

COMPARATIVE STUDY OF REGULATORY REQUIREMENTS OF NUTRACEUTICALS IN INDIA, MENA AND SEA COUNTRIES AND ITS SIGNIFICANCE IN CORONA VIRUS

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ABSTRACT

Nutraceuticals, is any food or part of a food that offers medical advantages, including forestalling or treating illness, have arisen as a requirement for shoppers in both created and non-industrial nations. A wide reach of products are marketed as nutraceuticals. These include vitamins and essential minerals, polyunsaturated and monounsaturated fatty acids, and a variety of herbal products that have different claims of health-promoting properties. The nutraceutical business has arose as an important part of the food business. With high economic growth, increasing income and changing ways of life, the market is growing enormously. For the control of value and wellbeing of the items different administrative rules set by the particular governments become significant; This can be a genuine driver of the business' development. This article gives a concise outline of the nutraceuticals guideline of the Indian MENA and SEA nations. It principally centers around the examination of the legitimate system and design of nutraceuticals in SEA MENA and India with the fit specialized prerequisites for enrolling a nutraceutical item around there. This audit clarifies the significant impacts of nutraceuticals and dietary or wellbeing supplements on repressing viral section and offers another point of view for the anticipation and treatment of COVID-19.

KEYWORDS: Nutraceuticals, SEA, MENA, India, COVID 19.

INTRODUCTION

Nutritious food is an expansive term used to portray food sources got from food varieties. Notwithstanding their fundamental healthy benefit in food varieties, they likewise have other medical advantages. Think about utilizing vague natural treatments to improve general wellbeing, control side effects, and forestall dangerous tumors.^[1]

The nutraceutical business has arose as an important part of the food business. With high economic growth, increasing income and changing ways of life, the market is growing enormously. Globally, the nutraceutical market was placed at 65 billion dollars in 2002 and was

expected to grow to 250 billion dollars by 2005. In India, this market is at about Rs. 1, 600 crore at present, with an annual growth rate of 25%.^[1]

The global nutraceutical market has experienced maximum growth in the last decade. Although nutraceuticals as an industry arose in the early 1990s, the world has saw its explosive growth in the first decade of this century. From 1999 to 2002 the business developed at an annual average growth rate of 7.3 percent, while in this century the rate doubled to 14.7 percent.

Today, global nutraceutical market is estimated at 117 billion USD. Personalization and customization are current patterns in the development of nutraceuticals,

especially in developed markets of the world. Interest in research and development to find innovative approaches, checking health claims of the products and market research represent key strategies for the business.

In developed nations, unsurprising components are the principle justification the development of the sustenance and medical care industry. Higher expendable livelihoods, way of life changes brought about by undesirable eating regimens, Increased medical issues, and a maturing populace with extraordinary dietary requirements for keeping up great wellbeing have all added to improvement. Albeit the business is additionally extending in non-industrial nations, it is hard to foresee its development rate. Regardless of the above circumstance, India's nourishment and wellbeing items industry additionally has wide possibilities.

Nutraceuticals Regulation In Sea Countries

Southeast Asia composed of 11 countries with various culture, history which are as follows Thailand Brunei, Burma, Myanmar Cambodia, East Timor, Indonesia, Laos, Malaysia, Philippines, Singapore, Vietnam.^[2]

A unit of the Traditional Medicine and Health Supplements Product Working Group (TMHA PWG) assist makers with understanding the administrative methodology in these nations/areas.^[3]

By 2025, the market size of nourishment and wellbeing items in Southeast Asia is relied upon to reach 8.22 CAGR assumed to be at US\$1.3 billion.^[4]

In the Philippines, Myanmar medical conditions, for example, hypertension, weight and diabetes are more normal and require expanded venture by worldwide wellbeing food makers in the area likewise support interest from nearby providers.^[4]

Regulatory requirements for registration of nutraceutical in Myanmar as a leading Asian country

The Food and Drug Administration (FDA) was set up in 1995 and is important for the Ministry of Health. In April 2013, the FDA was revamped into a free division. The motivation behind this office is to guarantee the security and nature of medicines, medical gadgets and cosmetics. The settle of the FDA in the nation is situated in NayPyiTaw, the capital of Myanmar.

The 2014 FDA rules^[1] specify that the enrollment of food added substances is equivalent to the enlistment of medications. The candidate should be a Myanmar inhabitant. For imported food added substances, the license should be rounded out by the area addressing the unfamiliar organization. The structure filled in through the FDA enlistment structure can be acquired from the FDA workplaces in Nay pyi taw Yangon at a cost of [1000] kyats.^[5]

DOCUMENTS REQUIRE FOR REGISTRATION

Administrative data^[6]

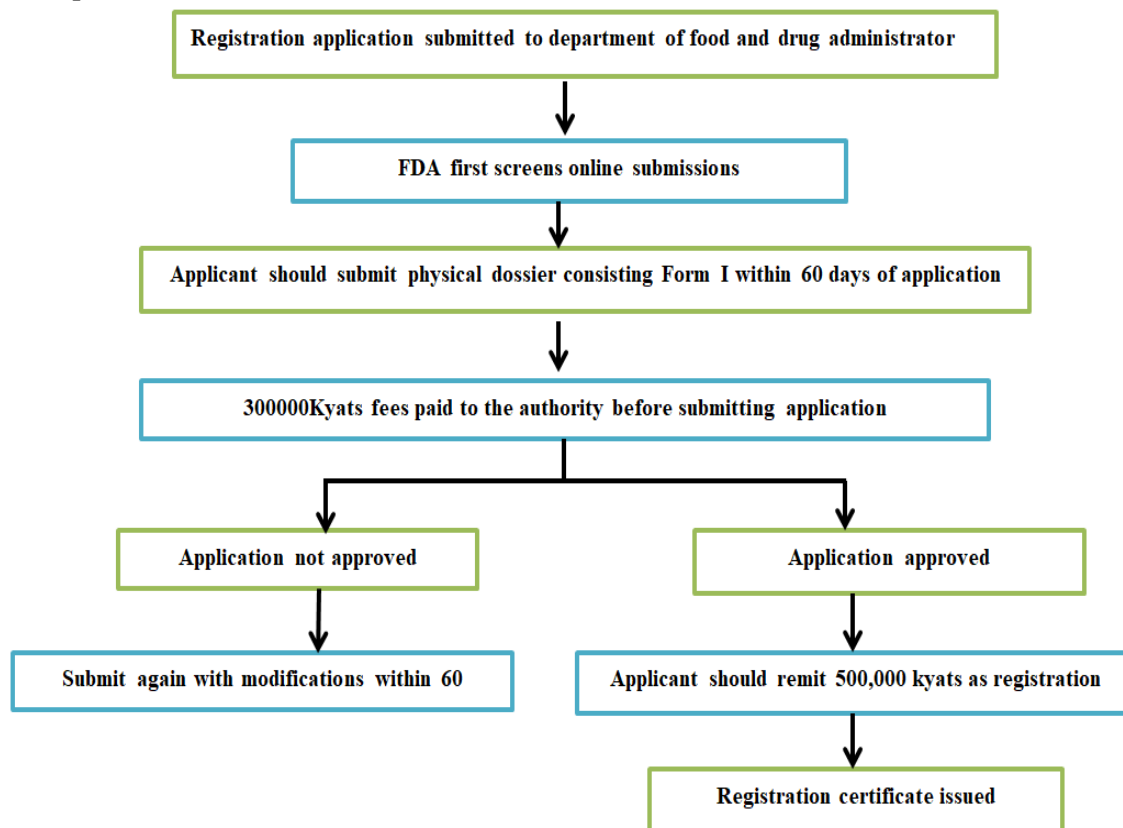
- (a) Letter of Authorisation
- (b) Free Sale Certificate issued by the authority in country of origin.
- (c) Properly endorsed Legalization of Manufacturing Licence copy
- (d) ISO Certificate (Standard)

Quality

- (a) Raw Specification, Source of raw material
- (b) Raw quality control
- (c) Master Formula
- (d) Manufacturing process
- (e) Finish product specification
- (f) Reference Text
- (g) Certificate of Analysis (Finish product)
- (i) Stability test of finish product

Safety & efficacy data

- a) Action of Active Ingredient; (Reference Text).
- b) Safety data of finish Product
- c) (Research Paper/ Literature of Food Supplement (endorsed by International Recognized Research Institute).

Registration process**Figure 1: Registration process of nutraceuticals in Myanmar.****Nutraceutical Regulations In Mena Countries**

Middle East and North African countries are Malta, Oman, Bahrain, Djibouti, Egypt, Iran, Israel, Jordan, Kuwait, Lebanon, Libya, Malta, Qatar, Saudi Arabia, Syria, Tunisia, United Arab Emirates, Suda.^[10]

The Middle East and Africa are one of the districts with gigantic improvement openings. Right now, it is the littlest market on the planet, however agricultural nations in South Africa, the United Arab Emirates, and Saudi Arabia give development openings.^[8]

Regulatory requirements for registration of nutraceutical in UAE as a leading MENA country

The UAE is an alliance of seven emirates: Abu Dhabi, Dubai, Sharjah, Ajman, Umar Quinn, Lhasa al Haima and Fujairah. The UAE is an individual from the Cooperation Council of the Arab Gulf States, regularly alluded to as the Cooperation Council of the Gulf States. (GCC). This GCC is a provincial intergovernmental political and financial coalition made out of Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates. The detailing of the food law is important for Gulf standardization.(GSO) and acknowledged by taking part nations. All Gulf Cooperation Council part states, including the UAE, reserve the privilege to figure institutional food laws to enhance the food laws detailed under the GSO.^[9]

GSO will generally embrace its current principles in the wake of refreshing the norms of existing part states and guarantee that it conforms to the rules as well as the Codex Alimentarius relates to the guidelines. Global Organization for Standardization (ISO).Food is dependent upon sterile control at the passage to guarantee that it meets the GCC specialized necessities of sanitation guidelines, GCC specialized guidelines identified with prepackaged food naming, food timeframe of realistic usability, labelling, and so forth.

In 2018, the UAE proposed the "National Food Registration and Certification Scheme". As a component of this new arrangement, an electronic food enrollment gateway has been set up, regularly known as "ZAD".The framework will enlist all food varieties before they are sold in the UAE and check that the item follows the country's food laws. As a component of the enrollment A duplicate of the authority endorsement of the equipped position to affirm the wellbeing or healthful prerequisites of the item should be given.

Documents required for registration^[10]

In the United Arab Emirates (UAE), the General Sales List (GSL) includes dietary supplements, medical cosmetics, preservatives and disinfectants, as well as various products that contain pharmaceutical ingredients and/or medical indications and cannot be classified as

pharmaceuticals. The applications submit in English or Arabic.

1. New application and receipt form (printed) for GSL product registration. Available in the "Technical Issues" section.
2. According to the WHO certification system, the certificate of product (CPP) or the free sale certificate (FSC) of the product. It is issued by the competent authority of the country of origin and must be certified by the Ministry of Foreign Affairs of the United Arab Emirates or the GCC embassy in the country of origin.
3. Product package insert certified by the competent authority (if any)
4. Three (3) product samples in the final package
5. COA of same batch of samples submitted for registration.
6. The parent company declares that the product does not contain hormones, heavy metals, antibiotics, steroids, pork derivatives and any chemical substances or any harmful Natural ingredients will affect human biology and behavioural functions.
7. The halal certificate issued by the accredited organization
8. the certification contract between MAH and the agent list the products that the agent will be responsible for.
9. The applicant should have a medical store licensed by the Ministry of Health of Respected country
- a) 10. A valid company registration certificate issued by the UAE Control Board/Health Authority.
10. applicant has toSubmit the BSE/TSE Absence Certificate to the authority of the country of origin
11. outer and inner label and insert of product on company letter.
12. CD with pictures (external label, internal and insert). The JPEG format of the product.

Registration process

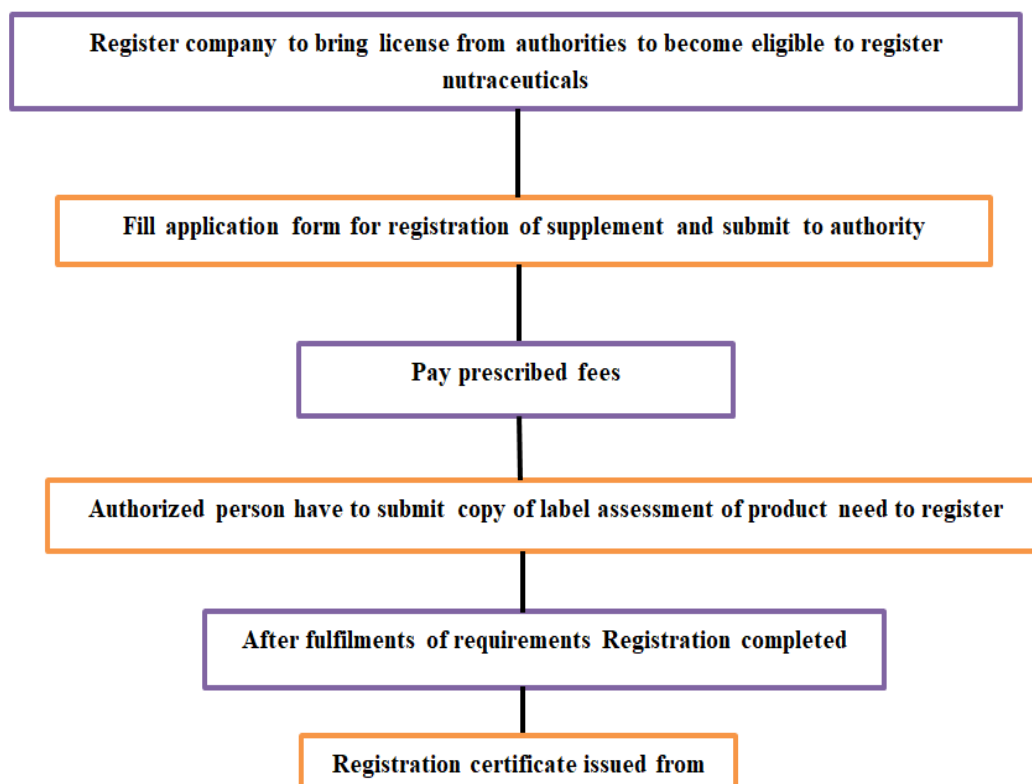


Figure 2: Nutraceutical registration process United Arab Emirates.

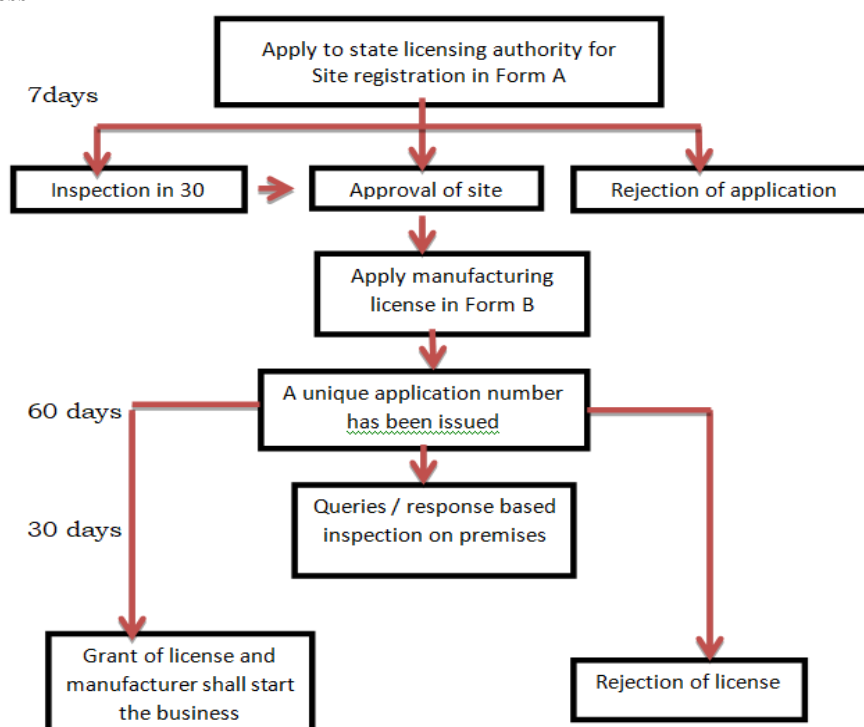
Nutraceutical Regulations In India

FSSAI 2006 formulated various health food regulations. Foods that replace food fixings also include foods and their standards in the processing of organic products, including patented products and new products that are unsafe yet not mentioned in the law. Compound foods or modern foods obtained from biotechnology, which have been obtained as genetically modified or processed organisms, may also contain these foods, and have also been included in the law.^[11]

The FSSAI law is composed of 21 chapters. Article 4, which is 22 of the law, involves nutritious foods, dietary supplements and various functional foods. These products can be manufactured, sold (for example sold or appropriated), and imported cargo forwarders can be manufactured by anyone in the company. These foods can include nutraceuticals, nutritional supplements, functional foods, organic foods, unprocessed foods, canned foods, new foods and irradiated foods.

Documents for registration

1. The FSSAI license requires the following basic documents:
2. the photo ID of the food operator.
3. Proof of full ownership of the premises (such as a lease agreement).
4. Company documents or certificate of registration.
5. The following are the documents required for FSSAI registration of food additives, nutritious foods and new foods: arrangements/plans of technical units, specifying the size and distribution of work areas in meters/square meters (only mandatory for production and processing plants).
6. Director with complete address and contact information (required only for companies).
7. Name and list of equipment and machinery and quantity, installed capacity and power). Water analysis (chemistry and bacteriology) reports, used by recognized/public health agencies as ingredient information.
8. Alcohol confirmation laboratory.
9. Issue the photo of the production unit, ID photo and proof of address Proof of the ownership of the government power site of the owner/partner/director/authorized person (purchase/lease/electricity bill, etc.)
10. partnership agreement/ownership self-declaration/articles of association and the articles of incorporation of the registered company.
11. Form IX: Nomination of Persons by Board

Registration process**Figure 3: India nutraceutical registrations Process.****Nutraceuticals In Corona Virus**

Since December 2019, the coronavirus caused a global crisis, caused by SARS-Cov-2, approximately 79% genome similar. As a coronavirus, it showed that it transmitted from bats to humans. The first case was in, China. The World Health Organization (WHO) declared it a pandemic on March 11, 2020. The proposed propagation method mainly occurs through human-to-human contact through the released droplets. The clinical course of the disease ranges from asymptomatic cases to extreme pneumonia. However, the common clinical symptoms are fever, dry cough, myalgia, insomnia, shortness of breath and anorexia, which can quickly lead to respiratory failure.

Supplements like Zinc Vitamin A, D and C, Polyphenols are the nutraceutical which boost invulnerability and help to battle the covid 19.^[12]

Table 1: Nutraceutical supplements role in Covid 19.

Sr.no	Supplement	Importance in covid	Dose
1	Zinc	Advantageously regulate the innate and adaptive immune system. Advantageously regulate virus-induced cell pathological processes, binding, and replication.	30 to 60 mg per day.
2	Vitamin D	Activated vitamin D a steroid hormone and a modulator of immune Prevent upper respiratory tract infections.	5,000 IU orally daily in absence of serum levels.
3	Vitamin A	Beneficial effect on defense mechanism and cell regeneration. T helper cell regulation. SIgA modulation.	10,000-25,000 IU/d
4	Vitamin C	Vitamin C can be used to reduce this cytokine storm and oxidative stress, thereby preventing complications related to COVID 19.	oral administration of 1-3 grams per day
5	N-acetyl cysteine	Beneficially regulates cell defense and repair mechanisms	600-900 mg orally twice a day
6	Polyphenol	antiplatelet and anticoagulant effects. They reduce platelet aggregation and inhibit thrombin activity	

Table 2: Comparison of regulatory requirements of nutraceutical in MENA, SEA and India.

Sr.No.	Region or countries	SEA Region (Myanmar)	MENA Region (United Arab Emirates)	India
1.	Names	Food supplements /dietary supplements	Nutrition supplement/dietary supplement	Nutraceuticals/ food supplement/dietary supplement/health supplement many more
2.	Rules/regulations for nutraceuticals registration	Myanmar FDA Guidance of 2014 ^[1] for registration	National Scheme for Food Accreditation and Registration 2018 for registration	Food safety and standard act FSSAI 2006
3.	Year	2014	2018	2006
	Regulatory authorities	Department of Food and Drug Administration (FDA) under the Ministry of Health and Sports	Ministry of Health and Prevention (MOHAP)	Food Safety and Standards Authority of India (FSSAI)
4.	Basic requirements	Administrative data Quality data Safety efficacy data	Technical data CPP, Halal certificate, TSE BSE certificate CD artworks of product, COA	Administrative, technical, safety data
5.	Fees	500,000Kyats	-	Basic FSSAI registration - Rs 1799/- State FSSAI license - Rs 15000/- Central FSSAI license - Rs 20000/-
6.	Health claim	-	In accordance with GSO standard for PERMITTED HEALTH, FUNCTION AND NUTRITION CLAIMS MADE ON FOOD AND THEIR CONDITIONS OF USE and many more	India specific labelling and packaging requirements Packaging of the consignment composition of the consignment and approach to market the same Need for sample material and declaration for registration Label content and claim Structure - function claim
7.	Forms	Form I application for registration	forms are PART ONE (for MAH) & PART TWO (for manufacturing site)	Form A, B and C

CONCLUSION

Nutritional health products have attracted much attention because of their recognized safety and promising nutritional and therapeutic effects. Pharmaceutical and food companies realize that the financial success of many health-seeking consumers and the disruptive model

are driving the proliferation of these value-added products, which purportedly target diseases ranging from heart disease to cancer. In many ways, this regulation provides a very difficult situation for the globalization of nutraceuticals. Basically, differences in regulations between countries make global trade and marketing

difficult. In view of technical, regulatory, and logistical challenges, food and pharmaceutical companies are using more and more nutraceuticals in more and more ways. The biggest scientific need is to standardize nutrition and health products, and carefully design and conduct clinical studies to provide a basis for health claims Consumers and nutrition and health companies. This overview outlines the nutraceuticals in the Middle East and North Africa, India and south East Asia markets, and clarifies the role of nutraceuticals in the new coronavirus.

CONFLICT OF INTREST

The author not declare any conflict of interest.

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