IJBPAS, December, 2022, 11(12): 5856-5863

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

MARKETING AUTHORIZATION REQUIREMENTS FOR HERBALS & NUTRACEUTICALS IN INDIA, SINGAPORE AND SAUDI ARABIA: A REGULATORY OVERVIEW

BALAMURALIDHARA V[1*], DEEKSHA K S[2], RAMYA SHREE G[3] AND S. SUMAN SHEKAR[4]

1: Associate Professor- Regulatory Affairs Group, Department of Pharmaceutics, JSS College of Pharmacy, Mysuru, Jagadguru Sri Shivarathreeshwara University, Mysore – 570 015, Karnataka, India

2: PhD- Research Scholar, Regulatory Affairs Group, Dept. of Pharmaceutics, JSS College of Pharmacy, Mysuru, Jagadguru Sri Shivarathreeshwara University, Mysuru-570015, Karnataka, India

3: Research Student, Regulatory Affairs Group, Dept. of Pharmaceutics, JSS College of Pharmacy, Mysuru, Jagadguru Sri Shivarathreeshwara University, Mysuru-570015 Karnataka, India

4: Regulatory Affairs Group, Department of Pharmaceutics, JSS College of Pharmacy, Jagadguru Sri Shivarathreeshwara University, Mysore-570015, Karnataka, India

***Corresponding Author: Dr. Balamuralidhara V: E Mail: baligowda@jssuni.edu.in**

Received 26th Dec. 2021; Revised 25th Jan. 2022; Accepted 12th March 2022; Available online 1st Dec. 2022

https://doi.org/10.31032/IJBPAS/2022/11.12.6654

ABSTRACT

Herbals and nutraceuticals are collective terms that refer to any product obtained from a natural or food source. Nutraceuticals are herbal powders or capsules created from vitamins, minerals, and plants that have unique therapeutic qualities that aid in the prevention and treatment of disease. Herbal medicines are preferable to conventional pharmaceuticals because they are less expensive, have less side effects, and incorporate a natural healing process for boosting the immune system. The market for herbal nutraceuticals would be considerably impacted by the growth of herbal medicines and their medical products. By

2026, the Global Herbal Nutraceuticals Market is estimated to reach $64.3 billion, growing at a 11.4% compound annual growth rate during the forecast period. The major purpose of this study is to get an understanding of the herbal and nutraceutical marketing authorization/registration procedure in emerging markets, including India, Singapore, and Saudi Arabia. In general, there is no specific regulation/guidance document for this product worldwide; nonetheless, different nations have unique registration methods; so, this study provides an overview of the registration procedures in the aforementioned countries. Comparative analysis enables an understanding of the numerous distinctions between emerging market registration processes. The primary objective is to gain a better understanding of the influence of regulatory and quality requirements on the herbal and nutraceutical product registration process in emerging markets.

Keywords: Herbals, India, Marketing Authorization, Nutraceuticals, Singapore, Saudi Arabia

INTRODUCTION:

Nutraceuticals

In the phrase "nutraceutical," the words "nutrient" (a nourishing dietary component) and "pharmaceutical" (a pharmaceutical product) are combined (a medical drug). The name was coined in 1989 by Stephen DeFelice, the founder and chairman of the Foundation for Innovation in Medicine, an American organisation based in Cranford, New Jersey, which was founded by DeFelice in 1989. Despite the fact that the phrase nutraceutical is often used in marketing, there is no regulatory meaning for the term.

According to DeFelice, "A nutraceutical is any substance that is a food or a part of a food and provides medical or health benefits, including the prevention and treatment of disease. Such products may range from isolated nutrients, dietary supplements and specific diets to genetically engineered designer foods, herbal products, and processed foods such as cereals, soups and beverages **[1]**."

Generally nutraceuticals are classified based on the source **[2]**:

Plant	**tomato , garlic, fruits**
Animals	**shark liver oil, cod liver oil**
Minerals	**Iron, Calcium, magnesium, phosphorus**
Micro – organisms	**Probiotics, lactobacilli**

Herbals

Herbs

Herbs include crude plant material such as leaves, flowers, fruit, seeds, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.

Herbal materials

Herbal materials are either complete plants or raw portions of therapeutic plants. Herbs, fresh juices, gums, fixed oils, essential oils, resins, and herb dry powders are among them. In other nations, these materials may be prepared using a variety of local methods, such as steaming, roasting, or stir baking with honey, alcoholic beverages, or other ingredients.

Herbal preparations

Herbal preparations are the foundation for completed herbal products and might comprise comminuted or powdered herbal materials, extracts, tinctures and fatty oils, expressed juices, and processed exudates of herbal materials. They are created through extraction, distillation, expression, fractionation, purification, concentration, fermentation, or other physical or biological processes. They also include preparations created by steeping or heating herbal components in alcoholic beverages and/or honey, or in other materials **[3]**.

Regulation in India

The Food Safety and Standards Authority of India (FSSAI) is a government body that has launched an online application system known as the Food Licensing Registration System (FLRS) to enable Food Business Operators (FBOs) to apply for fssai registration, fssai state licence, and fssai central licence certificate in accordance with their firm's turnover. FBOs can track their applications on the FLRS system using the reference number provided by FSSAI when Following approval of registration/licensing, the Department will send a copy of the fssai registration certificate or licence copy to the FBO by email, using the email address that the FBO has submitted to the FLRS System. The FSSAI Department would need a total of 75 working days to complete the process. For a maximum of 5 years, FBOs can submit an application through a fssai licencing consultant through the FLRS system **[4]**.

In India, Herbal Medicines are being used in Ayurveda, Siddha, Unani, Homeopathic system of medicine. Initially there was no regulation for controlling the quality of medicine and to identify the source of the plant. Gradually some regulation developed and the first organized regulation on Quality is Drug & Cosmetic Act 1940 & Drug & Cosmetic Act 1945 **[5]**.

Regulation in Singapore

In Singapore, Health Supplements and Traditional Medicines regulated by Health Science Authority. Heath Supplements & Traditional Medicines contain low- risk ingredients and the substance derived from natural sources, and not intended to diagnosis, treat or prevention of any diseases.

Health supplements and traditional medicines are, as a result, exempt from pre-market clearances and licencing

requirements for their manufacturing, importation, and sale in Singapore, in contrast to medicines that contain powerful medical components. Dealers are required to confirm the safety and quality of their health products before they may be promoted, according to the Health Sciences Authority (HSA) **[6]**.

Regulation in Saudi Arabia

The goal of the SFDA establishment is to supervise, manage, and control food, drugs, and medical equipment, as well as to establish required standard requirements for these products, regardless of whether they are imported or manufactured in the country where they are produced **[7]**. The SFDA is in charge of checking the quality and efficacy of health and herbal goods, as well as assuring their safety -and supervising manufacturing facilities-, as well as overseeing the importation and registration of these items **[8]**.

Comparison of Herbals in Emerging Markets

Herbals	India	Singapore	Saudi Arabia
Regulatory agency	Ministry of AYUSH	Health Science Authority	Saudi Food & Drug Administration
Classification	ASU Drugs	Complementary Health Product	Drug Sector
Regulations	Drugs and Cosmetics Act, 1940 Drugs and Cosmetics Rules,1945	No regulation	Data requirements for herbal & health products
Input Application	Form 24D	NA	Marketing Authorization Application of Herbal Product
Mode of Submission	Paper submission	NA	Electronic or Paper
Format of Submission	Country Specific	NA	eCTD Format
Critical Documents for Submission	- Site Registration - Academic Qualification - Labels - Drug Information	NA	- Labeling Requirements - GMP Certificate - Free Sale Certificate - Declarations
Fees	1000/-	NA	
Quality Requirements(GMP)	As per Schedule T	As per PIC/s guidelines	Available
Approval Timelines	3 months	NA	155 days
Output approval	Manufacturing License	NA	Marketing Authorization Certificate
Validity	5 years	NA	5 years

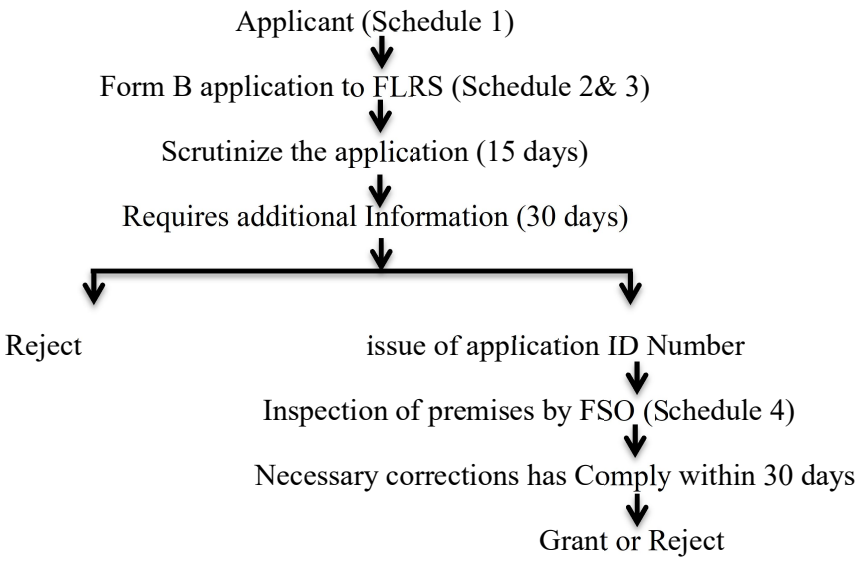
Comparison of Nutraceuticals in Emerging Markets

	India	Singapore	Saudi Arabia
Regulating agency	**Food Safety & Standards Authority of India**	**Health Science Authority**	**Saudi Food & Drug Administration**
Classification	**Food**	**Complementary Health Products**	**Drug**
Regulations	**FSSA 2006 FSSA regulation 2011**	**No regulation**	**Data requirements for herbal & health products**
Input application	**Form B**	**NA**	**Marketing Authorization Application of Herbal Product**
Mode of submission	**Online through FLRS Portal**	**NA**	**Electronic or Paper**
Format of submission	**Country Specific**	**NA**	**CTD Format**
Critical Documents	**- Form B - Labels - Site Registration - Food Category**	**NA**	**Labeling Requirements - GMP Certificate - Free Sale Certificate - Declarations**
Fees	**7500/-**	**NA**	
Quality requirements(GMP)	**Yes**	**Limits of heavy metals Microbial contamination limits**	**Yes**
Approval Timelines	**Approx. 60 days**	**NA**	**155 days**
Output approval	**FBO/Manufacturing License**	**NA**	**Marketing Authorization Certificate**
Validity	**1-5 years**	**NA**	**5 years**

Registration Process:

India: [9]

Regulatory Pathway for FBO License: (approx. 60 days)



Saudi Arabia: [10]

Marketing Authorization for Herbal and Health Products Timeline is **155 Days**

CONCLUSION

Nutraceuticals & Herbals plays an important role in the development of future therapeutics but it depends on the role of Quality, Safety & Efficacy of the product. Hence, when any new product wants to enter the market of particular country, it is very important to comply with the Regulatory Framework of that particular country.

ACKNOWLEDGMENT

We extended our thanks to JSS Academy of Higher Education and Research, Mysuru

REFERENCE

[1] Helmenstine AM, Ph.D. What Is a Nutraceutical? [Internet]. ThoughtCo. [cited 2018 Feb 14]. Available from: https://www.thoughtco.com/definition-of-nutraceutical-604584

[2] Salma Sayeed. NUTRACEUTICALS [Internet]. 05:13:35 UTC [cited 2018 Feb 14]. Available from: https://www.slideshare.net/nimatanamikaze/nutraceuticals-45465067

[3] LexUriServ.pdf [Internet]. [cited 2018 Feb 14]. Available from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0085:0090:en:PDF

[4] FSSAI License in India [Internet]. [cited 2018 Feb 14]. Available from: http://www.sooperarticles.com/business-articles/consulting-articles/fssai-license-india-1616729.html

[5] Regulatory Requirements for Herbal Medicines in India [Internet]. Biology Discussion. 2016 [cited 2018 Feb 14]. Available from: http://www.biologydiscussion.com/herbal-medicines/regulatory-requirements-for-herbal-medicines-in-india/25359

[6] Hermes. Regulation of health supplements: HSA, AVA reply [Internet]. The Straits Times. 2015 [cited 2018 Feb 14]. Available from: http://www.straitstimes.com/forum/letters-in-print/regulation-of-health-supplements-hsa-ava-reply

[7] Worldfolio T. Trust and experience in healthcare [Internet]. Theworldfolio. [cited 2018 Feb 14]. Available from: http://www.theworldfolio.com/news/ayman-m-tamer-n375/375/

[8] SFDA - Saudi Food & Drug Authority [Internet]. Emergo. 2014

[cited 2018 Feb 14]. Available from: https://www.emergogroup.com/resources/saudi-arabia/saudi-food-drug-authority

[9] Food Safety and Standards Regulations [Internet]. [cited 2018 Mar 7]. Available from: http://www.fssai.gov.in/home/fss-legislation/fss-regulations.html

[10] Regulations & Guidelines [Internet]. [cited 2018 Mar 7]. Available from: https://www.sfda.gov.sa/en/drug/drug_reg/Pages/default.aspx

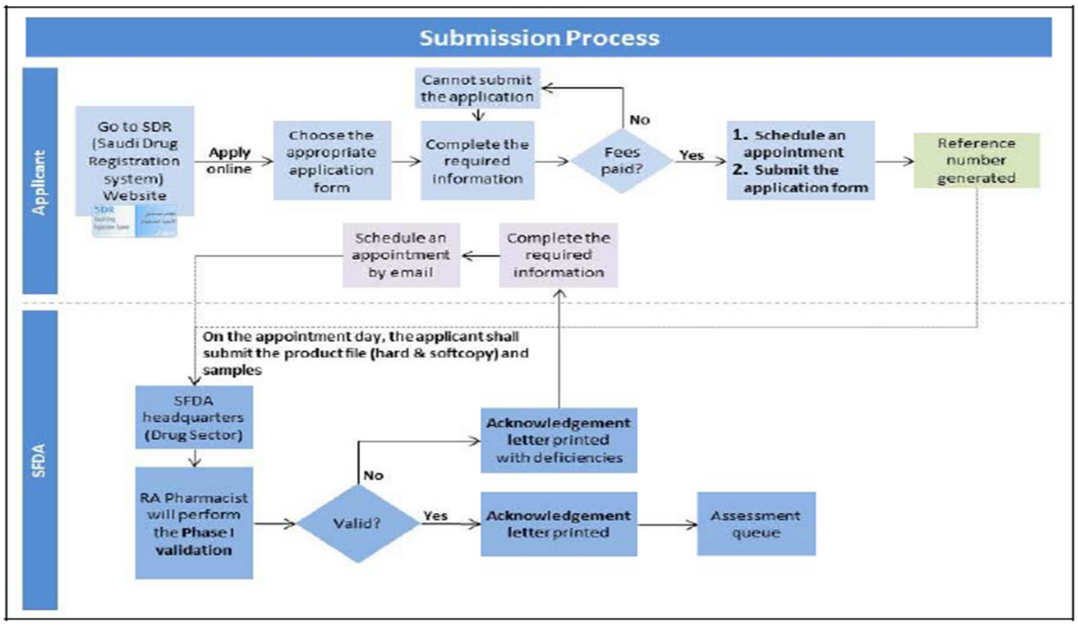


Figure 1: Flow Chart of Submission Process in Saudi Arabia

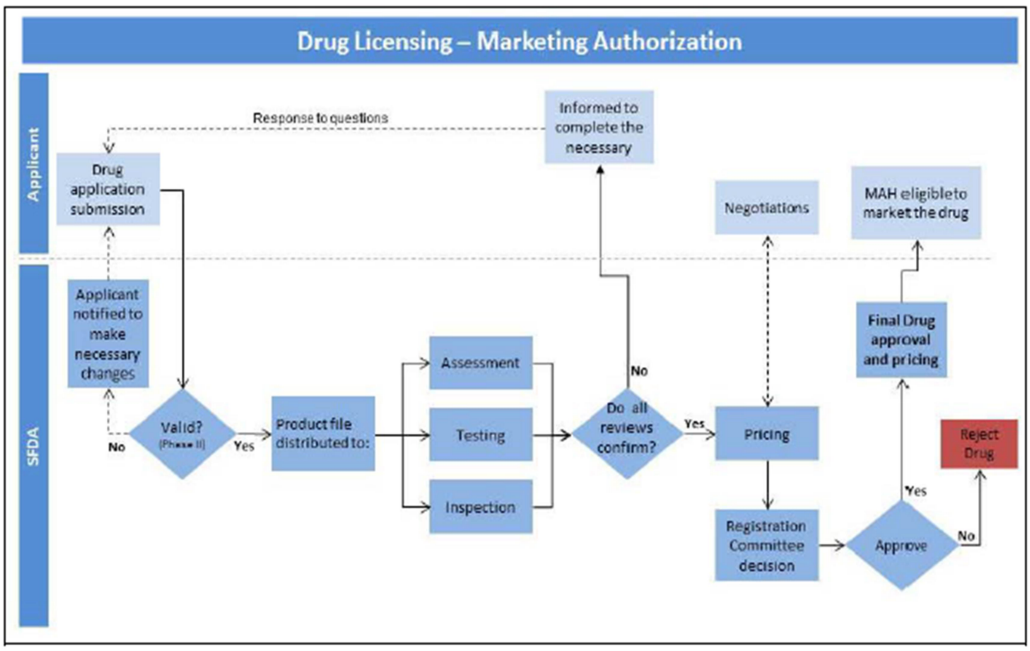


Figure 2: Marketing Authorization Process in Saudi Arabia