

Nutraceutical Regulations: A country-by-country review of global regulatory requirements

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How does the regulatory process for supplements differ in emerging markets around the world? One expert reviews the differences.



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Across the world, countries are recovering from the COVID-19 pandemic, with people still struggling with lockdowns, health status, job security, and income while coping with this new normal. In times like these, tools for boosting immunity and preventive health remain popular. This presents an ongoing opportunity to the food supplement industry as consumers around the world use supplements to maintain their health and wellbeing. Some countries also permit the use of supplements for medicinal purposes.

Indeed, there are more global opportunities for these products than before. But dietary supplement companies that develop, manufacture, sell, market, distribute, or import/export their products first need to ensure they meet the regulatory requirements of each country's specific Health Authority (HA) and Ministry of Health (MoH). Failure to do so can result in significant penalties.

Compliance issues are complex, and gaining a comprehensive understanding of different countries' nutraceutical laws and regulations is often extremely challenging. This article aims to review regulatory requirements across regions.

Demand Goes Global

The pandemic marked significant growth in the usage of dietary supplements across the world. Consumers across regions have become more health-conscious, driving the growth of the dietary supplements market. Considering this growth, investors in the dietary supplement market are increasing. Health authorities have also framed the regulations accordingly to ensure the safety of products and their use.

The Asia-Pacific (APAC), Middle East/North Africa (MENA), Latin America (LATAM), and African markets have shown tremendous growth in dietary supplement demand compared to the already-mature U.S. and EU markets.

- The APAC nutraceutical and functional food market is projected to witness 5%-10% CAGR in the coming years.
- The MENA dietary supplement market is projected to witness a CAGR of 8.2% during 2020-2025.
- The African nutraceutical market is projected to register a CAGR of 6.05% during 2020-2025.
- The LATAM region is estimated to reach a CAGR of 7.3% by 2026.

Health Authority / Ministry of Health

Dietary supplement companies that develop, manufacture, sell, market, distribute, or import/export their products in these markets should ensure they know who each country-specific Health Authority (HA) and Ministry of Health (MoH) is, as well as how these products are classified—e.g., as dietary supplements, food supplements, or health supplements. A comparative table of product classification and respective Health Authorities across regions is provided below (Tables 1-4).

Table 1. ASEAN

Country	Classification of Nutrition Products	Health Authority
Brunei	Health Supplements	Ministry of Health (MoH)
Cambodia	Health Supplements	Ministry of Health (MoH)
Indonesia	Food Supplements	The National Agency of Drug and Food Control of Indonesia (BPOM)
Malaysia	Health Supplements	National Pharmaceutical Regulatory Agency (NPRA)
Philippines	Food Supplements	Philippines Food and Drug Administration (PFDA)
Singapore	Health Supplements	Health Sciences Authority (HSA)
Thailand	Health Supplements	Thailand Food and Drug Administration (TFDA)
Vietnam	Dietary Supplements	Ministry of Health (MoH) / Drug Administration of Vietnam (DAV)

Table 2. Middle East

Country	Classification of Nutrition Products	Health Authority
Bahrain	Health Supplements	National Health Regulatory Authority (NHRA)
Egypt	Health Supplements	Egyptian Drug Authority (EDA) / Egyptian Ministry of Health (MoH)
Israel	Health Supplements	Ministry of Health (MoH)
Jordan	Health Supplements	Ministry of Health (MoH)
Kuwait	Health Supplements	Ministry of Health (MoH)
Lebanon	Health Supplements	Ministry of Health (MoH)
Oman	Food Supplements	Ministry of Health (MoH)
Qatar	Health Supplements	National Health Authority (NHA)
Saudi Arabia	Food Supplements	Saudi Food and Drug Authority
Turkey	Health Supplements	Ministry of Health (MoH)
United Arab Emirates (UAE)	Health Supplements	Ministry of Health (MoH)

Table 3. Africa

Country	Classification of Nutrition Products	Health Authority
Nigeria	Dietary/Health Supplements	National Agency for Food and Drug Administration and Control (NAFDAC)
South Africa	Complementary Medicines	South African Health Products Regulatory Authority (SAHPRA)
Kenya	Health Supplements	Ministry of Health (MoH)
SADC	Health Supplements	Ministry of Health (MoH)

Table 4. LATAM

Country	Classification of Nutrition Products	Health Authority
Brazil	Dietary / Health Supplements	Brazilian Health Regulatory Agency (ANVISA)
Peru	Dietary / Health Supplements	Dirección General de Medicamentos, Insumos y Drogas (DIGEMID)
Colombia	Health Supplements	Ministry of Health (MoH)
Mexico	Food Supplements	Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)
Argentina	Health Supplements	Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT)

Regional Regulations

Now, let's take a look at regulations across various markets. Each market has its own requirements in terms of legalizing foreign/local products within its territory. Certain markets follow pathways of regulated countries while developing strong internal regulations.

In the APAC market, most countries require a product to be registered with the country-specific Health Authority before it can be marketed. Certain countries like Singapore and Hong Kong are compliance-based markets—meaning once you are compliant with the local regulations, you can launch the products in the market. Certain markets like Thailand, Malaysia, Indonesia, the Philippines, Vietnam, and Taiwan require product registration with their respective Health Authority. Countries like Japan, South Korea, and China have stringent rules and regulations for product registration. Documentation and testing details are required to be submitted based on the formula and claims of the product.

In the Middle East countries, before placing a product in the respective market, companies need to ensure it meets the country-specific regulations along with GCC Standardization Organization regulations, and get the product registered with the assistance of a specified local agent. The case is similar in the African and LATAM markets.

Key Markets

Here's the list of a few key markets for dietary supplements (Table 5):

Table 5. Key Markets for Dietary Supplements

Country	Country	Country	Country
Brazil	Philippines	China	Malaysia
Peru	Singapore	South Korea	Indonesia
Colombia	Thailand	Japan	Sri Lanka
Mexico	Vietnam	South Africa	India
Argentina	Taiwan	Nigeria	Australia / New Zealand

Finding a Local Agent

Any foreign manufacturer/brand owner willing to enter these markets requires a local office or a local agent appointed by them to facilitate registration activities and to liaise with respective the Health Authority to answer technical queries.

Selecting this local agent is critical, as most countries have certain prerequisites. This local agent is called by different names across countries, including Legal Representative/Market Authorization Holder (MAH) and Responsible Person (RP). The local agent can be an entity or a person as well. Below is the list of the factors to consider when choosing the right local agent. Certain parameters might vary across countries.

- Is the local agent a citizen of the country?
- Is the entity or representative person acting as local agent self-registered with the respective health authority in the country?
- Will the local agent possess the company's licenses?
- The local agent should be authorized by the ministry to import food supplements.
- The local agent should possess a valid commercial registration.
- The local agent should be a science graduate or come from a pharmaceutical background or be a pharmacist.
- In certain countries, the local agent can be the distributor as well.

Product Registration

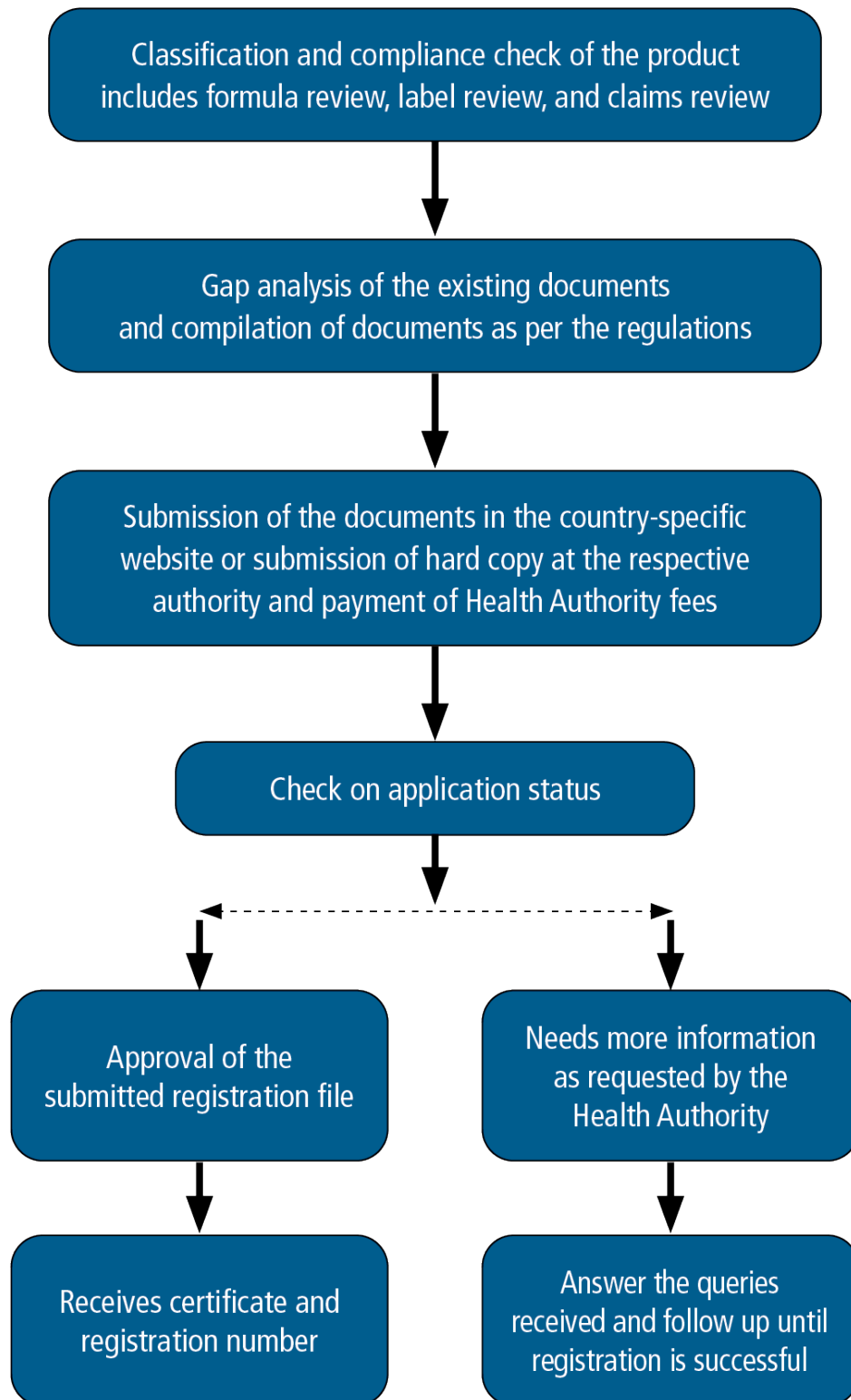
Once the local agent is selected, the next step is the process of getting the product registered under the country's regulations. Below is a high-level list of documents required for registering a product:

1. Cover letter from the local agent and respective license details
2. Application form
3. Valid Good Manufacturing Practice (GMP) certificate/manufacturing license of the manufacturer (legalized)
4. FSC/product license from the country of origin (legalized)
5. Composition of the product
6. Finished-product specification
7. Mock-ups for the outer label, inner label, and package leaflet
8. Samples for laboratory test (as applicable)

9. Health Authority fees payment proof

Also keep in mind that each country has its own checklist for registering a product. In certain countries like South Africa, the dossier must be submitted in the form of a CTD (common technical document) format.

Below is a flow chart that describes the registration process of various countries in detail:



Product Classification

Classification is one of the key steps to be performed before launching a product in any market. The definition of a dietary supplement varies a bit across countries; for example, in South Africa, dietary supplements are classified as Complementary Medicines; in Nigeria, they are classified as Herbal Medicine and Related Products; in Malaysia, they are classified as Health Supplements; and in Thailand, there is an option to reach out to the FDA for classification inputs. In Indonesia, a Health Supplement is a product that is meant to complement the nutritional need; maintain, increase, and improve health function; contain one or more ingredients in the form of a vitamin, mineral, amino acid, or other ingredient (originating from plant or non-plant sources) that have nutritional value and/or physiological effect; and not be intended as food.

Each country has its own definitions and classification criteria; hence, it is important to ensure your product is classified correctly before proceeding ahead with the registration/notification process, because classification will provide a clear pathway.

Compliance Check

Once classification is complete, the next step is to check the product for regulatory compliance, including formula review, label review, and claims review. Looking at every parameter gives a complete picture of whether the product is compliant with the country's regulations. At times, regulations for certain ingredients accepted across countries might differ by country in terms of limits on usage. Also keep in mind that certain additives might be new to a country, or the main ingredient itself might be a new/novel ingredient for that country. In that case, it is necessary to take the further steps of getting the new/novel ingredients registered first, followed by product registration.

In a nutshell, the process mentioned above is a common process across countries. Now, let's see the overall picture for certain countries in the table below (Table 6):

Table 6. Registration Details Across Countries

Country	Health Authority	Registration Process	Registration Valid For:	Local Agent/LR/MAH Required
Brazil	ANVISA	Sanitary Registration	5 years	Yes
Peru	DIGEMED	Sanitary Registration	5 years	Yes
Colombia	INVIMA	Sanitary Registration	10 years	Yes
Mexico	COFEPRIS	Notice of Operation	–	Yes
Argentina	RNPA	Sanitary Registration	5 years	Yes
Philippines	PFDA	Certificate of Product Registration	3 or 5 years	Yes
Singapore	HAS	Compliance-Based Market	–	–
Thailand	TFDA	Registration Certificate	5 years	Yes
Vietnam	DAV/MOH	Registration Certificate	5 years	Yes
Taiwan	Taiwan FDA	Registration Certificate	5 years	Yes
China	CFDA	Registration Certificate	5 years	Yes
South Korea	MFDS	Registration Certificate	5 years	Yes
Japan	MHLW	Registration Certificate	5 years	Yes
South Africa	SAHPRA	Registration Certificate	5 years	Yes
Nigeria	NAFDAC	Registration Certificate	5 years	Yes
Malaysia	NPRA	Registration Certificate	5 years	Yes
Indonesia	BPOM	Registration Certificate	5 years	Yes
Sri Lanka	NMRA	Registration Certificate	5 years	Yes

Overall, most countries currently have a good demand for food supplements, and most of them have been updating their existing rules and regulations to boost the market. Some country regulations share certain similarities but are vastly different in their approach. Manufacturers and

brand owners need to navigate a narrow pathway in this ever-changing regulatory landscape to ensure compliance with the local regulations so that they do not miss any opportunities.

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