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Scientific and regulatory aspects of nutraceuticals

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The term Nutraceuticals was coined by Dr. Stephen L. DeFelice, chairman of the Foundation of Innovation Medicine (FIM), New Jersey, USA. Dr. DeFelice defines Nutraceuticals as "food or part of food that provides medical or health benefits, including the prevention and/or treatment of a disease". The current market of Nutraceuticals in India is around Rs 4,400 crore which is expected to be more than double by 2013. Nutraceuticals can be classified as (i) Dietary supplements e.g. iron supplement capsules (ii) Functional foods e.g. table salt fortified with iodine, and (iii) Medical foods e.g. slowly digested carbohydrates used for management of diabetes mellitus. Health benefits of Nutraceuticals have been established through a number of scientific studies conducted around the world. For example, soy protein is found useful in reducing the risk of heart disease; dietary fibers are used to treat constipation; carotenoids, lutein and zeaxanthin can be used in the treatment of cataract etc. Manufacture, storage, distribution, sale and import of Nutraceuticals in India are regulated under the Food Safety and Standards Act, 2006. This Act consolidated the laws relating to food and established the Food Safety and Standards Authority of India for laying down science based standards for articles of food. However, no separate regulations for Nutraceuticals exists in India. This paper presents a review on latest research conducted on the health benefits of Nutraceuticals and throws light on the current regulatory aspects of Nutraceuticals in India.

Biography

Mr. Manish Sharma is presently pursuing M. Pharmacy in Pharmaceutical Management & Regulatory Affairs branch at Lachoo Memorial College of Science & Technology, Pharmacy Wing, Jodhpur, India.

Clinical research in India: The regulatory aspects

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The clinical research industry in India was estimated at $485 million in 2010 and is expected to reach at around $600 million by 2012. The country offers the advantages of low trial costs, large English speaking population, well-trained medical staff and large population of qualified patients with a set of regulatory framework and guidelines. In India, regulations for approval of clinical research are governed by the Drug Controller General of India (DCGI). The DCGI falls under the Central Drugs Standard Control Organization (CDSCO), which in turn operates under the health ministry. Schedule Y of the Drugs and Cosmetics Rules defines the requirements and guidelines on clinical trials for import and manufacture of new drugs for sale. An expert committee set up by CDSCO in consultation with clinical experts formulated the Indian Good Clinical Practices (GCP) guideline for generation of clinical data on drugs. In July 2011, CDSCO published draft guidance on approval of clinical trials and new drugs in India. As per this guidance for new drug substances discovered in India, clinical trials are required to be carried out in India right from Phase I. For new drug substances discovered in other countries, Phase I data generated outside India shall be submitted to the DCGI. Then, DCGI may grant permission either to repeat Phase I trials and/or to conduct Phase II trials and subsequently Phase III trials. Indian Council of Medical research (ICMR) prescribed the ethical guidelines for clinical research in India in 1980 and subsequently revised these guidelines in 2000 and later in 2006. The regulatory aspects to carryout clinical research in India are discussed in this presentation.

Biography

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