

Nutritionals Nutraceuticals Functional Foods Dietary Supplements

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GST A Major Business Reform

Old wine in a new bottle



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There is confusion over the terms nutraceuticals, dietary supplements, food supplements and pharmaceuticals. 'Nutraceutical' products may range from isolated nutrients, dietary supplements and specific diets to genetically engineered designer foods and herbal products. A dietary supplement is a product consumed through mouth that contains ingredients intended to provide health ingredients such as vitamins, minerals, enzymes, etc. They can also be herbal extracts or concentrates and may be found in many forms such as tablets, capsules, liquids or powders. Functional foods are also foods that have components or ingredients added to give it a specific medical or physiological benefit in addition to a purely nutritional effect.

In India, the practice of 'Ayurveda' lays emphasis on food and the Ayurvedic preparations are herbal products with health benefits and they are classified as pharmaceuticals. Thus there exists a very thin margin between 'Nutraceuticals and Pharmaceuticals; Dietary Supplements and Functional Foods. Hippocrates, the father of western medicine highlighted, around 2000 year ago 'Let food be your medicine and medicine be your food'. The Indians, Egyptians, Chinese, and Sumerians are just a few civilizations that have used food as medicine. In contrast to the natural herbs, spices and folk medicines are been used for centuries throughout Asia and the nutraceutical industry has grown alongside the expansion and exploration of modern technology.

In fact many of the drugs have been derived after being isolated from the plant like digoxin, aspirin, metformin, etc. Thus the growth of 'Nutraceuticals' appears to be like presenting old wine in new bottle.

Pharmaceuticals are normally considered as chemicals that affects physiological functions. While the chemicals derived from plants, or proteins and vaccines derived from animal sources may have distinction of being called as nutraceuticals. The major difference one may claim is that pharmaceuticals are designed specifically for medical use under a physician's supervision, and are subject to Food and Drugs Administration approval. Health supplements (including nutraceuticals, food or dietary sup-



plements) may do not need medical supervision, or Food and Drugs Control Administration approval. Canada divides nutraceuticals between 'functional food' and 'nutraceutical health products'. A functional food is similar in appearance to (or may be) a conventional food that is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions, i.e. they contain bioactive compounds. A natural health product is a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with foods. A natural health product is demonstrated to have a physiological benefit or provide protection against chronic disease.

Utilisation of the ancient knowledge of Ayurveda with other traditional practices of medicine such that it is scientifically acceptable has remained a great challenge. In spite of large amount of money spent by governmental funding agencies and pharmaceutical companies for research on herbal research, the return on investment is significantly less than anticipated. Conventional drug development is slow and expensive, taking 12 to 15 years and \$1,500 million, \$1,800 million to develop a new drug. Despite these massive and very expensive efforts worldwide, the industry R&D pipeline is relatively dry and the attrition rate of new drug entities is very high. The number of

new drug approvals is on decline. The life of a new drug in the market is short. There have been several safety problems with respect to new drugs. Despite very stringent and demanding regulatory processes, there have been several post approval or post marketing withdrawals of new drugs including some of the major blockers.

Recently, some of the leading visionaries and scientists have promoted the concept of 'Reverse Pharmacology' in India for the research strategies in Ayurvedic drugs. The process of development of natural medicine through Reverse Pharmacology approach has provided a number of phytoconstituents leads and hits. As a result 'Reverse Pharmacology' proved successful in development of formulations of

- 1) *Mucuna pruriens* for Parkinson's disease
- 2) *Arogyawardhani*, the *Picrorrhiza kurroa* for hepatitis
- 3) *Commiphora mukul* in Phase I trial in volunteers
- 4) *Rubia cordifolia* for eczema
- 5) *Saraca indica* for dysfunctional uterine bleeding
- 6) *Curcuma longa* for cancer prevention and urticarial

7) *Commiphora mukul* for rheumatoid arthritis

8) *Panchvalkal* (5 plants combination) for burns and infected wounds

9) Volatile essential oils of spices for antimicrobial activity and many more.

A systematic phytopharmacology research correlating kinetics and the dynamics of the natural products is now been adequately pursued. The strategy of Reverse Pharmacology seems to have been accepted internationally. Willcox and others have reviewed the development of anti-malarial drugs using Reverse Pharmacology approach from herbal sources.

Although, there is a growing market for nutraceuticals worldwide, there are regulatory concerns for the safety and efficacy for the products. This situation is not different than what existed and is currently going on for the pharmaceuticals. The origin of drugs by and large from herbal sources, as history reveals, cannot be undermined. With increase in new clinical applications nutraceuticals are likely to fall within the novel foods and ingredients regulations but their purity, dosage requirements and clinical consequences exceed those of most health foods.

Further, the fact that effects obtained from nutraceuticals are due to complex mixtures or due to one or more individual substrates are making the situation more complex. Thus, nutraceuticals will play an important role in future disease management. However, their success will be governed by control of purity, safety and efficacy without inhibiting innovation. The application of pharmaceutical standards, standardisation of formulations, dosage forms and production controls are likely to be a challenge and present a threat that could paralyse the industry. [NS](#)