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## Column

### Indian nutraceuticals market – The road ahead

Thursday, June 30, 2011  
Rajashree Sharma

“Let food be your medicine,” so said Hippocrates, the father of medicine, and focussed on prevention rather than cure.

The term “Nutraceutical” was coined from “Nutrition” & “Pharmaceutical” in late ‘80s by Stephen DeFelice, founder and chairman of the Foundation for Innovation in Medicine. It refers to extracts of foods, or parts of food or nutrients, that provide health benefits, including the prevention and treatment of a disease.

Nutraceuticals in the recent years have witnessed a tremendous increase in interest among consumers due to their potential of providing health benefits. Nutraceuticals can be defined as 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 to 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 authorisation procedures.

#### The categories

Nutraceuticals can further be broadly defined as nutrients that include substances which have established nutritional functions e.g. vitamins, minerals, amino acids, fatty acids, and so on and herbs or botanical products and the third category is dietary supplements such as probiotics, prebiotics, antioxidants, and enzymes. However, most common nutrients supplemented as nutraceuticals are minerals and vitamins, or in combination and or with other antioxidants. The Indian nutraceutical market is dominated primarily by the Fast Moving Consumer Goods (FMCG) and pharmaceutical industry.

#### Framing guidelines

Although India has no guidelines or regulations for the nutraceutical segment, the framework is underway. In order to achieve global acceptance, Government of India has taken certain initiatives 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.

The Food Safety & Standards Authority of India (FSSAI) is the apex body for food and nutrition and responsible for framing rules & regulations to govern the nutraceuticals market in India.

In 2006, the Indian government passed Food Safety and Standard Act (FSSA) to integrate and streamline the many regulations covering nutraceuticals, foods and dietary supplements. There were multiple laws and regulations covering the foods in India, but there was no single law that could have significantly regulated nutraceuticals and functional foods.



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### **The setbacks**

Further, the food safety administration is understaffed and around 250 food sample-testing labs are there which are not sufficient. India should gear up to increase number of testing labs & staff and enforce the upcoming regulation. With time, there will be a need to develop clinical documentation and establish a scientific basis to support health claims of safety & efficacy. There are also no subsidies for manufacturing nutra products in India because there is no regulation to control setting up of manufacturing units for such products. Since nutraceuticals are manufactured in pharmaceutical plants, current good manufacturing practice (GMP) guidance is followed during establishing such facilities as well as during the manufacturing of such products.

### **The new law**

The recently-held Nutra India Summit in Mumbai had 'innovate, collaborate, and accelerate' as its theme and focussed on outstanding issues that stakeholders wished to hear all these days. It was declared in the meeting that comprehensive law on novel food, food for special dietary use & functional food would soon be published and implemented and first cut draft was about to release.

Pertinently, the term 'nutraceutical' will not be used. According to the report the draft bill will cover the safety issues with regard to information provided to the consumers on products such as dietary supplement, functional foods, fortified food & infant food.

### **Labelling**

Nutraceuticals cover a wide range of products from novel food to probiotics & energy drinks to fat-free products. As reported, different categories of nutraceuticals will have different labelling such as special medical category will be labelled 'on medical advice,' novel food has to undergo risk analysis and marketing approval procedure. Special foods with a claim that they cure diseases will fall under the purview of drugs and not food. Proprietary food will not be included in a large way.

The lifestyle change, conscious about healthy living accelerated the growth of the nutra sector. There is a huge market potential since the sector is growing at Compounded Annual Growth Rate (CAGR) of 18%, though India's share in global market is minimal at 0.9 %.

### **Demand drivers**

The Indian nutra sector is driven by functional food & beverages. There is a latent market in India as the concept of nutraceutical is still infant and untapped and there is no regulatory framework in place. India should capitalise the opportunities to tap the latent nutra market to supplement India's healthcare agenda.

India and China are considered as fastest-growing markets as the products are gaining acceptance for their ability to address health issues. As per report, vitamins, minerals and nutrients constitute about 85% of the total nutra market while antioxidants and anti-agents account for 10% herbal extracts segment occupies 5% of the market globally.

The proposed legislation aims to establish a single window for all matters relating to food safety and standards, by moving from multi-level, multi-departmental control to a single line of command. It incorporates the salient provisions of the Prevention of Food Adulteration Act 1954 and is based on international legislations, Instrumentalities and Codex Alimentarius Commission and Codex approval would be significantly considered undergoing test on the basis of resource data for approval.

### **Scientific support**

The law will further take care of the need for scientific support for potential health claims for healthy foods as India is set to become a big player in this industry with its highly developed system of clinical documentation and scientific basis to support claims of safety and efficacy. Another issue was on constituting the panel for policy formulation and preparing separate guidelines for nutraceuticals. The panel comprised individuals from diverse backgrounds such as representatives from industries (not independent scientific experts) and scientific experts. However, the Supreme Court recently declared that their appointment is not in consonance with Section 13 (1) of the Prevention of Food Adulteration Act) and only specialised and experienced experts with sound experience should be the members. The panel will be reconstituted with a changed status of its members.

As health and wellness being the catchphrase, the claims attached to such products, are coming under scrutiny from regulators to protect the public from scientifically unsubstantiated claims. Once the law comes into force, health claims require to be

supported by scientific background & clinical reports. This will lead to clinical trials as companies also seek to build the science to support the efficacy and safety of their ingredients and products to develop credibility and capture the market.

#### **No magic bullets**

India has a great traditional knowledge base for nutraceutical products. Indian products are mainly based on the indigenous ingredients and herbal resources. However, we should keep in our mind that nutraceuticals potentially offer health benefits but they are not magic bullets against health problems. They are a positive, health-enhancing addition to an overall balanced diet and active lifestyle. The passing of the legislation will be a significant step. Further, nutraceuticals need to be categorised based on their natural ingredients as done in the US, Europe and Japan. A system of checks & balances, product recall, enforcement and so on should be in place. With the Indian regulatory body becoming more stringent, the market will grow in a much organised way in the future and there will be more Indian players, more collaboration among manufacturers, and public- private partnership in educating consumers about the benefit, India will be recognised as a huge market opportunity in coming years.

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