricing and lack of awareness. Several trends have also been identified in the market and this has been provided in the next section. The key trends include fortified foods, ayurvedic nutraceuticals, foreign tie-ups, players educating consumers, encapsulation. A section on government regulations in the industry has also been included. It discusses the Food Safety and Standards Act 2006 that regulates the industry.\(29, 30\)

11. FUTURE PROSPECTS OF NUTRACEUTICALS

Currently Indian nutraceuticals market is highly urban centric. However with the rise of rural market and if the growth trajectory remains the same, Indian nutraceuticals market is going to be more than double of current market within next five years and by the end of current decade may become fivefold since the beginning of decade. Currently functional food enjoys largest share of the Indian nutraceuticals market followed by dietary supplements. This trend will drive the market for fortified foods and pro-biotic. With the rise of life style related diseases in urban India and penetration in rural India, the nutraceuticals products going to remain in high demand. “Though having healthy size of health conscious consumer segment in India, still market has not adopted nutraceuticals for regular consumption. Indian consumers are still at ‘awareness’ or somewhat ‘interest’ stage of product adoption cycle.
Nutraceuticals players need to redefine their marketing strategies to bring customers at ‘trial’ and ‘evaluation’ stage to harness the immense growth potential of Indian Nutraceuticals market”.[31]

Increasing awareness levels about fitness and health, spurred by media coverage are prompting the majority of people to lead healthier lifestyles, exercise more, and eat healthy. The expanding nutraceutical market indicates that end users are seeking minimally processed food with extra nutritional benefits and organoleptic value. This development, in turn, is propelling expansion in the nutraceutical markets globally. The emerging nutraceuticals industry seems destined to occupy the landscape in the new millennium. Its tremendous growth has implications for the food, pharmaceutical, healthcare, and agricultural industries. Many scientists believe that enzymes represent another exciting frontier in nutraceuticals. "Enzymes have been underemployed they're going to be a hot area in the future.” Fermentation technology using microbes to create new food products also represents potential. Global trends to healthy products cannot be reversed. Companies taking the lead by investing strategically in science, product development, marketing and consumer education will not go unrewarded.[32]

12. CONCLUSION

It is the wish of all people to live healthy. It is natural that people’s focus is shifting from medical treatment for sickness to a positive approach for prevention of diseases to stay healthy. In order to prevent diseases and be healthy, new food products, which have been proven by the human trials to be effective to prevent diseases, should gradually penetrate into the society. This will improve QOL (quality of life) of all people. India is currently a nascent market for nutraceuticals, without a concrete business model in place. Both MNCs as well as domestic companies in the pharmaceutical and food and beverage space have tested the market with a variety of launches, with some success. This has resulted in increased product launches in the recent past. However, in terms of ingredients, especially in the case of plant extracts and phytochemicals, Indian companies have entrenched their place as suppliers, both locally as well as globally. Globalization 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. Hence, when any new participant wants to enter the Indian nutraceutical market, it is very important to comply with the regulatory framework, so that the business is run smoothly.
13. REFERENCE


15. The Food Safety and Standard Authority of India New Delhi, India. FSSAI Announcements; http://www.fssai.gov.in/Notifications/ViewNotifications.aspx.


22. A brief report on Nutraceutical products in India by corporate crystal India, August 2013: 2-6.


27. Indian Nutraceutical Market: Poised from Neutral to Top Gare, Indian infoline services, August 23,2013.


31. http://www.indiainfoline.com, part of the IIFL Group, a leading financial services player and a diversified NBFC.