Vol. 12/2 (2012) 103- 107

JOURNAL OF NATURAL REMEDIES

Status of nutraceuticals in European Union with special emphasis on botanical sources

Baidyanath Mishra*

Regulatory Affairs, Natural Remedies Pvt. Ltd., 5-B, Veerasandra industrial estate, Electronic City, Bangalore-560100, INDIA

Abstract

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. Based on various aspects we may understand that "*Nutraceutical is 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.*" 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. In this review article, multifocal aspects of the nutraceutical, their usages and regulatory status in European Union are discussed.

1. Introduction

Nutraceuticals are food or food ingredients that have defined physiological effects. They do not easily fall into the legal categories of food or drug and often inhabit a grey area between the two. These products in general terms cover health promotion.

'Botanical nutraceutical' is coined to those nutraceuticals which are present with botanicals with proved and/or reported activities as one of the ingredients that extend health benefits. These group presents with additional challenges with various regulatory authorities because of their complex and composition particularly with respect to the quality aspects, which in turn affect safety parameters and over all efficacy of the products.

In this review article, regulatory status of botanical nutraceuticals as food supplement, food ingredient, functional and fortified food, novel foods and foods for particular nutritional use in the diversified, complex and ever-changing European regulatory environment are described.

2. Definitions and description

There is a lot of confusion regarding the terminologies like "nutraceuticals", "functional foods", "dietary supplements", "medical foods",

* Corresponding author
Email:baidyanath@naturalremedy.com, baidyanathmishra@hotmail.com

"pharma foods" etc. There seems to be thin dividing line in their interchangeable usage by different people on different occasions.

"Pharmaceuticals" may be considered as drugs used mainly to treat diseases, while "nutraceuticals" are those that are intended to prevent diseases. The above distinction between pharmaceuticals and nutraceuticals is adorable, but phony and mistaken. Pharmaceuticals are substances which have (or have had) patent protection as a result of expensive testing to conform to the specifications of respective Governments. However, many nutrients may never receive government approval since no one could justify the expense of testing requirements for substances that cannot be protected by patent laws. Both pharmaceuticals and nutrients can restore to health and thwart disease(s) but only pharmaceutical produucts have governmental sanction. Many pharmaceuticals have their origin sourced from botanicals and animals are no less "natural" than nutrients.

A dietary supplement is a product that is intended to supplement the diet that bears or contains one or more ingredients like, vitamin, mineral, a herb, an amino acid or a concentrate, metabolite, constituent, extract, or combinations of these. The use of nutraceuticals, as an attempt to accomplish desirable therapeutic outcomes with reduced side effects, as compared with other therapeutic agents has gained a wide reputation allowing an enormous globalization.

3. Significance of nutracueticals in promoting health

Basically to define, nutraceutical is a marketing term developed for nutritional supplement that is offered with the objective to augment health, treat, or prevent specific disease condition by modulating vitality and thus has no common regulatory definitions. Hence a "nutraceutical" is any substance that may be considered a food or part of a food and provides medical or health benefits, encompassing, prevention and treatment of diseases. Such products may range from isolated nutrients, dietary supplements and diets to genetically engineered "designer" foods, herbal products and processed foods such as cereals, soups and beverages. Thus, nutraceuticals differ from dietary supplements in the following aspects [1]: (1) nutraceuticals must not only supplement the diet but should also aid in the prevention and/or treatment of disease and/or disorder; and (2) nutraceuticals are used as conventional foods or as sole items of a meal or diet.

Scientifically, bio-fortified crops have been considered as a complementary strategy for delivering nutrition to malnourished populations. Dairy products that contain probiotic organisms such as *Lactobacillus* and *Bifidobacterium* species represent a new research area which improves gut health by modulating gut microbial composition. The ability of nutraceuticals to influence chronic diseases like diabetes, different types of cancers, etc. should be recognized as an enormous opportunity in their treatment [2]. It is of no doubt that these type of products will play important role in future therapeutic developments globally.

Practice of botanicals in complimentary medicine, nutraceuticals, functional foods and dietary supplements have been grown considerably in the last couple of years which is basically perhaps due to lesser adverse reaction and wide acceptability. Use of indigenous drugs from botanicals or plant origins forms a major part of complimentary therapies.

This has led to increased demand of medicinal plants and related products as an opportunity sector in Indian trade and commerce. Widespread and growing demand of the botanical derived medicines and functional foods have created a challenge in managing quality and safety as well. Regulatory authorities

of various countries have developed various guidelines addressing the botanical sourced products to safeguard in the interest of the public.

Nutraceuticals, dietary supplements etc., have received considerable interest because of their presumed safety and potential nutritional and therapeutic effects. Pharmaceutical and nutritional companies are aware of the success taking advantage of the more health-seeking consumers and the changing trends resulting in abundance of these value-added products aimed at various health benefits including those of metabolic disorders, cancer, and many other chronic disorders [3-4].

Majority of the functional foods are claimed to possess multiple therapeutic benefits though substantial evidence is lacking for the benefits as well as unwanted effects [5].

Some of the examples include

1. *Zingiber officinale*, one of the most widely used species of the ginger family, is a common condiment for various foods and beverages. Ginger has a long history of medicinal use in *Ayurveda, the science of life*. Various phytoconstituents present in the rhizome of ginger has been proved with anti-inflammatory and antiemetic activities. Some pungent constituents present in ginger and other zingiberaceous plants have potent antioxidant and anti-inflammatory activities, and some of them exhibit cancer preventive activity. The anticancer properties of ginger are attributed to the presence of certain pungent vallinoids, viz. [6]-gingerol and [6]-paradol [6].

2. Dietary fiber preparation from defatted rice bran has laxative and cholesterol-lowering ability with attendant benefits towards prevention or alleviation of cardiovascular disease, diabetes, diverticulosis and colon cancer [7].

4.Regulatory perspectives in European Union

Within European Union (EU) law the legal categorization of a nutraceutical is, in general, made on the basis of its accepted effects on the body. Thus, if the substance contributes only to the maintenance of healthy tissues and organs it may be considered to be a food ingredient. If, however, it can be shown to have a modifying effect on one or more of the body's physiological processes, it is likely to be considered to be a medicinal substance.

As coined by Dietary Supplement and Health Education Act (DSHEA,1994), a dietary supplement may contain 'an herb or other botanical' or 'a concentrate, metabolite, constituent, extract or combination of any ingredient from the other categories', a wide variety of botanicals and other substances have been sold as dietary supplement ingredients, including many that are considered to be medicinal substances under most regulatory regimes in EU countries [8].

Within European medicines law a nutraceutical can be defined as a medicine for two reasons:

1. If it presented for the prevention, treatment or cure of a condition or disease, or

2. If it can be administered with a view to restoring, correcting or modifying physiological functions in human beings.

In some EU countries, botanical products are sold as foods, or incorporated in functional/ fortified foods or as food supplements, meaning that no medicinal claims are made, whereas in other EU countries these preparations are seen as herbal medicines registered by full or simplified registration procedures. In some countries, the medicinal product status is automatically linked to pharmacy-only status.

If botanicals are categorized as food or food ingredient, Article 2 of Regulation (EC) No. 178/ 2002 giving the definition of a food ingredient must be taken into consideration. For example

whole foods with benefits beyond basic nutrition (for example, whole grain oats for cholesterol lowering effect), the material must be well identified and characterized [9].

In addition to the above related to the botanical sourced ingredients, Novel Food Regulation (EC) No. 258/97 defines a novel food as foods or food ingredients, which have not been used to a significant degree for human consumption in the EU before 15 May 1997. A comprehensive safety evaluation is required before approval for use in foods is given prior to the approval [10].

Directive 89/398/EEC defines foods for particular nutritional use (PARNUTS) as foods, "which, owing to their special composition or manufacturing process are clearly distinguishable from food stuffs for normal consumption, which are suitable for claimed nutritional purposes, and which are marketed in such way as to indicate such suitability". This category covers the dietetic foods. Examples are: infant formulae, baby foods for infants and young children, slimming foods, foods for special medical uses, sports foods, food for diabetics, etc.Food supplements are defined in Article 2 of Directive 2002/46/EC, as "Food stuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drops dispensing bottles and other similar forms of liquids and powders designated to be taken in measures small unit quantities" [11].

Traditional herbal products containing a dose of herbal substances or herbal preparations which is below pharmacological level will accordingly fall under food legislation. The posology/dosage and possible *pharmacological actions* should be considered on the basis of original or bibliographic data as a second decision point [11]. For Example:-

1. If the posology is equal or above the pharmacologically active dosage demonstrated by the studies or by bibliography related to medicinal use, the product is likely to be classified as medicine.

2. If the posology is lower or if such data do not exist, the product may be classified as a food supplement, if the conditions as set out by Directive 2002/46/EC (e.g. safety, listing) and other relevant legislationrelated to food (e.g. evidence for claims) are met.

Directives 89/398/EEC on "Food for special purposes" and Regulation (EC) No. 258/97 on "Novel Foods" that provide additional channel for some botanicals and botanical preparations further poses problem while carefully categorizing the botanicals under proposed positive listing to be annexed to Food Supplement Directive 2002/46/EC thus provides very limited opportunity.

5. Conclusion

The EU has not yet considered the concept of grades of evidence that includes "convincing", "probable", "possible" and "insufficient", but it is crucial to support scientific initiatives to find an approach where the term "generally accepted scientific data" include not only generic or well-established linkage between food and food components and health benefits, and to establish standards which should not be revoked or reversed by emerging science at a later stage. Earlier, the objectives of Indian food standards under PFA (Prevention of Food Adulteration Act) and those of food standards laid down by Codex Alimentarius were different. The emphasis under the PFA Act was on prevention of food adulteration. Standards laid down under PFA Rules were deemed to be minimum standards of quality whereas the aim of Codex Alimentarius is to develop standards with the object of promoting fair trade practices in

International trade and protect the health of consumers, whereas these queries/concerns have been answered in the present Food Safety Standards Authority (FSSA) Rules 2011. In India, effort was made to develop a food regulation that is of international standard for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. It was emphasized to bring the harmonization between food regulations laid down by Codex Alimentarius Commission (CAC) for a uniform global platform. In addition to the above, the Indian food regulations were comprised of various food laws that have been enacted at different points of time and are under the ambit of various ministries prior to the recent FSSA Act, 2006. Earlier the acts that were meant for various foods were : food laws resulting in many standard making bodies such as BIS under the BIS Act, CCFS under the PFA Act, Food Processing Ministry under the FPO, Agriculture Ministry under AGMARK. But there was no definite regulations existing for the supplements. By implementation of current food safety regulation (FSSA) in India, which is committed to provide better safety of the food, thus brings certain enforcements and regulations there of import, export, development, storage, transport, and sale as well which were not listed earlier for all food categories including of the supplements.

The work on the control of botanically derived substances and particularly herbs, in food supplements and other foods has barely started and controls of these ingredients in food supplements in EU. Looking for the wide varsity in guidelines, the companies wishing to market products in the EU will have to continue to assess their regulatory status in each member state.

References

1. Kalra E.K. Nutraceutical–Definition and Introduction. *AAPS PharmSci*. 2003, *5*, 25

2. Avrelija Cencic *et al*. The Role of Functional Foods, Nutraceuticals, and Food Supplements in Intestinal Health. *Nutrients* 2010, *2*, 611-625; doi:10.3390.

3. Liu R H. Potential synergy of phytochemicals in cancer prevention: mechanism of action. *J. Nutr*. 2004, *134*, 3479S-3485S.

4. Laparra J.M.; Sanz Y. Interactions of gut microbiota with functional food components and nutraceuticals. *Pharmacol. Res*. 2010, *61*, 219-225.

5. CSPI Reports. Public Health Boon or 21st Century Quackery? International, Functional Foods, Center for Science in the Public, 1998.

6. Anonymous. *Zingiber officinale*. Alternative Medicine Review .Vol. 8, No. 3. 2003. 331-335.

7. James M. Lattimer et al. Effects of Dietary Fiber and Its Components on Metabolic Health. Nutrients. 2. 1266-1289

8. Dietary Supplement Health Education Act (DSHEA) of 1994. Public Law 103–417, available at FDA Website: http://www.fda.gov.

9. Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

10. Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel and novel ingredients

11. Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of member states relating to food supplements.