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Review Article

DIETARY SUPPLEMENTS: A LEGAL STATUS IN INDIA & IN FOREIGN COUNTRIES

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ABSTRACT

Nutrition plays a very important role in the development of human resource. Human resource is one of the strengths of any stronger nation. A healthy population can lead the nation better in all the frontiers like education economics agriculture defence medical and other sciences in the Country. Therefore in all the countries depending on the nutritional status of the population and the availability of foods dietary guidelines are formulated. These dietary guidelines are the steps enable the population lead a healthy life. Demand of the dietary supplements are increasing on a greater fold in developing countries like the BRIC (Brazil, Russia, India, China) and some of the Asian countries and of course it has taken its own place in the developed world. In this communication we are highlighting some of the basic concepts and the legal status of the dietary supplements and other nutraceuticals in pharmerging market and in developed countries.

Keywords: Nutraceuticals, Dietary supplements, Regulation of the Dietary supplements, Legal status of Dietary supplements

INTRODUCTION

The term nutraceutical was coined in the USA and is used to describe foods or food components which have the potential to cure specific disease conditions[1-2]. In case of the nutraceuticals and dietary supplements vitamins and minerals in multiple ingredient product and as single ingredients remain very popular in the market. But now a day an enormous growth in interest in other ingredients such as carotenoids glucosamine isoflavones omega 3-fatty acids and probiotics substances for industries as well as public interest increases under the name of nutraceuticals, functional foods, food supplements in the developing as well as developed countries. The increase in such a demand may be due to awareness of the public about their health, in simple means we can say that public is becoming more and more health conscious because of the increase in the epidemiology of the mortal diseases as well as the change in the environmental condition in the developing country and in developed countries as well. The amount of information about the food supplement as well as nutraceuticals has grown exponentially during the last few years. Most of it appearing on internet and fully accessible to places to the public like shelves on the pharmacy store, supermarkets and shopping mall.

By seeing this trend in the enormous growing field there is a compulsion for the regulation of the standard as well as quality and safety of the nutraceuticals as well as dietary supplements for the concern of the public health as well as healthy competition among the manufacturers' of the same.

Individuals go with dietary supplements for many different reasons viz. to improve overall health and fitness to prolong vitality and delay the onset of age related problems as a tonic, for symptoms of stress to improve performance and body building in sports and athletics to prevent or treat various signs and symptoms associated with disease.

In the developed country nutraceuticals have become a part of the day to day life. It is used in disease condition such as joint pain, insomnia, rheumatoid arthritis, degenerative eye condition, enlarged prostate, perimenopause, weight management, cardiovascular health, immunomodulators and memory loss[3-4].

Recently a report published by the FICCI it is stated that Nutrition related risk factors contribute to more than 40% deaths in the developing countries including India. Around one fifth of the Indian population lacking the purchasing power to consume a diet which is rich in calories sufficient to uptake it on a day to day life[5]. From the above statement we can clearly say that although India is one of the largest producer of the food products but the people of India lacking nutrient uptake which are the causes of malnutrition.

Dietary supplements

A dietary supplement is a product taken by mouth that contains a dietary ingredient and / or a new 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. A new dietary ingredient is one that meets the above definition for a dietary ingredient and was not sold in the U.S. in a dietary supplement before October 15, 1994[6]. Numerous definitions and nomenclature for dietary supplements exist worldwide. Like Natural Health product in Canada, Dietary supplement in USA, Food for Special Health Use (FOSHU) in Japan, Biologically active Food supplements in Russia, Complementary medicine in Australia, Food supplements in European Union (EU) and Foods for special dietary use in India.

The Indian definition for the dietary supplements as per the Food Safety and Security Act 2006 list down the ingredients that a product should have and it also specifies general properties of nutraceuticals.

In the USA, the Dietary Supplement Health Education Act (DSHEA) 1994 defines a dietary supplement as a product (other than tobacco) taken by mouth that is intended to supplement the diet which bears or contains one or more of the following dietary ingredients: a vitamin a mineral a 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. It 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 and is labelled as a dietary supplement[6].

The European Union (EU) Directive on food supplements the term food supplements means: foodstuffs 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 drop dispensing bottles and other similar forms of liquids and powders designed to be taken in measured small unit quantities[7-8].

In the UK, the definition developed by the Proprietary Association of Great Britain (PAGB), British Herbal Manufacturers' Association (BHMA) and the Health Food Manufacturers' Association (HFMA) is that they are foods in unit dosage form e.g. tablets capsules and elixirs taken to supplement the diet. Most are products containing nutrients normally present in foods which are used by the body to develop cells bone muscle etc to replace co-enzymes depleted by

infection and illness and generally to maintain good health. This definition also covers ingredients such as garlic fish oils evening primrose oil and ginseng which can be taken to supplement dietary intake or for their suggested health benefits along with minerals and vitamins[9].

Differentiation of supplements from other foods is that they are consumed in unit quantities in addition to normal food intake. But in case of fortified foods and functional foods, to which nutrients are added along with supplements. From the above definitions we can also make a point that a major difference in the US definition is the inclusion of 'herbs or other botanicals' in the list of dietary ingredients[10]. In the UK herbal products are currently marketed under a variety of arrangements – either as fully licensed medicines, under the Traditional Herbal Medicines Product (THMP) Directive, 'medicines exempt from licensing' under section 12 of the 1968 Medicines Act, or as cosmetics or foods, so they do not fall entirely in the food supplements category[9].

Market trends

The market for nutraceuticals and functional foods are rapidly expanding throughout the world. But the market trend in the India, European country and USA are totally different. The nutraceutical industry has emerged as an important part of the food industry. Globally, the food industry is an evolved market. The processed food market is a whopping $ 3.2 trillion and contributes to three-fourth of the total world food sales. But these food industries are mainly grooming in the three region of the world, viz., USA, Europe and Japan[5]. These countries contribute greater than 50% of the packed food products they are shown in figure 1.

Today Indian food industry is in unique position with an impact of Green Revolution in the country. Around 26% of GDP in India come from food and agriculture. Apart from this tremendous growth in food industry the export of processed food from India rose only 1% during the span of 12 years from 1990 to 2002. During this period the export from the other Asian countries rose markedly. During this period the imports of processed foods in India increased from 20% to 41%.

The percentage of the nutraceuticals and functional food user are higher in USA and that's what the market analysis has a huge impact. In the nutraceuticals market the consumer preference of the formulation are shown in the figure 2 (USA survey, 2004).

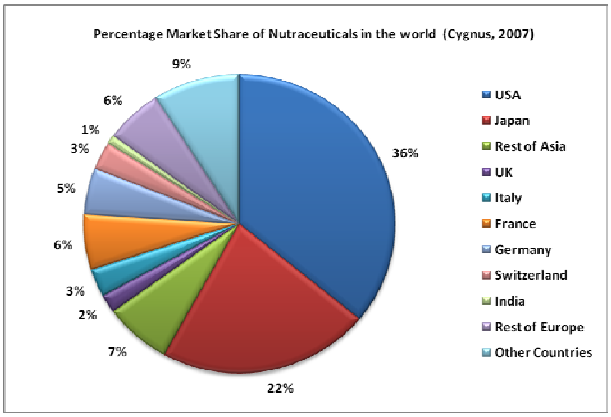

Fig. 1

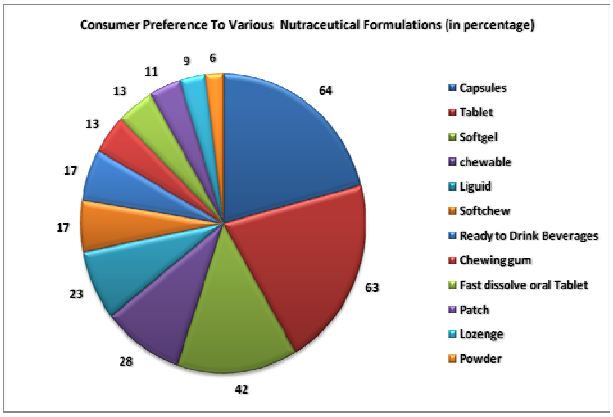

Fig. 2

According to Ernst & Young report Indian nutraceutical market in 2008 estimated US $ 1 billion. Of this functional food market, dietary supplement market and functional beverages market is estimated 54% 32% and 14% respectively. In 2013 the global nutraceutical market is expected to show growth rate of 7% CAGR and in India it is expected to show 11% CAGR in dietary supplement market. A report published by FICCI on nutraceuticals it is expected that among the nutraceutical market fuctional food functional beverages and dietary supplement market are expected to be of US $ 57 49 and 71 billion respectively in 2013. But in Indian nutraceutical market functional food market is largest followed by dietary supplement market but the functional beverage market is totally empty. According to this report the expected increase in the GDP of India upto 1.2% by 2015 related to the nutrition related disorder[5].

Legal status

India

India is one of the country, where the market of nutraceutical and dietary supplement growing enormously. Nutraceuticals and dietary supplements are sold in India under the name of Fast Moving Healthcare Goods (FMHG). Of course India has passed Food Safety and Standard Act in a year 2006 – a modern integrated food law to serve as a single reference point in relation to regulation of food products including nutraceutical dietary supplements and functional food[12]. The food safety and standard act has needed to still make considerably substantive with infrastructure and appropriate stewardship for it to match with international standards of U.S. and Europe. But till now India does not have the strict and clear cut guidelines related to the this fastly growing field. Many agencies viz. HADSA (Health Food and Dietary Supplements Association) , NIN (National Institute of Nutrition) FDTRC (food and Drug Toxicology Research Centre) NNMB (National Nutrition Monitoring Bureau) are working to set up a guidelines for this pharmerging field.

Health Foods and Dietary Supplements Association (HADSA) was formerly known as Indian Health Foods and Dietary Supplements Association (INHADSA). The name INHADSA was changed to HADSA in view of grant of registration of association as a Public Trust under section 18 of the Bombay Public Trust Act 1950 vide certificate no. 641 dated 19th April 2004[13]. Health Foods and Dietary Supplements Association is a national non-profit association founded in April 2002. HADSA works with the aim and objectives of to represent the interest of health foods dietary supplements nutraceuticals and healthcare industry in general comprising of manufacturers and suppliers of vitamins minerals botanical products sports nutrition products and herbs to support science based environment to ensure responsible marketing of health foods dietary supplements and nutraceuticals to promote and defend regulatory environment conducive to health foods dietary supplements nutraceuticals and healthcare industry in general as well as consumer protection to prevent eradicate malpractices if any in the health foods dietary supplements and nutraceuticals industry and to establish a code of ethics for observance by its members in the line with the prevailing regulations to initiate timely actions that are likely to improve the regulatory climate reputation and consumer confidence in health foods dietary supplements nutraceuticals and healthcare industry to secure the most favourable duty / tax structure for the health foods dietary supplements nutraceuticals and healthcare industry segment[13].

National Institute of Nutrition (NIN) was founded by Sir Robert McCarrison in the year 1918 at the Pasteur Institute Coonoor, Tamil Nadu. Within a short span of seven years this unit blossomed into a "Deficiency Disease Enquiry" and later in 1928 emerged as full-fledged "Nutrition Research Laboratories" (NRL) with Dr. McCarrison as its first Director. It was shifted to Hyderabad in 1958[14]. NIN has attained global recognition for its pioneering studies on various aspects of nutrition research with special reference to protein energy malnutrition (PEM). NIN is working under the aegis of Indian Council of Medical Research (ICMR). The objectives of NIN are to identify various dietary and nutrition problems prevalent among different segments of the population in the country to continuously monitor diet and nutrition situation of the country to evolve effective methods of management and prevention of nutritional problems to conduct operational research connected with planning and implementation of national nutrition programmes to dovetail nutrition research with other health programmes of the government to disseminate nutrition information to advise governments and other organisations on issues relating to nutrition. FDTRC (Food and Drug Toxicology Research Centre) and NNMB (National Nutrition Monitoring Bureau) are the part of the NIN. The main objectives of FDTRC are to study drug nutrient interactions particularly with reference to drug metabolism and toxicity and to evaluate and identify naturally occurring food ingredients which are rich in antioxidants hypoglycemic hypolipidemic and cancer prevention properties in relation to the nutrient and dietary supplements[15]. NNMB established by ICMR (Indian Council of Medical Research) in the year 1972 with a Central Reference Laboratory at NIN and units in the states of Andhra Pradesh Gujarat Karnataka Kerala Madhya Pradesh Maharashtra Orissa Tamil Nadu Uttar Pradesh and West Bengal. The main objectives of NNMB are to collect data on dietary intakes and nutritional status of the population in each of the States on a continuous basis, to evaluate the on-going National Nutrition Programmes, identify their strengths and weaknesses and recommend mid - course corrections to improve their effectiveness[16].

United Kingdom (UK) [17-19]

In the UK, the majority of dietary supplements are classified legally as foods, and sold under food law. There are just a few exceptions (e.g. Abidec, Pregaday, Epogam, Efamast, Maxepa and some generic vitamin and mineral preparations) which are licensed medicines. Unlike medicines, most supplements are not, therefore, subject to the controls of the Medicines Act (1968). Because supplements classed as foods do not require product licences, they do not have to go through such rigorous clinical trials, and are therefore much cheaper to put on the market than medicines. Dietary supplements are not controlled by quite the same strict conditions of dosage, labelling, purity criteria and levels of ingredients as medicines. Dietary supplements containing levels of vitamins in excess of those in prescription-only medicines are available to the public. However, in recognition of the fact that consumers are increasingly using high-dose products, the Food Standards Agency (FSA) Expert Group on Vitamins and Minerals (EVM) has published safe levels of intake for vitamins and minerals. Claims that can be made for supplements are currently regulated by food law as well as by European level. Advertising of dietary supplements is regulated by various advertising codes for both the broadcast media (TV and radio advertising standards codes) and the nonbroadcast media. These codes are policed by the Advertising Standards Authority (ASA), an independent body set up by the advertising industry.

European Union (EU)[7-8]

The diversity of regulation for food supplements has been wide across the countries of the European Union (EU), with several approaches to regulating vitamin and mineral supplements such that one product of the same strength (e.g. vitaminC 1000 mg) can be a food in one country but a medicine in another. However, the regulatory environment in Europe is changing rapidly. The European Commission has adopted Directive 2002/46/EC, which lays down specific rules for vitamins and minerals used as ingredients for food supplements (see http://europa.eu.int). All food supplements containing vitamins or minerals as well as other ingredients should conform to the specific rules for vitamins and minerals laid down in the Directive. The Directive was implemented in the UK in August 2005. The Directive includes a 'positive list' of vitamins and minerals permitted in food supplements, and a second list identifying the chemical substances that can be used in their manufacture. Only vitamins and minerals in the forms listed may be used in the manufacture of food supplements. However, until 31 December 2009, Member States may allow the use of vitamins and minerals not listed or in forms not listed provided that the substance was an ingredient in a food supplement marketed in the EC before 12 July 2002; the European Food Safety Authority (EFSA) has not given an unfavourable opinion in respect of the use of the substance, or its use in that form, in the manufacture of food supplements, on the basis of a dossier supporting use of the substance that had to be submitted to the Commission by the Member State not later than 12 July 2005. Specific rules concerning food supplements like fatty acids, amino acids, fibre, and herbal ingredients other than vitamins and minerals, which are having nutritional or physiological effect have also been included into the Directive. The Directive has also established maximum permitted levels of vitamins and minerals for food supplements. These are established by taking into account upper safe levels of vitamins and minerals by scientific risk assessment based on generally accepted scientific data, intake of vitamins and minerals from other dietary sources and the varying degrees of sensitivity of different consumer groups. Upper levels of vitamins and minerals unlikely to have adverse effects have been published by the EU Scientific Committee on Food (SCF), the UK Expert Vitamin and Mineral Group and the US National Academy of Sciences. The Directive also pays attention to advertising, presentation, purity criteria and labelling of content and dosage. Labels on dietary supplements express their nutrient content in terms of RDAs. EU RDAs are based on the requirements of men and are said to apply to average adults. They take no account of differences in nutritional requirements according to age, sex and other factors, and are therefore simple approximations used for labels only. Labelling should not imply that a varied and adequate diet cannot provide sufficient quantities of nutrients. In addition, 'medicinal' claims relating to the prevention, treatment or cure of disease in the labelling, advertising or promotion of food supplements are prohibited. Health claims are regulated by the Health and Nutrition Claims Regulation. Health claims such as 'calcium is good for your bones' may be used on a label so long as they are proven to apply to the food supplement in question. Within 3 years of the Regulation entering force, the Commission has to draw up a list of well-established health claims to be used on labels, and Member States has been asked to submit a list of claims already approved at national level. New health claims or any disease risk reduction claims such as 'calcium helps reduce the risk of osteoporosis' or 'X reduces cholesterol', will have to be assessed by the European Food Safety Agency (EFSA) and be approved by the Commission. In the UK, the work of the Joint Health Claims Initiative (see http://www.jhci.org.uk) has helped to inform health claims regulation at European level. This EC Regulation will also apply to trademarks. Within 15 years of the Regulation entering into force, existing brand names suggesting health benefits (such as promises of weight loss) that do not meet the requirements of the Regulation must be phased out and removed from the market. However, certain generic descriptors such as 'digestives' may apply for derogation from this rule.

United States of America (USA)[20-25]

In the USA, the Food and Drug Administration (FDA) regulates dietary supplements according to the Dietary Supplement Health and Education Act (DSHEA) 1994. Under this law, supplements are regulated in a similar manner to food products, while prohibiting their regulation as medicines or food additives. This Act includes a framework for safety, guidelines for third-party literature provided at the point of sale, guidance on good manufacturing practice (GMP) and labelling standards. Under DSHEA, manufacturers are responsible for marketing safe and properly labelled products, but the FDA bears the burden of proving that a product is unsafe or improperly labelled. However, the FDA has insufficient resources for doing this, and there is concern that not all supplements are marketed according to best standards of practice. DSHEA regulates

the labelling of supplements and the claims that can be made. This includes permissible statements describing the link between a nutrient and a deficiency or between a nutrient and its effect on the body's structure or function, or its effect on wellbeing. Examples include 'promotes relaxation' or 'builds strong bones'. But to make these claims, the supplement label must also carry the disclaimer: 'This statement has not been validated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease'. Under the US Nutrition Labelling and Education Act of 1990, a number of specific health claims are also permitted. These describe the link between a specific nutrient and the reduction in risk of a particular disease or condition and they are based on significant scientific agreement. Claims applicable to dietary supplements include those in relation to calcium and osteoporosis, folic acid and neural tube defects, soluble fibre (from oat bran and psyllium seed) and coronary heart disease and soya and coronary heart disease. Federal Trade Commission (FTC) regulates the advertisement related to dietary supplements.

International standards [26-29]

Global standards for vitamin and mineral supplements have also been developed and adopted at an international level by the Codex Alimentarius Commission. The Codex Alimentarius Commission or Codex was created by two UN organisations (the Food and Agricultural Organization and the World Health Organization) and its main purpose is to protect consumer health and ensure fair practice in international trade in food through the development of food standards, codes of practice, guidelines and other recommendations. The Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) is responsible for determining the need to develop standards and guidelines on the nutritional quality of foods, including dietary supplements. The Codex guidelines on vitamin and mineral supplements are voluntary and apply to supplements that contain vitamins and/or minerals that are regulated as foods. The guidelines address the composition of vitamin and mineral supplements, including the safety, purity and bioavailability of the sources of vitamins and minerals. They do not specify upper limits for vitamins and minerals in supplements, but provide criteria for establishing maximum amounts of vitamins and minerals per daily portion of supplement consumed, as recommended by the manufacturer. The criteria specify that maximum amounts should be established by scientific risk assessment based on generally accepted scientific data and taking into consideration, as appropriate, the varying degrees of sensitivity of different population groups. The guidelines also address the packaging and labelling of vitamin and mineral supplements.

Table 1: Regulatory agencies of some countries for the regulation of are listed in the

S. No.	Name of the country	Regulatory agency / agencies
1	India	Health Foods and Dietary supplements Association (HADSA) National Institute of Nutrition (NIN) Food and Drug Toxicology Research Centre (FDTRC) National Nutrition Monitoring Bureau (NNMB) Food Safety and Standards Authority of India (FSSAI)
2	US	Dietary supplement Health & Education (DSHEA) Act, 1994 Federal Trade Commission (FTC)
3	UK	Food Standards Agency (FSA) Expert Group on Vitamins and Minerals (EVM) Advertising Standards Authority (ASA) Medicines and Healthcare products Regulatory Agency (MHRA)
4	Brazil	Agência Nacional de Vigilância Sanitária (ANVISA) Ministério da Agricultura, Pecuária e Abastecimento (MAPA)
5	Japan	Food of Special Health Uses (FOSHU) Act Japan Health Food Association (JHFA) Japan Health Food and Nutrition Food Association (JHNFA)
6	Malaysia	National Pharmaceutical Control Board (NPCB) Drug Control Authority (DCA)
7	ASEAN countries¥	ASEAN Traditional Medicine and Health Supplement Product Working Group (TMHS-PWG) ASEAN Consultative Committee for Standard and Quality (ACCSQ) ASEAN Alliance Health supplement Associations (ASHSA)
8	Russia	Ministry of Health and Social Development
9	Canada	Food and Drug Authority
10	Australia	Department of Health and ageing

¥ASEAN countries include Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philipines, Singapore, Thiland and Vietnam.

Brazil [30-34]

In Brazil there is not updated official data, but it is estimated that this market turns around US$ 160 million by year, growing in an annual rate of 15%, while the synthetic medicines market grows around 4% by year. Considering the full productive chain, the herbal medicines sales comprise, yearly, about US$ 500 million (FEBRAFARMA, 2002) and this amount does not include the currency spending on handicraft products as well as at the popular marketplaces. The first regulation for herbal medicines was published in 1967 (Resolution 22/1967) by the extinct Serviço Nacional de Fiscalização da Medicina e Farmácia (SNFMF). This guideline defined all the essential aspects to the herbal medicines registration, such as the proper botanical identification of the drug, basic quality standards and the need of efficacy and safety proofs. That guideline has been periodically updated and the fourth and current version is the guideline RDC 48/2004.

The Ministry of Health of Brazil published two policies stating the role of medicinal plants and herbal medicines in Brazilian Public Health System: the National Policy of Integrative and Complementary Practice (PNPIC) in the Unified Health System (SUS)

- MS/GM 971/2006 (Ministério da Saúde/Gabinete do Ministro) and the National Policy of Medicinal Plants and Herbal Medicines (PNPMF, Decree 5813/2006). These documents have been promoting and stimulating the research and use of medicinal plants and herbal medicines (mainly from the Brazilian biodiversity origin), according quality, safety and efficacy statements. The trade of medicinal plants is regulated by Brazilian Law 5991/1973, which states: "Dispensing medicinal plants is privative from pharmacies and herb stores ("ervanarias"), obeyed the proper packaging and botanical classification" (BRAZIL, 1973). Currently, the Brazilian major authority for regulation of medicinal plants and derivatives is the Agência Nacional de Vigilância Sanitária (ANVISA). ANVISA was established in 1999 by Ministério da Saúde (MS) decree to "protect and promote people health ensuring the safety of products and services and take part in framing their access" (BRAZIL, 1999). Apart ANVISA, the Ministério da Agricultura, Pecuária e Abastecimento (MAPA) defines the regulation of herbal medicines for veterinary use and some classes of foods, such as drinks from herbal origin. In accordance to the Brazilian Law 986/1969, medicinal plants registered as food cannot present therapeutic claims. On the other hand, these products can be registered as "*special food*" that can present "functional" or "health" claims. According to ANVISA, functional claim means food has some role on growth, development, maintenance and other functions of the standard and healthy human body. A health claim, for instance, suggests or infers in a relationship between food with ailment amelioration or any other condition related to health. ANVISA guideline 18/1999 fixes the basic specifications for so-called functional or health properties on food labeling, while the guideline 19/1999 determines the requirements for its registration. Register food containing such claims should be supported by strong scientific information. Health claims - reference to the cure or prevention of disease - are not allowed. ANVISA also classify medicinal plants as "*new food*", defined as "foods or substances with no history of consumption in the country, or foods added by substances already consumed or used at much higher levels than those currently observed in the regular human diet". New food products label can bring functional health claims, but ANVISA guideline 16/1999 states that to apply to registration of these products, foods industries must present strong technical and scientific information about safety and functional and health claim evidence. Dried parts of plants can be register as "*Tea*", regulated by ANVISA guideline 23/2000, which provides the basic procedures for registration of these products. Teas are exempt from registration according to guideline RDC 278/05. The guideline RDC 267/2005, updated by guideline RDC 219/2006, fixes the technical requirements of plant species to prepare teas. Examples of medicinal species cited by these guidelines are: Camomila (*Matricaria recutita*), Capim limão (*Cymbopogon citratus*), Chá verde (*Camellia sinensis*), Erva cidreira (*Melissa oficinalis*), Erva doce (*Pimpinella anisium*), Guaraná (*Paullinia cupana*), Hortelã (*Mentha piperita*), Boldo (*Peumus boldus*) and Uva (*Vitis vinifera*). Considering all these plants have been used as food since ancient times, but also present pharmacological effects, these products comprise a gray area between food and medicine.

CONCLUSION

Among the BRIC countries Brazil leads the vitamins and minerals market. China is home to the second largest vitamins and minerals market, led by multi-vitamins, while its single minerals category displays rapid growth. Among the developed country manufacturing packaging labelling and marketing of nutraceuticals and dietary supplements are regulated by the well furnished and managed government regulatory body. But in the developing country like India there is no government body which can regulate the pharmerging and enormous growing INR 44 billion market field through to 2012 from INR 27 billion market in 2009. Ernst & Young Partner Muralidharan Nair pointed out that the global nutraceuticals market is US $117 billion (INR 5148 billion), of which India has less than 1% share but which is growing at a CAGR of 18% per annum[5].In the developing country there is no such a law like bioterrorism act as in US so the standard of the dietary supplements manufacturer are of very much concerned regarding safety and quality. Recently, USFDA has warned India and other developing countries about selling of recalled samples of the dietary supplements from the US market are being making their way through the medium of internet to the market of developing countries[35]. Though in the country like India government is running a national rural health program there is no authority which can control the advertising regarding the dietary supplements as well as nutraceuticals where most of the human resources reside in the rural areas of the country, where most of them are illiterate. Any misleading information that has been printed on to the label of the dietary supplements may lead to the mass consumption of the supplements and that may cause a huge casualty to the human resource. Though National institute of Nutrition have given a dietary guideline of about 14 topics its not enough for this enormous growing field and it needs an urgent attention of the government or the regulatory body in this direction.

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