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Research paper

Plant-Based Health Supplements: An Indian Perspective

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Abstract

The market for health supplements is expanding steadily as a result of changing lifestyles, rising incomes, and greater health consciousness. The vitamins and minerals segment of health supplements dominates the current market. The FSSAI, India's health supplement authority, with its well-defined framework for licensing health supplements, ensures science-based guidelines for food and health supplements. The Indian market for supplements, predicted to grow to a value of USD 10 billion by 2025, necessitates quality and safety throughout their production and sales. The present study gives a glimpse of the plant-based health supplement market scenario in India along with its challenges. To sustain the steady growth of the health supplement sector, it is of utmost importance that customer trust, R&D related quality issues, and regulatory mechanisms need to be strengthened.

Keywords: *Health Supplement; FSSAI; Network Graph; Herbals.*

1. Introduction

Health supplements are consumed for keeping the body in good physical and mental condition, and also to compensate for the deficient ingredients missing from the diet, which are required in the body. As a result, the human system would be less prone to exhaustion and at the same time injuries and fatigue could be avoided [1]. Their use has become more prevalent in recent years. They are defined as an external food product added to a person's normal diet as per the recommendation of a physician. Health supplements can be consumed by people above the age of five years. Their products consist of vitamins and minerals, proteins, plants, or botanicals consumed in the form of powder, concentrate, or extract in water, ethyl alcohol, or hydroalcoholic extract, either alone or in combination. These are not drugs as defined in clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), and the rules made thereunder. [Sec 22, FSS Act] (fssai.gov.in). The majority of these supplements are available in the form of tablets or powder. Different countries use various terms for supplements, such as health supplements in India, dietary supplements in the United States, Health food in Japan and China, and Natural health products in Canada [2]. These different terms for supplements were all placed under the food category 13.6. of the Global Food Category System used by the Codex Alimentarius and International trade. Another term, "nutraceuticals," is also used in the Indian legislation. These play a dual role as a health supplement and for therapeutic purposes [3]. The term 'nutraceutical' is not used in other countries [4].

Health supplements are in high demand worldwide. The most cited reason for taking supplements is to maintain general well-being and to develop a strong immune system [5]. Estimates suggest that demand for natural products increased by over 30% in the post-COVID-2019 period. The health supplement market is segmented into different categories. Most of the health supplement market in India is occupied by vitamins and minerals (40%), followed by probiotics (30%), herbal supplements (plant-based health supplements) (10%), Omega-3 fatty acids (5%), and others (15%). (https://www.maximizemarketresearch.com/market-report/nutraceutical-market-global/2936/).

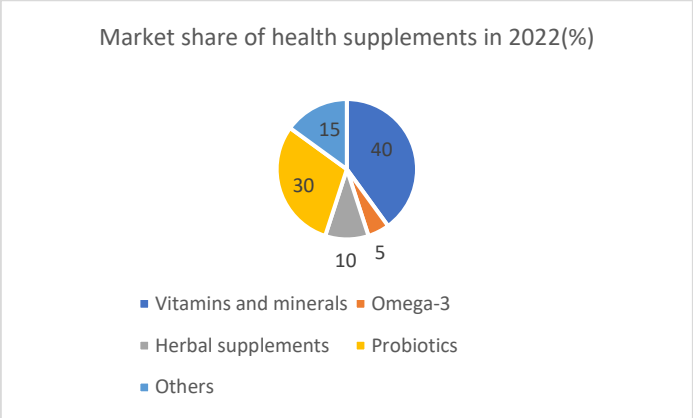

Fig 1: Percentage Share of Health Supplements in India (https://www.maximizemarketresearch.com/market-report/nutraceutical-market-global/2936/).

The uses of the different health supplements are listed below:
Vitamins and Minerals: Vitamins are metabolic regulators. They affect several key body processes critical for physical activity, athletic performance, and overall health. To produce energy, B-complex vitamins are involved in the metabolism of lipids and carbohydrates. Vitamins C and E are antioxidants crucial for preventing oxidative damage to the structure and function of cells and subcellular structures during exercise and training. Fatigue and weaker bones are two symptoms of vitamin D insufficiency that might increase the risk of osteoporosis. Hormonal balance, metabolism, and brain function all depend on vitamin B12[6].
Minerals that are most popular in the Indian market are calcium, iron, and zinc. For maintaining good bone health, calcium is essential, particularly for women whose bone density has decreased because of menopausal estrogen decline. Additionally, it is essential for preserving bone mass and lowering the incidence of osteoporosis in older adults. Iron is used for the formation of haemoglobin and the management of anaemia. Its deficiency affects 51% of women between the ages of 15 and 49. Zinc is known to increase circulating T cells; increase the killing capacity of lymphocytes, and reducing
the incidence of the common cold [6].
Herbal Supplements: Herbal supplements are made from botanical parts. They often include 'bioactive substances" (food constituents vital for boosting general well-being and preventing disease, even though they are not as necessary for survival as traditional nutrients such as vitamins and minerals) [7]. Some examples of bioactive compounds are carotenoids, flavonoids, etc. So herbal supplements with bioactive substances are thought to provide health advantages such as boosting the immune system, revitalizing the body, helping in weight management, enhancing mood, and improving sleep. They are sold in the form of capsules, pills, tablets, but are also found in liquid or powder forms. The herbal or plant-based supplements are preferred by those who have digestive issues while consuming regular supplements. Besides, these plant-based supplements are more readily absorbed by the body than regular supplements. (https://reviews.indiatimes.com/ published on January 18, 2024). Also, herbal supplements have sustained popularity given the fact that these are natural (i.e., derived from plant roots, leaves, or bark).
Amino Acid Supplements: Proteins are made up of amino acids. Athletes use supplements such as branched-chain amino acids (BCAAs) comprising leucine, isoleucine, and valine. These help with muscle repair in athletes. They also help in neural function, blood glucose and insulin regulation, as well as protein metabolism [8]. Plotkin et al [8] also stressed that leucine, valine, and isoleucine boost muscle growth and enhance exercise performance.
Omega-3 fatty acids: They are widely known for their capacity to lower inflammation and hence enhance heart health. Omega-3 fatty acid supplements are also known to improve function and reduce the chance of decline in cognitive abilities. They also lessen inflammation all over the body, supporting health and encouraging muscle repair.

2. Regulatory Framework for Plant-Based Health Supplements in India

"The Food Safety and Standards Act, 2006 (Act No. 34 of 2006) was passed by the President of India in August 2006. This act was passed to build a safe food culture in India. It brought under one ambit/umbrella the eight older laws related to food processing. The FSS only dealt with the standards of the final food products and not the raw materials. There was a problem in corroborating the standards for both raw material and final products. In this context, the Food Safety and Standards Authority of India (FSSAI) was formed in 2008, but it started working only in 2011. Since then, several rules have been introduced or updated, catering to various aspects of food product standards such as licensing and registration, contaminants, toxins, and sample analysis [2]. Until 2015, there was no mention of health supplements or nutraceuticals in the Indian regulatory framework for food products. The draft for nutraceuticals/health supplements was only published in 2016. After its introduction, one year was given to food product manufacturers to comply with these regulations; hence, the final effective date of these regulations was considered as 01 January 2018 only. The regulations governing plant-based health supplements are the same as those governing other types of health supplements. This must comply with the rules of the FSSAI.
India has developed a strong regulatory framework for health supplements; however, the FSSAI needs to follow a more coordinated approach and robust system for the effective implementation of the guidelines. Compared to India, the regulatory framework for other countries is already well developed and strictly adhered to. The FSSAI has revised the regulations on health supplements that are effective from 01 April 2022.

2.1. Comparison of the regulatory framework of India vis-à-vis other countries

In India, the FSSAI classifies health supplements as food. The ingredients/levels must conform to the list as specified in Schedule I/II/IV/VI/VII/VIII of FSSAI. It describes allowed vitamins, minerals, botanicals, amino acids, probiotics, etc. Products do not require premarket approval if they conform to the ingredient lists and conditions. Manufacturing follows food GMP, and claims are restricted to functional/structure-like claims, with no therapeutic or disease claims. Post-market oversight is through recalls and enforcement by FSSAI. There is no dedicated, mandatory serious adverse event reporting system.

In the US, herbal supplements are regulated as food under the Dietary Supplement Health and Education Act (DSHEA). They do not require pre-market approval unless they contain a novel dietary ingredient (NDI). Manufacturing must comply with current good manufacturing practices (cGMP), and claims are limited to structure/ function statements with disclaimers, but disease claims are prohibited. It is mandatory to report in case of serious adverse events.
In Canada, herbal supplements fall under the Natural Health Products (NHP) regulations. It requires both an in-site licence and a product licence (NPN) supported by evidence. Labels must display authorised indications and compliance with NHP-specific standards.
Australia regulates herbal supplements as "complementary medicine" under the Therapeutic Goods Administration (TGA). The products are divided into two categories: low risk or high risk, available from the Australian Register of Therapeutic Goods (ARTG). All products must meet the TGA GMP (Good Manufacturing Practices) requirements, and labels should display ARTG numbers.
In China, herbal supplements are classified as "health foods". New or high-risk products require registration, while those using raw materials listed in the government catalogue follow a simplified filing procedure. Post-market surveillance and safety reporting are mandatory.
Japan regulates herbal supplements under the Food with Health Claims Framework. It includes three categories: Food with Nutrient Function Claims (FNFC), Food for Specified Health Use (FOSHU) requiring government approval, and Food with Function Claims (FFC). Herbal products may be used in FFC products if supported by evidence. FOSHU products undergo a rigorous approval process. Manufacturing follows food GMP, and post-market monitoring of claims is carried out by the Consumer Affairs Agency (CAA).
In summary, India and the US regulate herbal supplements as foods unless medicinal claims are made, while Canada and Australia classify them as therapeutic goods. Japan and China apply a hybrid system with a structured food claim framework. The regulatory framework for herbal supplements across the globe shows no harmony for recommending intake levels of health supplements, even for the same botanical product [2].

3. Plant-Based Health Supplements Licensing in India

Companies and individuals must follow the stringent regulations laid out by the FSSAI to sell health supplements in India. For any health supplement to be commercialized, many forms, such as FORM A and FORM B, must be completed and approved. The process for registering health supplements is as follows:

1) Submit an online application through FSSAI's portal.
2) Complete product information, including ingredients, formulation, purpose, and safety, should be provided. Scientific evidence demonstrating the safety and product efficacy, particularly for new ingredients, should be provided.
3) The product label requirements should be as per FSSAI labelling requirements, including accurate nutrition and claims.
4) Provide information on the manufacturing facility, including equipment, quality control measures, and details of the facility.
5) The source and quality of the product should be mentioned.
6) Packaging information should meet the FSSAI standards.
7) The FSSAI will review the application, evaluate the product's safety and effectiveness, and grant registration if necessary.
8) Compliance and surveillance: After approval, the FSSAI continues to monitor and audit the product to ensure its quality and safety. Fig 2 shows a flow chart for the process followed for the licensing and registration process of health supplements in India [9].

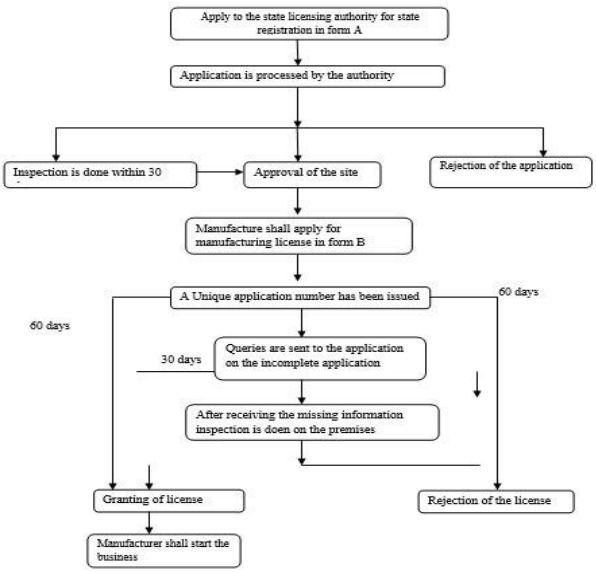

Fig. 2: Licensing and Registration Process of Health Supplements in India (Flow Chart).

4. Market Scenario for Health Supplements in the US and India

The size of the U.S. market for dietary supplements was estimated at USD 65.7 billion in 2023 and is projected to increase at a compound annual growth rate (CAGR) of 9.47% from 2024 to 2033, reaching USD 162.4 billion. (https://www.precedenceresearch.com/dietary-supplements-market)
Some key points from the report are as follows:

- The size of the North American dietary supplement market was estimated at USD 50 billion in 2023 and is projected to increase at a compound annual growth rate (CAGR) of 8.2% from 2024 to 2033, reaching around USD 109.9 billion. For the European region, the estimate was USD 32.3 billion in 2023 and projected to increase at a CAGR of 6.5% from 2024 to 2033, reaching around USD 60.4 billion.

- The size of the Asia Pacific dietary supplement market was estimated at USD 65.7 billion in 2023 and is projected to increase at a CAGR of 9.5% from 2024 to 2033, reaching around USD 162.4 billion. (Fig. 3).

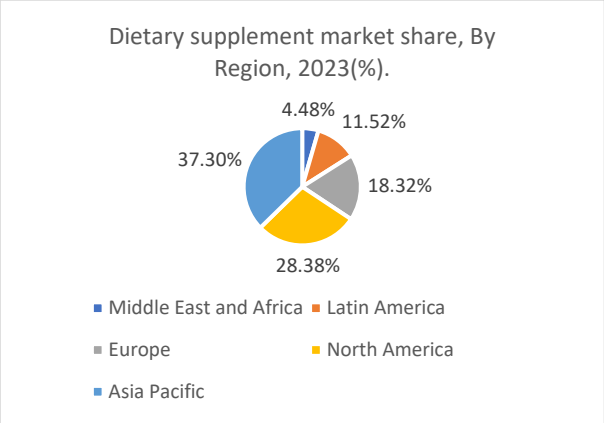

Fig. 3: Dietary Supplement Market Share, by Region.

As per the Custom Market Insights survey, the Indian Health/Dietary Supplements Market will grow at a compound annual growth rate (CAGR) of 10.2% between 2024 and 2033. The market is expected to grow to USD 23,975.2 million by 2024. Its worth is projected to reach USD 57,464.2 million by 2033. Fig 4 shows the future trends in the Indian supplement market (by application) from 2024 to 2033. https://www.custommarketinsights.com/report/india-dietary-supplements-market/.

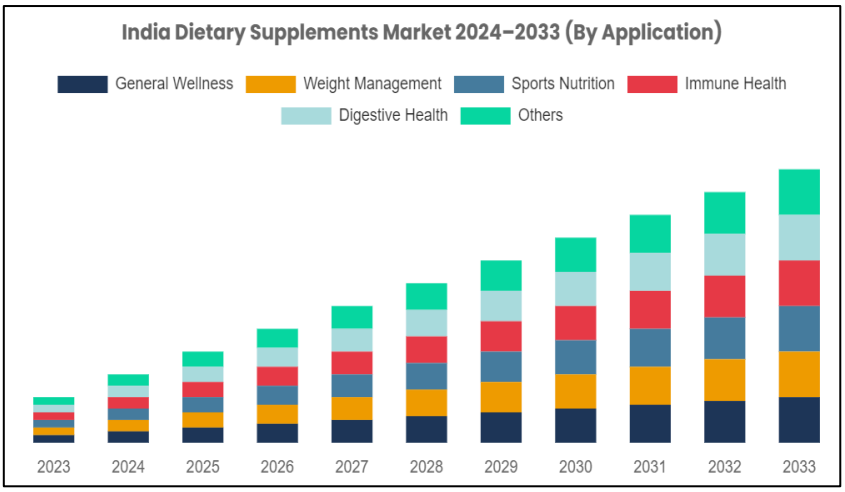

Fig. 4: Indian Health/ Dietary Supplement Market 2024-2033 (by Application).

5. Health Supplements (from Plant Sources) in the Indian Market

India has an extensive list of plant-based products/ botanical ingredients that can be used to supplement the diet. Various products containing Ashwagandha (Withania somnifera), Tumeric (Curcuma longa), Amla (Emblica/ Phyllanthus officinalis), Tulsi (Ocimum sanctum), Brahmi (Bacopa monnieri), Stinging nettle, etc., have also shown beneficial effects in improving learning and memory or health-related benefits [10]. Of these, the Financial Express newspaper (financialexpress.com) cited that supplements containing curcumin (turmeric) and ashwagandha (Withania somnifera, NCBI: txid126910) jointly command over $278 million global market of health supplements. Both plants (Table 1) have been used in traditional Indian medicine, but do not have credible scientific data needed for global credibility.

Table 1: Description of Withania Somnifera and Curcuma Longa

Ashwagandha (Withania somnifera)	Referred to as the 'prince of herbs. It belongs to the family Solanaceae. Used for maintaining overall health and vitality. Conventionally used to cure nervous exhaustion, soothe the mind, arthritis, delay ageing, and increase sexual vigour. It has antimicrobial, antioxidant, immunomodulatory, hepatic, anticarcinogenic, and cardiovascular properties. Some other benefits are: diuretic, anti-epileptic [10-11].
Turmeric (Curcuma longa)	Turmeric is the dried root of the Curcuma longa plant. It belongs to the family Zingiberaceae. It is a powerful antioxidant, anti-inflammatory, antimutagenic, antimicrobial, and anticancer agent [12].

They received global attention when their health benefits were validated by clinical trials. Numerous studies related to their health benefits and validation by clinical trials have been published. This has been illustrated in Fig. 5(A) and (B). It shows publications related to Ashwagandha and Curcumin in the form of a network graph, generated using connected papers (www.connectedpapers.com). Connected papers is a visual exploration tool that identifies relevant literature based on content similarities and displays the result in the form of visual clusters. The author selected the most pertinent papers for Ashwagandha and Curcumin supplementation; this is known as the 'origin paper. The findings are presented as a graph based on the original study. The graph shows the correlation between papers rather than how many times a paper has been cited. In the graphs, each node represents a research paper related to the source document that was selected because it has the highest number of citations and a relationship with the objective of this review. The "origin paper' is Perez-Gomez, 2020 [13] for Ashwagandha and Panknin, 2023 [14] for curcumin.

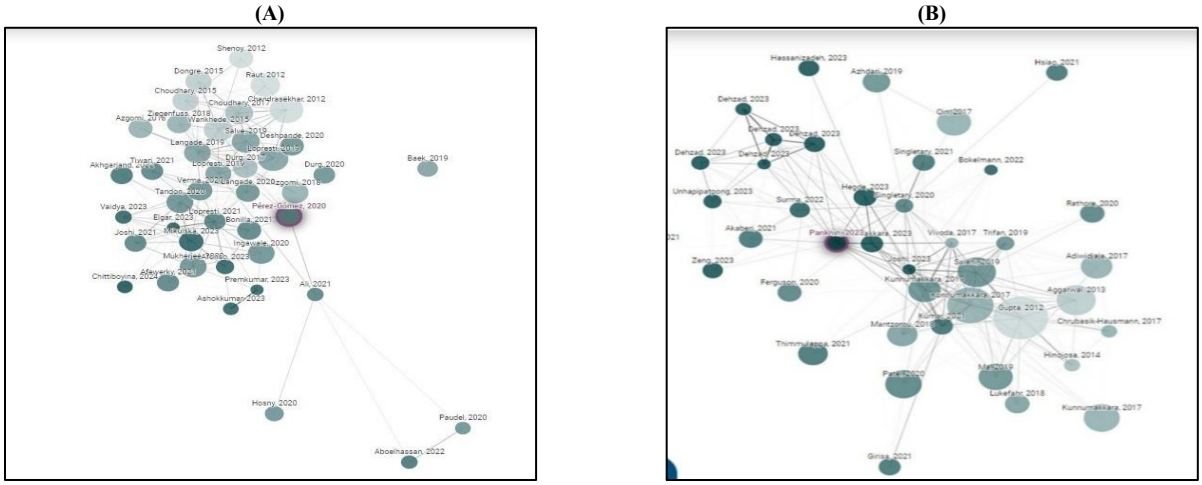

Fig. 5: A). Network Graph of Studies Related to Ashwagandha Supplementation. B). Network Graph of Studies Related to Curcumin Clinical Trial. Node Size Is Proportional to the Number of Citations and the Publishing Year's Colour. The Graph Is Developed Using Connectedpapers.com Accessed on 1 May 2024. Node Size Is Proportional to the Number of Citations.

While Ashwagandha's potential medicinal applications are supported by data, the exact molecular processes through which it works are unclear [15]. Determining the exact mechanisms of action of Ashwagandha is crucial for creating more specialized and successful treatment plans. Perez-Gomez et al [6] demonstrated Ashwagandha's benefits for VO2max (maximum oxygen concentration) in athletes and non-athletes, but small sample sizes and short trial durations limit generalizability, as noted by Bonilla et al [15]. Similarly, for Curcumin, most of the clinical trials conducted were restricted to a small number of patient groups. Other barriers to curcumin's clinical efficacy are its poor bioavailability (absorption by the body). Efforts have therefore been dedicated to developing curcumin formulations with greater bioavailability and systemic tissue distribution [16]. In recent times, Urtica dioica (Stinging nettle) has garnered attention as a potentially useful ingredient in herbal supplements. A variety of bioactive chemicals are abundant in the leaves. Antirheumatic, anti-infective, immunomodulatory, anti-hyperglycaemic, and allergy alleviation are just a few of its many biological properties [17]. Future research should concentrate on the correct formulation, stability testing, and therapeutic activity of stinging nettle-containing supplements [18].

Besides the plants already mentioned above, Table 2 presents a list of additional plants/parts utilized as supplements, their suggested dosage according to FSSAI, and the bioactive ingredients that confer the distinct properties of these plants. The importance of the bioactive compounds is supported by references as mentioned in the table. It details plant resources listed and sanctioned in Schedule I/II/IV/VII/VIII of the FSSAI (Food Safety and Standards Authority of India). As per FSSAI, health supplements must include ingredients listed in Schedule I, Schedule II, Schedule IV, Schedule VII, Schedule VIII, or solely enzymes from Schedule VI. A substance mentioned in Schedule IV can be part of the health supplement, either alone or alongside botanicals, or their extracts, in unprocessed or processed forms, or in any other format authorized by the Food Authority.

Table 2: Important Plant (Bioactive) Ingredients Commonly Used as Health Supplements for General Wellbeing/Fitness

S. No	Common name	Scientific Name	Parts used	Applications as given in FSS Schedule IV	Bioactive ingredients	References no.
1	Ashwagandha	Withania somnifera Family: Solanaceae	Roots Fruits Extract	3-6g 3-10g 0.5-1g	Flavonoids, tannins, alkaloids, glycosides, and steroid lactones (withanolides).	15, 19-20
2	Stinging nettle (bicchubuti)	Urtica dioica	leaves	10-20g	Flavonoids, phenolic acids, amino acids, carotenoids, organic acids, fatty acids.	18, 21
3	Wild mangosteen (kokam)	Garcinia cambogia, G. pedunculata	Mature fruit	10-20ml (as juice) 5-10g (as powder) 5-10 ml/g (as juice/powder)	Phenolics and steroids, benzophenones, etc.	22-24
4	Gokhru	Tribulus terrestris	Fruit/whole plant	5-10g	steroids	25-26
5	keetjadi	Cordyceps sinensis	Whole plant	20-60mg	Sterols, amino acids, cordycepin, protein	27
7	Indian barberry (Daruhaldi/ Rasaunt)	Berberis aristata	Fruit/stem extract	5-10 gm (fruit); 0.5-1 gm	Alkaloid: beberine	28
8	Long pepper (Pippali)	Piper longum Piper nigrum	fruit	15 mg/day of piperine, Max (Duration of use: maximum 30 days)	piperidine	29-30
9	Turmeric	Curcuma longa	Rhizome Fresh rhizome	2-5g(powder) 5-10ml(juice)	Curcumin	12, 31-32

6. Challenges of Plant-Based Health Supplements

The popularity and consumption of health supplements are increasing. People become more aware of their health benefits if they are taken along with a regular diet. This has given rise to a multi-billion-dollar industry that aggressively markets its products not only to sportspersons but also to normal individuals who want to lead a disease-free, productive lifestyle. However, supplements are often adulterated, inducing harmful side effects. Adulteration with heavy metals, unlisted or banned ingredients, poses health risks as highlighted by

Djaoudene et al., 2023[5] and Sellami et al.,2018 [27]. Standardized testing protocols could ensure product safety. In this regard, FSSAI in September 2024 issued an order regarding the provisions for Food for Sportsperson (under the category Food for Special Dietary Use) under FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical purposes, Functional Food and Novel Food) Regulations 2016. This provision inter alia mentions "Prohibited substances declared by the World Anti-Doping Agency shall not be added in any of the articles of food specified for sports persons. Food business operators must ensure to check the list of prohibited substances, which is published annually by the World Anti-Doping Agency and is effective from January 1 every year. FSSAI has notified a laboratory in Gandhinagar, Gujarat, that can be used by the authorities to get such products tested (https://myfssai.in/fssai_updates/). The presence of heavy metal contaminants has been reported by several studies, but very few have been conducted with extensive health risk assessment and large sample numbers. Lou et al., 2021[33] reported the presence of five heavy metals, copper, lead, cadmium, arsenic, mercury, using Inductively Coupled Plasma Optical Mass Spectrometry (ICP-MS) analysis in 1773 plant extracts from 2014 to 2019, representing 86 different kinds of commonly used herbal medicines. Cadmium concentration was highest in Ashwagandha and Curcumin. Therefore, it is of great advantage to establish universal standards and quality requirements for hazardous elements in herbal medicines so that this natural resource can continue and expand further, to benefit health globally [34]. Also, there should be clear regulatory guidelines and methods to evaluate the authenticity of the product labels. The FSSAI has developed a strong regulatory framework for health supplements. There should be more stringent rules of usage for corporate housing and rigorous clinical trials for research on the plant ingredients used in supplements. In this context, the Government of India has set up a panel to explore the possibility of bringing food products under the apex drug regulator, Central Drugs Standards Control Organisation (CDSCO), instead of the food regulator FSSAI, to address regulatory issues and promote consumer safety (https://economictimes.indiatimes.com/industry/cons-products/food/, dated 18 February 2024).
Last but not least, the negative impacts of sourcing botanical ingredients from the wild are a major area of concern. The evolving role of plants in global healthcare presents complex challenges to human health and biodiversity conservation. Howes et al. 2020 [35] emphasized that meeting healthcare needs with nature-derived materials must be reconciled with conservation strategies that ensure ecological sustainability. Emerging technologies, viz. genetically engineered plants, plant cell culture, etc., offer new hope for safeguarding essential natural products for the future, by relieving pressure on wild populations. These strategies, using innovative pathways to enhance yields, stabilize supply chains, and safeguard supplies of valuable medicinal compounds for future generations.

7. Conclusion

The health supplement market in India is growing at an unbelievable rate. This is due to increased awareness of the importance of nutrition to maintain a healthier lifestyle. Despite the challenges faced by the industry, such as regulatory changes and increased awareness among consumers for quality products, the market still offers ample growth opportunities. By giving utmost weight to the genuineness of products, innovation by studying global standards, and consumer education/awareness, stakeholders can effectively leverage the potential of the health supplement market in India.

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Conflict of Interest

None.

Funding

Nil.

Ethics Statement

None.

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