

A Comparative Study of Regulatory Registration Procedure of Nutraceuticals in India, Canada and Australia

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ABSTRACT

“Nutraceuticals” are the combination of Nutrition and pharmaceutical. The term Nutraceutical was given by Dr. Stephen in 1989. A dietary supplement is a product taken by mouth that contains a dietary ingredient (Vitamins, Minerals, Herbs, Amino acids etc.) Numerous definitions and nomenclature for dietary supplements exist worldwide. In India Food Safety and Standards authority (FSSA), defines Nutraceuticals as “foods for special dietary uses or functional foods or health supplements”. In Canada Nutraceuticals are known as Natural health Products. In Australia, traditional, herbal, natural and alternative medicines and remedies are referred to as ‘complementary medicines’.

Every country has their own guidelines, regulatory requirements which deal with regulatory registration procedures of Nutraceuticals. In order to enter the Indian nutraceutical market, some of the very important areas of focus include product evaluation, actual product analysis, procuring licenses and developing India specific health and label claims. In Canada Product licensing, Site licensing, GMP, Adverse drug reporting, Clinical trials & Health claims. And in Australia Product licensing, GMP, Site licensing, Labelling & Health claims are required.

Keywords: Nutraceuticals, Registration procedure of Nutraceuticals in India, Canada and Australia, Regulatory requirement of Nutraceuticals in different countries, Health Claims

INTRODUCTION

A dietary supplement is a product taken by mouth that contains a dietary ingredient (Vitamins, Minerals, Herbs, Amino acids etc.) and / or a new dietary ingredient intended to supplement the diet. 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 and Foods for special

dietary use in India. ^[1]

India: Nutraceuticals are known as “Foods for special dietary uses” in India. Food Safety and Standards authority (FSSA), defines “foods for special dietary uses or functional foods or nutraceuticals or health supplements” as:

a) foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition or specific diseases and disorders and which are presented as such, wherein the composition of these

foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist, and may contain one or more of the following ingredients, namely:

- i. Plants or botanicals or their parts in the form of powder, concentrate or extract in water, Ethyl Alcohol or Hydro Alcoholic extract, single or in combination;
 - ii. Minerals or vitamins or proteins or metals or their compounds or amino acids (in amounts not exceeding the Recommended Daily Allowance for Indians) or enzymes (within permissible limits);
 - iii. Substances from animal origin;
 - iv. A dietary substance for use by human beings to supplement the diet by increasing the total dietary intake;
- b) (i) A product that is labeled as a "Food for special dietary uses or functional foods or nutraceuticals or health supplements or similar such foods" which is not represented for use as a conventional food and whereby such products may be formulated in the form of Powders, Granules, Tablets, Capsules, Liquids, Jelly and other dosage forms but not parenterals, and are meant for oral administration;
- (ii) Such product does not include a drug as defined in clause (b) and Ayurvedic, Sidha and Unani drugs as defined in clauses (a) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made there under;
- (iii) Does not claim to cure or mitigate any specific disease, disorder or condition (except for certain health benefit or such promotion claims) as may be permitted by the regulations made under FSSA;
- (iv) Does not include a narcotic drug or a psychotropic substance as defined in the Schedule of the Narcotic Drugs and Psychotropic Substances Act, 1985 and rules made there under and substances listed in Schedules E and EI of the Drugs and Cosmetics Rules, 1945. [2]

Canada: According to Health Canada, A nutraceutical, is a product that is isolated or purified from foods that is generally sold in medicinal forms not usually associated with food, such as powders, tablets or capsules. It is demonstrated to have a physiological benefit, or to provide protection against chronic disease. AAFC describes nutraceuticals as products extracted, purified or produced from a plant, animal or marine source (e.g.

antioxidants from blueberries, elk velvet, fish oils), or produced from dried, powdered, or pressed plant material, such as ginseng. Omega-3 and lycopene capsules are examples of nutraceutical products that are sold in Canada. [3]

Natural Health Products (NHP): In Canada Nutraceuticals are known as Natural health Products. Under the Natural Health Products Regulations, which came into effect on January 1, 2004, natural health products (NHPs) are defined as:

Vitamins and minerals

Herbal remedies

Homeopathic medicines

Traditional medicines such as traditional Chinese medicines

Probiotics

Other products like amino acids and essential fatty acids

NHPs must be safe to use as over-the-counter products and not need a prescription to be sold. Products needing a prescription are regulated as drugs under the Food and Drug Regulations. [4]

Australia:

Complementary medicines: In Australia, traditional, herbal, natural and alternative medicines and remedies are referred to as 'complementary medicines'.

Complementary medicines include herbal medicines, vitamins, minerals and other nutritional supplements, Australian indigenous medicines, traditional Indian medicines, traditional Chinese medicines, homeopathic medicines and aromatherapy products. They may be of herbal or non-herbal origin. In complementary medicine, 'herb' means any part of a plant traditionally used as medicine and may include the leaf, flower, stem, root, fruit or bark of the plant. Some complementary medicines are made or supplied by naturopaths, homeopaths, herbalists and other practitioners, and some can be purchased from pharmacies and other shop. [5]

Regulatory Work: Nutraceuticals are regulated by different authorities in different countries.

India: Nutraceuticals are known as "Food for special dietary use" In India they are regulated by FSSAI (Food Safety and Standards Authority of India) which has been established under Food Safety and Standards Act, 2006. The Food Safety and Standard Rules, 2011 have been

S. No.	India	Canada	Australia
Definition	FSSAI define Nutraceutical as “Foods for Special dietary use”	NHPD define Nutraceutical as “Natural Health Products”	TGA define Nutraceutical as “Complementary Medicines”
Rules/Regulations for licensing and registration	The Food Safety and Standards Regulations	Natural Health Products Regulations	Therapeutic Goods Regulations.
Regulations came into force in year	2011	2004	1989
Responsible Regulatory authorities for Registration of Nutraceuticals	Food Safety and Standard Authority of India (FSSAI)	Natural Health Product directorate (NHPD), Health Canada	Therapeutic Administration (TGA)
Regulatory Requirements for Registration	A. Product evaluation B. Licenses C. Health & label Claim	A. Product licensing B. Evidence requirements for Safety & efficacy C. Labelling D. Site Licensing E. GMP F. Adverse Reaction reporting G. Clinical Trials	A. Product Application B. GMP C. Labelling D. Post-market Surveillance
Fees for registration	Rs. 100	Currently No fees required	\$AUS 720
Claims Approval Authority	FSSAI	Health Canada	FSANZ
Health Claims	1) Nutrient function claim, 2) Other function claims, 3) Reduction of disease risk claims	General Health Claims Specific Health claims	General Level Health Claim High Level Health claim

issued, effective from 5th May, 2011. The Food Safety and Standard Authority have also issued regulations about licensing and registration of food business, packing and labelling, food products standard and additive etc. In order to enter the Indian nutraceutical market, some of the very important areas of focus include product evaluation, actual product analysis, procuring licenses and developing India specific health and label claims.

Regulatory requirements in India:

1) Product evaluation: In order to perform product assessment as per Indian regulatory definition, it is of utmost importance to examine each active ingredient and additive in the context of permissibility, standards and dosage of vitamins / minerals allowed as per the Therapeutic, Prophylactic or Recommended Daily Allowance for Indians.

2) Licenses: To get a product registered in India, number of licenses (almost 4 - 5) might be required, depending on the actual product status.

3) Health & label claims: Developing health and label claims, specific to Indian regulatory guidelines, is a major element to be considered while entering the Indian market. Health Claims: “Health claims” means any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health and include the:

Nutrition claims which describes the physiological role of the nutrient in growth, development and normal functions of the body.

Ex: Food A is rich in calcium and calcium is good for bone health.

Other functional claims concerning specific beneficial

effect of the consumption of food or its constituents, in the context of the total diet on normal function or biological activities of the body and such claims relate to a positive contribution to health or to the improvement of function or to modifying or preserving health, or disease.

Ex: Food A is low GI food. Low GI food helps in sugar management.

Health claims can further be grouped into nutrient function claims, other function claims and reduction of disease risk claims.

Canada: In Canada Nutraceuticals are known as “Natural health products” (NHP) under the Natural Health Products Regulations, which came into effect on January 1, 2004. Natural health products are regulated by Natural Health Product directorate (NHPD), Health Canada.

Regulatory requirements in Canada:

Product Licensing: All natural health products must have a product licence before they can be sold in Canada. To get a licence, applicants must give detailed information about the product to Health Canada, including: medicinal ingredients, source, dose, potency, non-medicinal ingredients and recommended use(s).

Evidence requirements for Safety & efficacy: The safety and efficacy of NHPs and their health claims must be supported by proper evidence so that consumers and Health Canada know the products are indeed safe and effective.

Labelling: All NHPs must meet specific labelling requirements, to help make safe and informed choices about the NHPs which are chosen to use.

Site Licensing: A Site licence issued by the NHPD (Natural Health Products Directorate) gives the licensee authorization to manufacture, package, label and/or import NHPs.

Good Manufacturing Practices: Good Manufacturing Practices make sure proper standards and practices for the testing, manufacture, storage, handling and distribution of natural health products are met.

Adverse Reaction Reporting: The Natural Health Products Regulations require product licence holders to monitor all adverse reactions related to their product. License holders must report serious adverse reactions to Health Canada.

Clinical Trials: A clinical trial is when natural health

products are tested using human subjects.

Health Claims in Canada: health claim for food is considered to be “any representation in labeling and advertising that states, suggests, or implies that a relation exists between the consumption of foods or food constituents and health”

Types:

1) Specific health claims: are claims about the effects of a food, or food constituent, on a specific organ, disease, biomarker, or health condition.

2) General health claims: are claims that do not refer to a specific health effect, disease or health condition (e.g., broad “healthy for you” or “healthy choice” claims that promote choosing a food for overall health, promote healthy eating, or provide dietary guidance).

Australia: Nutraceuticals are referred to as 'complementary medicines' and are regulated as medicines under the Therapeutic Goods Act 1989.

Regulatory requirements in Australia:

Product licensing: All Complementary medicines (CMs) must be entered (on application to the TGA) in the ARTG.

Good manufacturing practice: All products must be manufactured in compliance with GMP.

Site licensing: The TGA licenses manufacturers and audits GMP compliance.

Labelling requirements: Registered medicines (higher risk) are identified on the label by AUST R followed by a unique number. Listed medicines (low risk) are identified on the label by AUST L followed by a unique number.

Post-market regulatory activity: The TGA takes a risk-based approach to post-market surveillance.

Health Claims in Australia:

General level claims: General level claims are claims where the manufacturer has to make an assessment of the evidence supporting the claim prior to the product going to market, and to hold the evidence.

High level claims: High level claims are those claims which make reference to a serious disease, including: Claims that refer to the potential for a food or component to assist in controlling a serious disease or condition.

RESULTS

From the above dissertation work we have been enlighten with the Comparative Study of Nutraceuticals Registration in India, Canada and Australia. There are number of Licenses, Application forms, Product evaluation, Health Claims etc. essential for registration of nutraceuticals. In India Nutraceuticals known as “Foods for Special dietary use” regulated & registered by FSSAI (Food Safety and Standards Authority of India), In Canada they known as Natural health products regulated and registered under NHPD (Natural health product Directorate), in Australia they Known as Complementary medicines regulated & registered by TGA (Therapeutic goods Administration). Approvals of Health Claims are essential for registration.

CONCLUSION

Nutraceuticals are playing an important role in the development of future therapeutics but it depends on the control of purity, efficacy and safety. Hence, when any new Product/entrant wants to enter in the Nutraceutical market of particular country, it is very important to comply with the regulatory framework of that country, so that the business is run smoothly. The focus areas should be product evaluation for each active ingredient in the context of permissibility, standards and dosage of vitamins/minerals allowed, product classification as per various healthcare laws (legal definition of the product), Country-specific health & label claims and advertising.

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