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Review Article

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A comparative evaluation of Regulatory requirements for Registration of Dietary Supplements in Brazil, Russia, India, China and South Africa

Kinjal Gajjar, Zuki Patel, Vinit Movaliya, Niranajan Kanaki, Shrikalp Deshpande, Maitreyi Zaveri*

K. B. Institute of Pharmaceutical Education and Research, Gandhinagar, Gujarat, India.

Abstract

Nutraceuticals are products that are rich in nutrients and provide health benefits, because of many factors like lifestyle changes and change in the dietary habits of people now a day, these products are widely used. Among all the other categories of Nutraceuticals Dietary supplement comprises huge part of Nutraceuticals. They are distinguishable from conventional food or drugs. They are intended to use to supplement the normal diet. The terms, nomenclature and definitions of the dietary supplements vary throughout the world. Different countries have their own regulation and legislative requirements. In regulated countries streamlined regulations are there, while well-structured and streamlined regulations for Nutraceuticals are lacking in other countries. In developing and emerging nations the regulation of dietary supplements are constantly evolving. It is necessary that the product complies all the regulatory requirements before they are placed on the market. The proposed study is based on the regulation and legislative requirements of dietary supplements in Brazil, Russia, India and South Africa.

Keywords: Nutraceuticals, Dietary Supplements, natural health products (NHPs), AMVISA, FSSAI (Food Safety and Standards Authority of India), CFDA, SAHPRA, Rospotrebnadzor

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*Corresponding author

1. Introduction

The term "Nutraceutical" was coined by Stephen De felice in 1989 MD, founder and chairman of the Foundation for Innovation in Medicine (FIM), Cranford, NJ, which combines two word, nutrition and pharmaceuticals. There are many categories of Nutraceuticals ranging from dietary supplements, Functional Foods, Polyphenols and Micronutrients. Among them Dietary supplements comprises huge market share. They are designed to be taken additionally to enhance body functioning, if one's lacking some or other nutrients, to prevent certain diseases, to prevent nutritional deficiencies etc. They are widely used additionally in some medical conditions also. The usage of this class has increased because of their easy availability, their quality to maintain or enhance health and also there are less side effects compared to others.

The global dietary supplements market size was valued at USD 151.9 billion in 2021 and is expected to expand at a compound annual growth rate (CAGR) of 8.9% from 2022 to 2030.

Dietary supplements are major class of nutraceuticals. The regulation and the usage of dietary Supplements differ from country to country, the product is known variously in different countries, including dietary supplements, natural health products (NHPs), complementary medicines or food supplement or Health supplement. The usage of a dietary supplement varies widely from country-to-country; in some

countries supplement use is just limited to general health and well-being while others permit use for medicinal purposes. Here the regulation of Five Emerging countries Brazil, Russia, India and South Africa are reviewed. (1-3)

2. Brazil

ANVISA that is the Brazilian Health Regulatory Agency which regulates the dietary supplements products among the other categories of products.

According to the Brazilian Regulation, Dietary supplement is defined as a "Product for oral intake, presented in pharmaceutical forms, intended to supplement the diet of healthy individuals with nutrients,

bioactive substances, enzymes or probiotics, isolated or combined".

In Brazil, until 2018 dietary supplements had no legal definitions and most products that were used as dietary supplements were classified into different categories.

In 2018, ANVISA passed the new regulation According to that, Dietary Supplements include:

- Vitamin and mineral supplements;
- Bioactive substances and probiotics;
- Novel foods;
- Foods with claims of functional properties;
- 5 Athlete supplements;
- Supplements for pregnant women and nursing mothers;
- Specific non-prescription medicines.

In Brazil, ANVISA Is responsible for permitting health claims. The use of the claims is optional, Except for food supplements with probiotics or enzymes. Also the Claims concerning the content and properties of food additives, the claims that supports any cure or prevention of any disease are not permitted.

Both function and health claims are defined and allowed. According to ANVISA, any claims related to disease prevention and cure is considered as Drug and not a Supplement.

ANVISA allows the food supplements to be registered based on their food substance. It is divided in two categories according to that:

1. Food supplements exempted from registration and

2. Food supplements require registration.

Checklist of Required Documents for Registration:

The required documents for Food supplements exempted from registration are;

- Company details;
- Manufacturing plant details;
- Product category;
- Product name
- Brand name
- Packaging type

The required documents for Food supplements with functional and/or health claims, including food supplements with probiotics and enzymes are;

- Cover sheet for filing;
- Petition forms 1 and 2;
- Label copy
- Company registration form
- Copy of the sanitary permit
- Technical-scientific report and scientific evidence applicable to prove the effectiveness of the proposed claim
- In the case of a new food or ingredient, proof of safety must also be presented in accordance with "RDC No. 16/1999", "RDC No. 17/1999" and "Guide for the Safety Verification of New Foods and New Ingredients
- Proof that the ingredients in the food supplement are restricted to those provided in "IN No. 28/2018" or approved resolution resulting from the request and evaluation of safety and effectiveness of an ingredient
- In case of probiotic the evaluation of safety and efficacy of the strain is required
- Analytical reports that confirm the food supplement complies with minimum and maximum limits set for its constituents (RDC No. 243/2018) until the end of the shelf-life period.
- Identity, purity and composition specifications for food additives and processing aids and information proof that the use of food additives and processing aids and other ingredients are compliant to "RDC No. 239/2018" and "Art. 6 of RDC No. 243/2018".
- Reports of stability studies that ensure the maintenance of the supplement's characteristics until the end of the shelf-life period. (4,5)

3. Russia

In Russia Dietary supplements are termed as, Biologically Active Supplements (BASs).

Defined as Concentrated biologically active ingredients for enhancing human diet with allowed daily amounts of health components. Those supplements are mostly produced from mineral, animal or herbal based raw materials.

According to the definition, the following products can be identified as a BAS:

- Polysaturated acids
- Mineral substances, micro and macro elements
- amino acids
- Some mono and disaccharides
- Food fibers
- Microorganisms present in human body
- Vitamins

In Russia BAFS/BAS requires state registration to the authority which is designed to assess the compliance with quality, safety and all the requirements stated in the regulations of Russian Federation and the Customs Union. According to the regulation, Manufacturers are responsible for product quality and Safety. Russia has positive and negative list of components. The positive

list of components approved for use in manufacturing of food supplements comprises 166 positions ranging from amino acids, vitamins, minerals, Biologically active substances, Probiotics etc. While the negative list of components is restricted for use in the manufacturing of supplements.

State registration of dietary supplements is carried out by the Federal Service for Supervision of Consumer Rights Protection and Human Welfare (Rospotrebnadzor).

Checklist of documents required for registration:

- Power of Attorney issued by the manufacturer
- Documents of the authorization of the manufacturer's country confirming, that given production is referred to BAS (nutritional products) or is not a drugs, and also confirming of safety of BAS
- Free sale certificate
- Document confirming, that production of given products is carried out in the correspondence with national and/or international specifications for nutritional BAS on issues of production organization. (for example: certificate ISO 9001, Certificate GMP)
- The copy of Certificate of trade mark, patent, license agreement
- Contract on executing functions of the foreign manufacturer in terms of ensuring the conformity of products to requirements of technical regulations of the Custom Union
- Documents about manufacturing of the product.
- Full ingredient composition of BAS
- Scheme and description of manufacturing process; – for BAS containing the alive microorganisms, it must be indicated in Latin language the kind and species of a microorganism, indication of the strain, and for BAS containing the parts of plants, it must be indicated the botanical title in Latin language, form and method of preparation (for example: an extract – 1:4, tincture – 1-10 etc.); information about methods of analysis of BAS.
- Declarations by manufacturer about use in composition of BAS of components obtained from generically of modified sources, nanotechnologies, about absence in composition of BAS of hormone, pesticides, toxic, drastic, psychotropic and narcotic compounds and synthetic pharmaceuticals.
- Instruction for use
- Written notification by manufacturer that product samples meets the requirements of the documents under which it is made: For example: certificate of quality, certificate of analysis or letter of manufacturer.
- Document by manufacturer about confirmation of safety and quality of test samples. Certificate of quality or certificate of analysis for the same batch as the samples provided for examination.
- Sample of an original label which was made in the manufacturer's country.
- Documents about specific activity of BAS (for BAS containing unknown components, informal composition).
- Protocols of examination (tests), scientific reports
- Copies of documents, confirming import of BAS to territory of Russian Federation (for example, invoice with customs mark).
- Declaration about the stability of BAS and its shelf life
- Declaration about safety of packaging material.
- Sample collection report
- Samples of BAS, in an amount necessary for realization of sanitary-epidemiological examination. (6)

4. India

In India, FSSAI (Food Safety and Standards Authority of India) regulates all the activity of manufacturing, storage, packaging, import, and sale to ensure the availability of food and food products within the country.

To register product in India, various licenses has to needed which depends on actual product,

- Import License
- License for manufacture
- License for marketing

Other state and national level clearances/licenses required from the regulatory side, which need to be taken care of before launching these products in India.

Checklist for documents required for registration:

- Form-B duly completed and signed (in duplicate) by the proprietor/ partner or the authorised signatory
- Blueprint/layout plan of the processing unit showing the dimensions in metres/square metres and operation-wise area allocation.
- List of Directors with full address and contact details
- Name and List of Equipments and Machinery along with the number, installed capacity and horse power used.
- Photo I.D and address proof issued by Government authority of Proprietor/ Partner/Director(s)/Authorised Signatory.

- List of food category desired to be manufactured. (In case of manufacturers).
- Authority letter with name and address of responsible person nominated by the manufacturer along with alternative responsible person indicating the powers vested with them viz assisting the officers in inspections, collection of samples, packing & dispatch.
- Analysis report (Chemical & Bacteriological) of water to be used as ingredient in food from a recognized/ public health laboratory to confirm the portability indicating the name of authorized representative of Lab who collected the sample and date of collecting sample
- Proof of possession of premises. (Sale deed/ Rent agreement/ Electricity bill, etc.)
- Partnership Deed/Affidavit/Memorandum & Articles of Association towards the constitution of the firm.
- Copy of certificate obtained under Coop Act - 1861/Multi State Coop Act - 2002 in case of Cooperatives.
- NOC from manufacturer in case of Re-labellers
- Food Safety Management System plan or certificate if any,
- Source of milk or procurement plan for milk including location of milk collection centres etc in case of Milk and Milk Products processing units.
- Source of raw material for meat and meat processing plants.
- Pesticide residues report of water to be used as ingredient in case of units manufacturing packaged drinking water, packaged Mineral water and/or carbonated water from a recognised/ public health laboratory indicating the name of authorised representative of Lab who collected the sample and date of collecting sample, including source of raw water and treatment plan.
- Recall plan wherever applicable, with details on which the product is distributed.
- NOCs from Municipality or local body and from State Pollution Control Board. (7, 8)

5. China

In China, Health Food is defined as a food that has specified health functions, suitable to be taken by specified groups of people, and for the regulation of the functional state of the human body and is not used for the treatment of diseases.

In China, The Health foods are divided in two parts:

- Nutritional Supplement also known as Dietary supplements
- Functional Health Foods

Nutritional supplements includes, Vitamins such as Calcium tablets while Functional Health foods involve Healthy foods such as Deep Sea fish oil, Ginseng Tablets etc.

Checklist for documents required for registration:

- Health Food registration application form
- A copy of Registration certificate of applicant
- Product's Chinese name approval notification
- Letter of guarantee stating no infringement or preparatory rights
- Copy of trade registration certificate
- product R&D report
- Product Formula
- Effective ingredients, contents and testing methods of the same
- Diagram of Productive techniques, detailed explanation, and related materials
- Product quality specifications (industry standard)
- Test certificate issued by an Authorized Testing Institute -toxicology safety, functionality
- evaluation, active ingredient analysis, product stability, sanitary inspection reports
- Sample product label and Product insert sheets with health claims and
- Specifications
- Certified/notarized documentation that show the applicant is empowered to act on behalf of the submitting organization
- Product packaging with all labels that will be used for the product in the marketplace
- Legal product qualification issued by country of origin
- Three samples of the product as they will be packaged and formulated for the market
- Any other documentation that can be used to support the claim and approval processing. (9)

6. South Africa

SAHPRA (South African Health Products Regulatory Authority) regulates dietary supplements as Complementary Medicines. According to regulation "Health supplement" means any substance, extract or mixture of substances that,(a) may— (i) supplement the diet; ii) have a nutritional physiological effect; or iii) include pre- and probiotics classified as schedule; and (b) are sold in pharmaceutical dosage forms not usually associated with a foodstuff and excludes injectable.

Table 1 Comparative Summary of Regulatory Requirements (10-15)

Sr. No	Parameters	BRAZIL	RUSSIA	INDIA	CHINA	SOUTH AFRICA
	Countries					
Regulations						
1	**Definition**	Defined as a "Product for oral intake, presented in pharmaceutical forms, intended to supplement the diet of healthy individuals with nutrients, bioactive substances, enzymes or probiotics, isolated or combined"	Defined as "Concentrated biologically active ingredients for enhancing human diet with allowed daily amounts of health components. Those supplements are mostly produced from mineral, animal or herbal based raw materials"	Defined as a product taken by mouth that contains a dietary ingredient and or a new dietary ingredient that is intended to supplement the diet.	Health Food is defined as a "food that has specified health functions, suitable to be taken by specified groups of people, and for the regulation of the functional state of the human body and is not used for the treatment of diseases"	"Health supplement" means any substance, extract or mixture of substances as determined by the Authority, sold in dosage forms used or purported for use in restoring, correcting or modifying any physical or mental state by (a)complementing health;(b) supplementing the diet; or (c) a nutritional effect and excludes injectable preparations
2	**Synonyms**	Dietary Supplements	Biologically Active Supplements (BASs) or Biologically Active Food Supplements(BAFS	Functional Food for dietary purpose	Nutrient supplement, health food	Health supplement
3	**Responsible Regulatory Authority for Registration of dietary Supplement**	ANVISA(Brazilian Health Regulatory Agency)	The Federal Service for Supervision of Consumer Rights Protection and Human Welfare (Rospotrebnadzor)	FSSAI(Food Safety and Standards Authority of India)	CFDA (China Food and Drug Authority)	SAHPRA(South African Health Products Regulatory Authority
4	**Rules and Regulation applied**	Resolution RDC 242/2018 (The Registration of Vitamins, Minerals, Amino Acids and Proteins classified as Specific Medicines for oral use)	TR TS 021/2011.	The Food Safety and Standard Regulation	Food Safety Law of the People's Republic of China	Health supplement complementary medicine law

Sr. No	Parameters	BRAZIL	RUSSIA	INDIA	CHINA	SOUTH AFRICA
5	**Regulatory Agency Website**	http://antigo.anvisa.gov.br/en/english	https://roszdravnadzor.gov.ru/en	https://www.fssai.gov.in/	http://www.sfdachina.com/	https://www.sahpra.org.za
6	**Timeline for approval of application**	~ 180 days	-	60 days without queries and 90 days with queries	1 – 2 years	12 Months
7	**Validity period**	5 Years	5 Years	1 to 5 years	5 Years	5 years
8	**Health Claims**	Allowed	Allowed	Allowed Ingredients Nutrition Claims Function Claims Health maintainance Claims Anti-aging Claims	Allowed (All the stated 27 claims whichever Is applicable)	Allowed Claims should meet technical requirements of quality, safety and efficacy.
9	**Authorities for approval of claims**	ANVISA	Rospotrebnadzor	FSSAI	CFDA	SFDA
10	**Health warning**	Required	Required	Required	Required	Required
Administrative and Technical requirements						
11	**Regulatory requirement for Registration**	Cover letter Label copy Company registration form Form 1 and 2 Copy of the sanitary permit Scientific evidence applicable to prove the effectiveness of the proposed claim Reports of stability studies	Power of Attorney Free sale certificate Documents of the authorization confirming, that given product is referred to BAS GMP Certificate or ISO 9001 certificate of quality, certificate of analysis Sample of an original label	Product Approval License / import license	Health Food registration application form A copy of Registration certificate of applicant Letter of guarantee stating no infringement or preparatory rights Test certificate issued by an Authorized Testing Institute Sample product label and Product insert sheets with health claims Legal product qualification issued by country of origin Three samples	SAPC certificate Copy of NDOH premises license Local area plan Building floor plan /Layout Equipment inventory Site Master File Confirmation of understanding of responsibilities Proof of Payment

Sr. No	Parameters	BRAZIL	RUSSIA	INDIA	CHINA	SOUTH AFRICA
Labelling and Packaging requirements						
12	**Labelling information**	product shall be designated as "Food Supplement or as "Suplemento Alimentar" the recommendation for use according to population group highlight and bold warning that, - "This product is not a medicine" - "Do not exceed daily recommendation of consumption indicated on the packaging" - "Keep out of the reach of children" instructions for storage, including after opening the package	The expiry date or end of shelf-life, storage conditions Food supplement's state registration that accompanied with the registration date and number manufacturer's address and company name the address and telephone of an organization authorized by the manufacturer Claims	Name and Complete Address of the Manufacturer Net Quantity Lot Number of Batch Date of Manufacture or Packing Country of Origin for Imported Food Instructions for Use Information Relating to Food Additives, Colours and Flavour Veg or Non-Veg Symbol	Name of Health Food; Health Food Logo and Certificate Number; List of Ingredients; Claim; Name and Address of the Manufacturer; Suitable and Unsuitable Group; Recommended Consumption Dosage and Instruction for Use; Manufacturing Date, Date of Minimum Durability the Expiration Date; Storage Conditions; Product Standard Code and Certificate Number; Precautions;	Name of Health Food; Health Food Logo and Certificate Number; List of Ingredients Function(S) Of Product and Its Determination; Net Quality; Claim; Name and Address of the Manufacturer; Recommended Consumption Dosage and Instruction for Use; Manufacturing Date, Date of Minimum Durability the Expiration Date; Storage Conditions; Product Standard Code and Certificate Number; Precautions
13	**Labelling language**	Portuguese If not an additional tag or cover label should be placed, containing the mandatory information in Portuguese.	Russian	English or Hindi	Chinese	English
14	**Nutritional information on labelling**	the quantities of all nutrients the percentage daily value (%VD)	The quantity and %NRV (Nutrient Reference Value)	Required	Nutritional Ingredients That Characterise Function(S) Of Product and Its Determination; Net Quality	Reference to the relative Nutrient Reference Value (NRV) as a percentage may also be included on the label where relevant

In South Africa, health supplements should not be intended for supply to any children under the age of seven months old unless where supplementation is medically warranted. The claims that indicates to cure or treat some specific disease cannot be used unless they are pre-approved by authority. The use of any claim must take account of minimum and maximum dosage levels prescribed for all substances and the levels must be within the limits prescribed in the regulation.

Documents required for a new license application include,

- SAPC certificate of recording of the pharmacy or proof of submission of the application to the SAPC
- Letter of authorisation of the responsible pharmacist to communicate with SAHPRA
- Latest CV of the Responsible Pharmacist 4 Copy of proof of SAPC registration of the Responsible Pharmacist (RP)
- Letter of authorisation of the responsible person to communicate with SAHPRA (if not the RP)
- CV of the responsible person
- Copy of NDoH premises licence or proof of application to NDoH Copy SAPC certificate of recording of the pharmacy for the site
- Copy of SAPC certificate of recording of the pharmacy owner for the site
- Site Master File (SMF) or the attestation and documentation as part of this application, and acknowledgement of responsibility to prepare and submit the SMF
- Local area plan
- Building floor plan
- Layout
- Equipment inventory
- Quality manual or Quality Assurance report (minimum SOPs and documentary evidence as required in the application preamble)
- Additional site copies of pharmacy premises licence, SAPC certificate of recording, and others as for primary site.
- Quality assurance report including complete SOPs for: Quality assurance product release Recall Finished product specifications and testing Determination of shelf-life Product sterilisation (if applicable) Records of Quality assurance product release Finished product specifications and testing Determination of shelf life (expiry date) List of SOPs (titles and numbers related to Quality management system)
- List of products
- Confirmation of understanding of responsibilities
- Proof of payment. (10)

7. Conclusion

The Dietary Supplements plays an important in public health and many people are using these products on everyday basis therefore they should be regulated in a correct manner and this work will be beneficial for that. It is wide umbrella term and they do not have stringent regulations, Also the regulatory and legislative requirements are different in all the countries mentioned above. The regulation varies but if we see in comparison of all the countries that have been mentioned above, South Africa is strict in terms of regulations and regulatory requirements for registration among others, it also requires highest number of documents and various licenses for registration of products.

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Conflict of Interest

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