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Nutraceuticals: An overview of regulations

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Abstract

The mankind has been making medicines since ancient times. The term “Nutraceuticals” was coined by Dr. Stephen Defelice. Nutraceuticals is defined as any food supplement or dietary supplement which ensures good gut health and are intended to cure the chronic diseases. Now days Nutraceuticals are gripping the health market due to its various potential to cure the chronic diseases. With recent development of nutraceutical agents, many scientists and researchers are developing approaches for assessing information from clinical studies on alternative therapies into responsible medical practice. This review article describes the meaning of Nutraceuticals, various classes of Nutraceuticals, the regulatory consideration in different countries and the current scenario of Nutraceuticals in Indian health market.

Key words: Nutraceuticals, Food supplements, Regulations, Current scenario of Nutraceuticals

Introduction

In 1989 Dr. Stephen coined the term “NUTRACEUTICAL” which is a hybrid of nutrition and pharmaceutical. Another definition was suggested by Dr. Lockwood in his book, stating that “Nutraceuticals is the term used to describe a medicinal or nutritional component that includes a food, plant, or naturally occurring material which may have been purified or concentrated and that is used for the improvement of health, by preventing or treating a disease”.

Nutraceuticals means a naturally occurring chemical compound having a physiological benefit or provide protection against chronic disease, isolated and purified from food or non-food source and may be prepared and marketed in the food format of granules, powder, tablet, capsules, liquid or gel and may be packed in sachet, ampoule, bottle etc. and to be taken as measured unit quantities. The food supplements or dietary supplements which provide good health as well as cure the disease are included in Nutraceuticals products. Nutraceuticals plays an important role in controlling the lifestyle diseases. Nutraceutical products may range from isolated nutrients, dietary supplements and specific diets to genetically engineered designer foods and herbal products. Many countries have adopted different terminologies for Nutraceuticals and have defined it in different ways.

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To understand the regulation I put forward my own modification in the present Nutraceuticals definition as follows: any product isolated or purified from the food, herbs, mineral origin or their synthetic derivatives delivered in the pharmaceutical dosage form such as pills, tablets, capsules, liquid orals or lotions that has a component incorporated into it to give a specific physiological benefit against chronic disease is defined as Nutraceuticals.

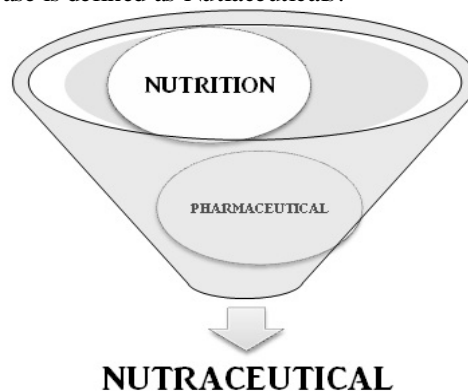


Fig. 1: Nutraceutical is a hybrid of nutrition and pharmaceutical

A number of consumers are turning to Nutraceuticals to improve health and prevent chronic disease because of healthcare costs and dissatisfaction with pharmaceutical agents. Hippocrates said that “let food be your medicine and medicine be your food”. Nutraceutical do not fall into the legit categories of

food and drug and often occupy the area between the two.

The concept of Nutraceuticals was started from the survey in UK, Germany and France which conclude or hereditary factors for achieving good health. [4]

The Nutraceuticals is an emerging industry that offers various opportunities to merge with discovery process to substitute the pharmaceutical agents with nutritional foods for the betterment of the consumers. Earlier, there was no regulatory definition for Nutraceuticals existed. Its meaning was modified by health ministry by Canada which defines Nutraceuticals as “a product isolated or purified from the food, generally sold in medicinal form not associated with food and demonstrated to have a physiological benefit. It also provides benefit against chronic disease”. [2, 3] Since ancient times, it is believed that foods not only provide source of various nutrients and energy but could also provide medicinal benefits. Based on this belief, Nutritional Therapy was introduced which heals the system using Nutraceuticals as a complimentary therapy. [8]

Health Benefits:

Nutraceuticals and functional foods may offer various health benefits. These are as follows:

- It avoids side effects.
- It increases the health value of the diet.
- It is perceived as more natural and less likely to produce side effects.
- It provides food with special needs (e.g. nutrient-dense foods for the elderly)

In the drug development process, the clinical test results from animal tests and studies are required for verification of the effects. Earlier, there was no verification method for foods in preventing lifestyle-related diseases. [4] To overcome this problem India has recently passed the Food Safety and Standards Act (FSSA) 2006. The passing of the Food Safety and Standards Act in India is a significant step, but much more has to happen regarding the laws and regulations. Yet, in India Nutraceuticals are not categorized separately as in the United States, Europe and Japan

Categories of nutraceuticals

Nutrients: The food provides various nutritional benefits such as vitamins, minerals, amino acid and fatty acid. The nutritional food products for dietary use are packed with vitamins & minerals along with natural herbs, antioxidants and dietary fiber which provide an ideal balance of nutrition without overloading unnecessary calories. Some of the common nutrients and their therapeutic benefits are shown in Table 1.

Herbals: The extracts and concentrates of herbs are used for their therapeutic activity. Nowadays, there are many nutraceutical products available in the market which holds a great promise to improve health and prevent chronic diseases with the help of herbals. The herbals provide various types of therapeutic benefits such as anti-inflammatory, anti-microbial, spasmolytic, diuretic, carminative, anti-pyretic etc. The various herbal products and their health benefits are mentioned in Table 2.

Dietary Supplement: Dietary supplements are those products which contain a dietary ingredient intended to add something to the foods you eat. They serve various functions such as sports nutrition, weight loss supplement, meal replacement. Supplements may contain vitamin, mineral, amino acid, fatty acid etc which can be administered in the form of tablets, capsules, liquids, powder, extracts and concentrates. Some of the examples of are as follows:

KETOGENIC DIETS- It comprises of foods with high and low protein, carbohydrate content, it improves seizure control and it is acknowledged to be palatable.

DIETARY FOODS- It contains friendly or probiotic bacteria claimed to promote gut health. Bio yogurts containing lactobacillus acidophilus & bifidobacteria lead the sector.

GLUCOSAMINE SULFATE AND CHONDROITIN SULFATE- They are effective and safer to alleviate symptoms of osteoarthritis.

Traditional Nutraceuticals: The foods in this category of Nutraceuticals are simply natural, whole foods with new information about their potential health qualities. Many fruits, vegetables, grains, dairy products contain several natural components that deliver benefits beyond basic nutrition such as lycopene, omega-3-fatty acid, saponin etc.

Non-Traditional Nutraceuticals: The food products which are prepared with the help of biotechnology are known as Non-Traditional Nutraceuticals. Food products which are engineered to produce food for human wellness comes under this category. The outcome from agricultural breeding or ingredients such as orange juice fortified with calcium, cereals with added vitamins or minerals and flour with added folic acid comes under the category of non-traditional Nutraceuticals. They are further classified into two types:

- a) **Fortified Nutraceuticals:** It constitutes fortified foods which are the outcome from the agricultural breeding or ingredients such as orange juice fortified with calcium, cereals with added vitamins or minerals and

flour with added folic acid, milk fortified with cholecalciferol etc.

- b) **Recombinant Nutraceuticals:** The production of energy-providing foods such as bread, alcohol, fermented starch, yogurt, cheese, vinegar and others are produced with the help of biotechnology.

Probiotics: There are certain bacteria which are believed to improve the gut health, heart diseases and various types of diseases. One of the common examples of a probiotic product is YAKULT which contains bacteria named lactobacillus Casei shirota which is known to improve gut health and maintains a healthy body.

Prebiotics: There are Nutraceuticals which promote the flourishing of probiotics. Before reaching the colonic region, the probiotic microorganisms have to survive the digestive enzymes and acids. To overcome this problem, Nutraceuticals in the form of prebiotics are available in the market. E.g. - Inulin (obtained from Chicory roots of *ichorium intibus*).

Nutraceutical market

Global Nutraceutical Market is growing rapidly due to increasing awareness about health, fitness and changing lifestyle. According to a study, the largest market for Nutraceuticals is the United States, followed by Asia-Pacific and the European Union. In Asia-Pacific, Japan is the largest market for nutraceutical with a CAGR of about 17%, followed by China (CAGR 10%). In 2008, the global nutraceutical market was estimated to be around \$117 billion, of which the India's share was 0.9%. The most rapidly growing segments of the Nutraceuticals industry were dietary supplements and natural/herbal products. [2] After the United States, Japan serves as the second largest market for Nutraceuticals and it is also believed that by 2020 china will take over this place due to the changing lifestyle of the middle class people of china. In today's world, consumers are more concerned about their health and the dietary supplements which improve the health. Therefore, with increasing health awareness, health care products, the Indian Nutraceutical Industry has shown a promising compound annual growth rate (CAGR) of 18% in the last three years.

The key players of nutraceutical industry are fast moving consumer goods companies and the pharmaceutical industries. In India, the companies which market nutraceutical products are GlaxoSmithKline, Dabur India, Cadila Healthcare, Himalaya Healthcare and Zandu Pharmaceuticals.

Market Demand for Nutraceuticals

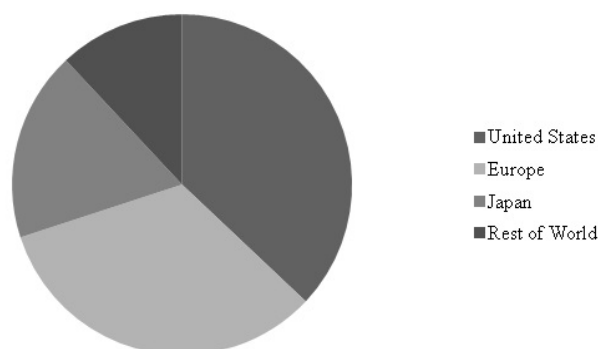


Fig. 2: Market demand for Nutraceuticals in 2016

Regulatory aspects of nutraceuticals in various countries

US Regulations

The FDA regulates Nutraceuticals in the same way they regulate all foods because Nutraceuticals have no official meaning or they do not belong to a distinct category of foods. The American food regulatory system is way more centralized than the European system. The Food and Drug Act (FDA) was enacted in June 1906 which prohibited interstate commerce of misbranded and adulterated foods, drinks and drugs. In 1938, Federal Food, Drug and Cosmetic Act (FDCA) was established which serves as a basic framework for food regulation by FDA and USFDA. The FDA plays a major role as it is responsible for taking actions against any unsafe dietary supplement and to ensure that it is safe before it is marketed.

In 1994, the United States introduced the Dietary Supplement Health Education Act (DSHEA) which showed a considerable flexibility between the food and medicines. It was established to regulate the manufacturing and marketing of Nutraceuticals. According to DSHEA, a dietary supplement may contain a "herb or other botanical" or "concentrate, metabolite, constituent, extract or a combination of any ingredient from the other categories". Under the Dietary Supplement Health and Education Act of 1994 (DSHEA):

Manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. That means that these firms are responsible for evaluating the safety and labeling of their products before marketing to ensure that they meet all the requirements of DSHEA and FDA regulations.

FDA is responsible for taking action against any adulterated or misbranded dietary supplement product after it reaches the market.

Indian Regulations

According to Indian legislation, there are no regulations for Nutraceuticals. If a claim was made that the Nutraceutical product implies nutritional benefit then the product would be required to comply with the regulatory requirements in respect of safety, efficacy, quality and marketing authorization procedures. For decades, FDA regulates the dietary supplements or Nutraceuticals to ensure that they were safe. Later in 2006, a regulation for Nutraceuticals i.e. Food Safety and Standards Act (FSSA) was passed by the Government of India which is yet to be implemented. The Food Safety and Standard Act, 2006 establishes the Food Safety and Standard Authority of India (FSSAI).

Food Safety and Standards Authority of India (FSSAI):

The FSSA came into existence in 2006 and the FSSAI was formed in 2008. It has 12 chapters with 101 sections and 2 schedules. The basic aim of FSSAI is to provide a reference for all matters relating to food safety and standards. The FSSAI is assisted by a Central Advisory Committee (CAC), Scientific Panel (SP) and Scientific Committee (SC). The Article 22 of the FSSA, 2006 addresses the need for regulations to manufacture, sell, distribute or import the food products.

Nutrition Labeling and Education Act (NLEA): In 1990, the labeling of food or nutrition was described by the NLEA in accordance with the definitions established by FDA. The Article 23 and 24 addresses the standards for packaging and labeling of food and restriction of advertisement regarding foods.

Current scenario of nutraceutical in India

In 2016, the nutraceutical market was expected to invest in Research and Innovation. The increasing consumer demands for Nutraceuticals drive the companies to bring in new innovative products. As the nutraceutical market is growing rapidly and more people are accepting nutraceutical products, the industry of nutraceutical is expected to go to mainstream.

Due to the increasing cost of drug products and awareness among people about other form of medicines led to an increase in the nutraceutical market. As drugs are known to have side effects along with being costly, people are shifting towards alternative medicines like Nutraceuticals. The regulations have started taking shape in India. There are various drafts and orders taken up by FSSAI to resolve the various issues related to the health of the

consumers but none of the drafts or orders has been finalized.

In nutraceutical market, the major challenges on the regulatory front are the lack of speed, lack of trust and understanding on behalf of the regulatory authorities.

The future of nutraceuticals

Nowadays, people are more aware of fitness & health and lead a healthy lifestyle. With the increasing rate of lifestyle-related diseases in rural & urban India, Nutraceuticals products remain in high demand. The expanding Nutraceuticals market shows that the Indian Nutraceuticals market is going to be more than double of the current market in the next 5 years.

The Indian market has not adopted Nutraceuticals for regular consumptions. 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.

To overcome the challenges faced by the regulatory front as well as to facilitate the business, the Indian legislation should implement certain policies. The policies should be in almost every area of Nutraceuticals business i.e. technical, innovation, R&D, regulatory, manufacturing, packaging and labeling, distribution and social aspects.

Conclusion

The market of Nutraceuticals is an emerging business in the world of pharma and the growth of Nutraceuticals in the forthcoming years are huge. The Indian Nutraceutical market is currently in a nascent stage. Nowadays, people are more focused towards fitness & health and lead a healthy lifestyle. This has resulted in increased Nutraceutical product launches in the recent past. Currently, there are no clear guidelines for Nutraceuticals in Indian legislation. In order to expand the Nutraceutical market, the government agencies should implement certain policies and regulations in order to maintain the purity and safety issues.

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