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Unlocking the Potential of Nutraceuticals

A Case Study of India's Market

White Paper / February 2024

Message from ASSOCHAM

Mr. Deepak Sood
Secretary General
ASSOCHAM

In recent years, India has witnessed a remarkable surge in the consumption and production of nutraceuticals, driven by evolving consumer preferences and an increasing awareness of preventive healthcare measures. In today's fast-paced world, many people may not obtain all the essential nutrients they need from their diet alone. Nutritional gaps arise due to factors such as poor dietary choices, restricted diets (e.g., vegan or vegetarian), medical conditions, or lifestyle factors. Nutraceuticals and dietary supplements provide a convenient way to address these deficiencies and ensure individuals receive adequate levels of essential vitamins, minerals, and other nutrients. As a result, the market for nutraceuticals has experienced exponential growth, presenting both challenges and opportunities for stakeholders across the industry.

Certain supplements are associated with specific health benefits and contribute to the prevention of various diseases. For example, vitamin D supplementation has been linked to improved bone health and reduced risk of osteoporosis, while omega-3 fatty acids are known for their anti-inflammatory properties and potential cardiovascular benefits. Antioxidant supplements like vitamins C and E help combat oxidative stress and reduce the risk of chronic diseases such as cancer and cardiovascular diseases. Certain demographic groups, such as pregnant women, infants, and the elderly, have unique nutritional requirements. Nutraceuticals and dietary supplements tailored to these populations help address specific needs and support optimal health outcomes. For instance, prenatal vitamins containing folic acid are recommended to prevent birth defects, while calcium and vitamin D supplements are often prescribed to older adults to support bone health and reduce the risk of fractures.

Our collaborative effort with TechSci Research aims to provide invaluable insights into this dynamic sector, offering a detailed analysis of market trends, growth drivers, challenges, and emerging opportunities. By delving into key aspects such as market segmentation, regulatory frameworks, and technological advancements, this paper equips industry players with the knowledge needed to navigate the complex landscape of nutraceuticals effectively.

Furthermore, the paper emphasizes the transformative potential of nutraceuticals in addressing prevalent health concerns and promoting overall wellness among the populace. With a diverse range of products catering to various health needs, nutraceuticals have emerged as a promising avenue for preventive healthcare, offering holistic solutions that complement traditional medical practices.

As we continue to witness rapid advancements in science and technology, it is imperative for stakeholders to collaborate and innovate, driving the nutraceutical industry forward. Through strategic partnerships, research initiatives, and policy advocacy, ASSOCHAM remains committed to fostering growth and sustainability within this vital sector, ultimately contributing to the well-being of our nation.

Message from the Director's Desk

Mr. Karan Chechi
TechSci Research Private Ltd.

Nutraceuticals, including fortified foods and supplements, are key for promoting wellness and preventing diseases. India faces a dual burden of malnutrition, with a significant portion suffering from both undernutrition and overnutrition. Globally, over two billion people, nearly half in India, have micronutrient deficiencies (MiNDs). Nutraceuticals help address these challenges by supplying essential nutrients to vulnerable populations and supporting weight management and disease prevention in overweight individuals. They bridge nutritional gaps, offering concentrated forms of vital vitamins, minerals, and other micronutrients crucial for health. The Government of India has prioritized tackling malnutrition and is executing various initiatives such as Anganwadi Services, the Scheme for Adolescent Girls, and the Pradhan Mantri Matru Vandana Yojana (PMMVY) as part of the broader Integrated Child Development Services (ICDS) Scheme. These targeted interventions aim to address the issue of malnutrition directly. Further, in June 2023, Chief Minister Pinarayi Vijayan announced the establishment of the Centre of Excellence in Nutraceuticals at the Life Sciences Park at Thonnakkal.

Growing health awareness, increasing prevalence of lifestyle conditions such as obesity, hair loss, and vitamin deficiencies, rising disposable income, and a growing interest in utilizing traditional Indian herbs in health supplements are driving significant demand for the Indian nutraceuticals market. Key players in the Indian Nutraceuticals Market comprise Haleon Plc., Dabur India Limited, Abbott India Limited, Bayer India Limited, Merck India Limited, Himalaya Wellness Company, Amway India, Baidyanath Group, Bigflex, Power Gummies, Kapiva, BigMuscles Nutrition, GNC, Oziva, Plix, among others. Companies in the market are investing heavily in research and development to create innovative nutraceutical products supported by scientific evidence. Collaborating with academic and research institutions, they conduct studies and clinical trials to validate product efficacy and safety, enhancing consumer trust and differentiating their offerings in a competitive market. For instance, in February 2022, Amway India partnered with the esteemed institution IIT Bombay to accelerate research in nutraceuticals, botanicals, and herbal supplements. Under this Memorandum of Understanding (MoU), a joint team comprising Amway's internal researchers and IIT Bombay experts will lead efforts to introduce groundbreaking methodologies and approaches for innovative advancements in health supplements, nutraceuticals, botanicals, and herbal supplements.

Foreign investors are increasingly interested in India's nutraceutical market since the implementation of 100% Foreign Direct Investment (FDI) in both nutraceutical and food supplement manufacturing. Global leaders such as MyHealth, Kamedis, Kreivo Health, and Baker Dillon Group are seeking collaborations and investments with Indian companies specializing in wellness and dietary supplements. The pandemic has highlighted the importance of immunity boosters and natural foods. India offers opportunities for various forms of nutraceutical delivery, including liquids, capsules, tablets, or chewable gummies.

The nutraceutical sector in India is poised for growth, supported by government regulations like the 2022 FSS (Nutra) Regulations, aimed at improving product delivery and ingredient quality. This advancement benefits both consumers and the market. The future looks bright for herbal plant-based supplements in India, driven by health consciousness, sustainability, and traditional herbal remedies. With evolving consumer preferences and regulatory support, the plant-based supplements market is expected to thrive further. However, maintaining high-quality standards and increasing awareness are crucial for ensuring the sector's sustainable growth.

Table of Contents

Executive Summary

The paper "Unlocking the Potential of Nutraceuticals: A Case Study of India's Market" delves into the burgeoning sector of nutraceuticals, which are food-derived products offering health benefits beyond basic nutrition. It discusses the regulatory framework governing nutraceuticals in India, highlighting the need for comprehensive regulations to ensure product safety and efficacy while fostering industry growth. The discussion begins with an overview of nutraceuticals, highlighting their distinction from conventional foods and pharmaceuticals due to their functional health benefits. Nutraceuticals have gained popularity among consumers seeking alternatives to traditional medicine, focusing on preventive health measures and holistic wellness. However, their regulation presents a complex challenge, balancing the need for safety and efficacy with fostering innovation and market growth.

Chapter 1: Delves into the foundational aspects of nutraceuticals, elucidating their classification, development process, and the evolving role of medical affairs in this domain. Furthermore, it sheds light on india's burgeoning nutraceutical market, driven by factors such as rising awareness of health issues and prevalent micronutrient deficiencies.

Chapter 2: Attention is turned toward the regulatory environment governing nutraceuticals in India. It outlines the current regulatory framework, anticipates future developments, and emphasizes the importance of effective labeling provisions to enhance consumer awareness and safety. Additionally, licensing requirements are discussed as pivotal elements in ensuring product quality and compliance.

Chapter 3: Explores emerging trends in the nutraceutical industry, forecasting upcoming developments and highlighting the impact of digitalization and technological advancements. E-commerce trends and innovative product formulations are key drivers of growth in this dynamic sector.

Chapter 4: The focus shifts towards Ayush practices, examining trends, industrial growth, and modifications to the Biodiversity Act. This section underscores the integration of traditional Ayurvedic knowledge with modern nutraceutical practices, presenting opportunities for innovation and market expansion.

Chapter 5: Addresses trademark challenges faced by nutraceutical start-ups, offering strategic insights to navigate these obstacles and foster success in a competitive market landscape. Moreover, it discusses product development challenges and proposes solutions to streamline the process.

Chapter 6: Provides concluding insights on the potential of nutraceuticals in India. It synthesizes key findings from the preceding chapters, underlining the significance of this sector in addressing public health concerns and fostering economic growth. Additionally, it emphasizes the need for continued research, innovation, and regulatory harmonization to realize the full promise of nutraceuticals in India.

In summary, this paper offers a comprehensive examination of India's nutraceutical market, encompassing its landscape, regulatory dynamics, emerging trends, Ayush practices, trademark challenges, and concluding insights. It serves as a valuable resource for stakeholders seeking to capitalize on the vast opportunities presented by this rapidly evolving industry.

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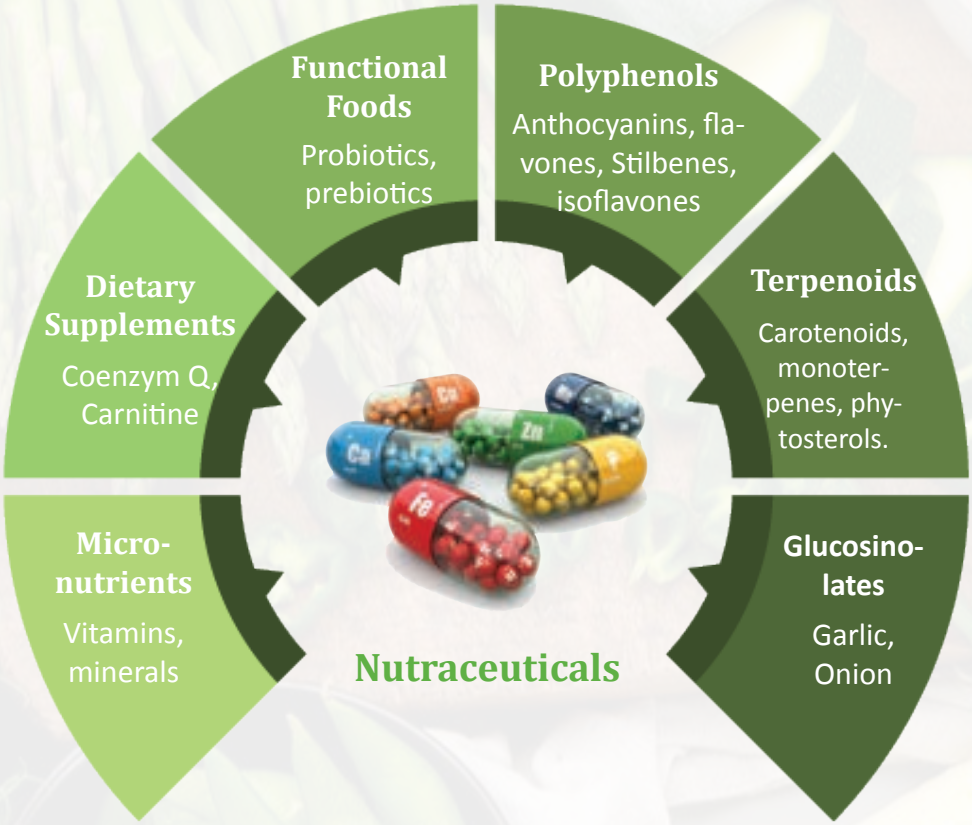
Chapter 1

Exploring the Promise of Nutraceuticals

A Deep Dive into India's Market Landscape - Introduction

Nutraceuticals: Food-Derived Products with Potential Health Benefits Beyond Nutrition

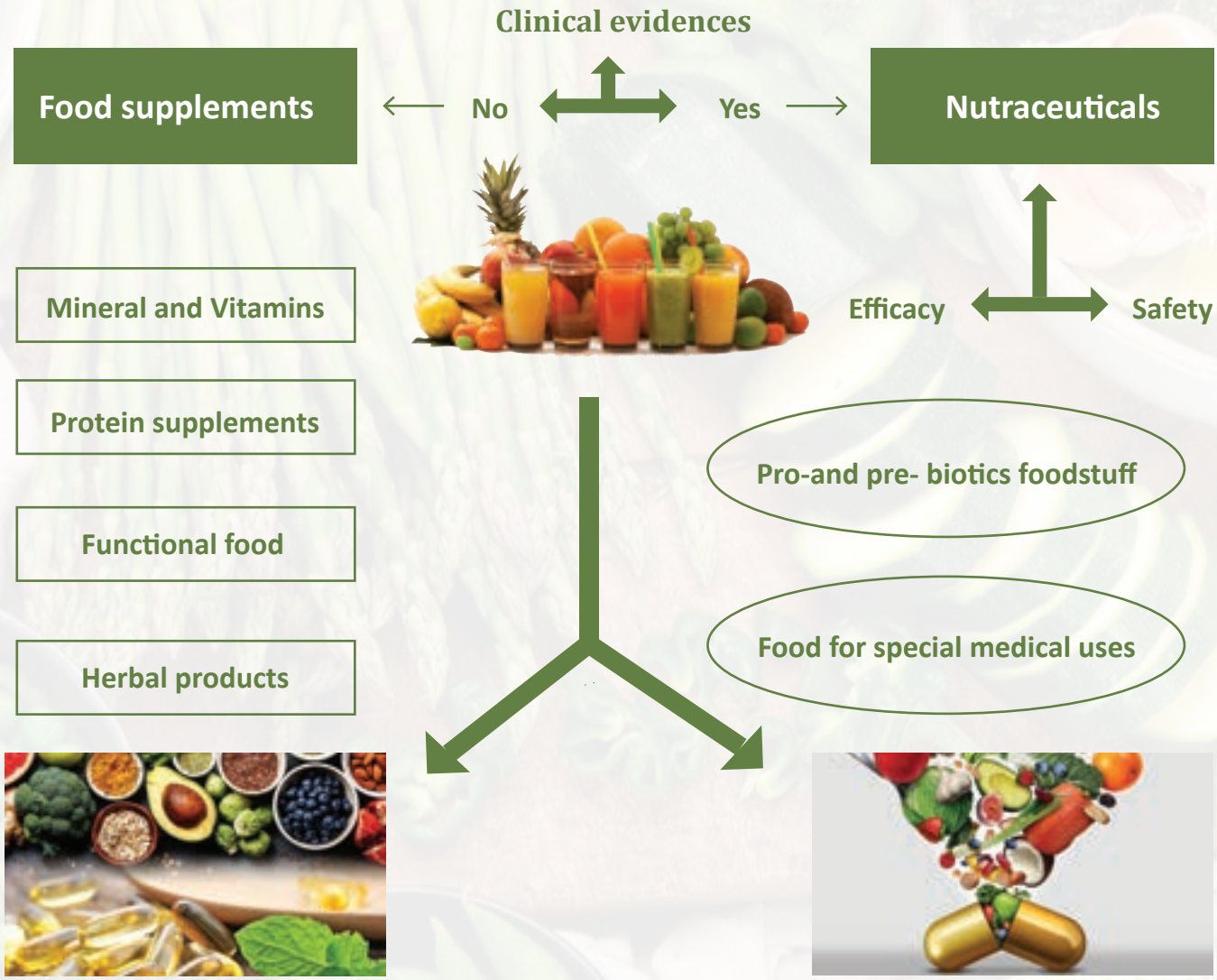
Nutraceuticals are specialized formulations that address specific dietary needs or provide preventative healthcare benefits. Coined by Dr. Stephen De Felice in 1989, the term blends "nutrition" and "pharmaceutical." These products encompass nutrients aimed at preventing and treating diseases while supplementing diets. Over time, terms like 'nutraceuticals,' 'food supplements,' and 'dietary supplements' have emerged, but regulatory bodies have yet to establish clear distinctions between them. Recent literature underscores the importance of redefining nutraceuticals, emphasizing factors like efficacy, safety, and toxicity. Food products serve to sustain life, provide energy, and promote growth, and isolating nutrients from them has become common practice.



Differentiating between food/dietary supplements and nutraceuticals often hinges on identifying epidemiological targets and conducting safety and efficacy studies. Nutritional supplements should demonstrate strong safety profiles and enhanced bioavailability with minimal side effects when supported by robust clinical evidence.

While the line between nutraceuticals and food supplements may blur, the distinction often lies in the

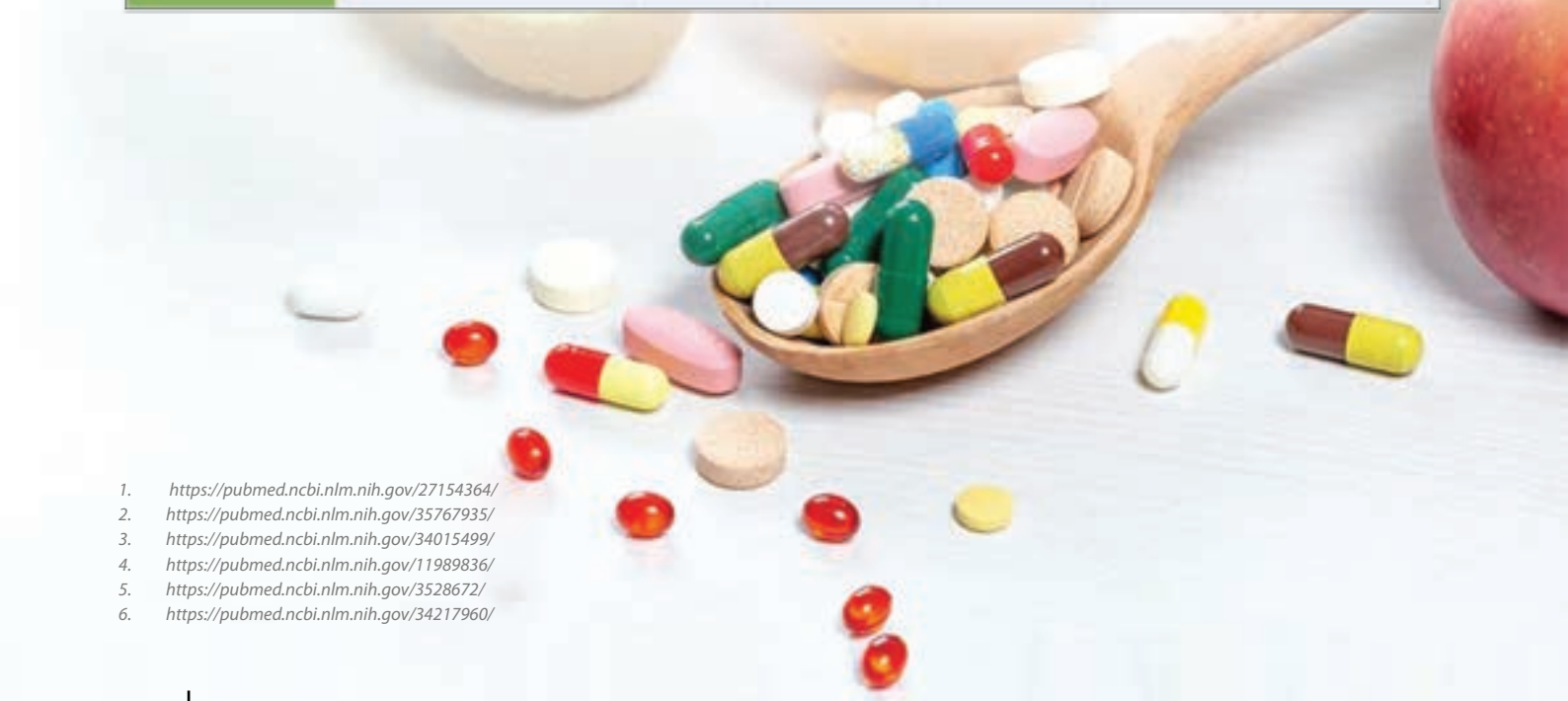
Differences between food supplements and nutraceuticals



claims made about their effects. Nutraceuticals encompass a range of products, including pro- and pre-biotic substances and food for special medical purposes, while food supplements include minerals, vitamins, proteins, functional foods, and herbal products. By potentially reducing or replacing the need for pharmaceuticals, nutraceuticals integrated into daily diets could aid in preventing pathological disorders. There's evidence suggesting that certain foods, spices, and herbs can lower disease risk and enhance quality of life. Nutraceuticals have shown promise in preventing and treating complex diseases, but their administration and prescription should be carefully regulated to mitigate misuse and adverse effects. Some researchers have explored drug compound-based nutraceuticals to enhance efficacy and bioavailability. The demand for nutraceuticals like antioxidants and omega-3 fatty acids, as well as various plants including algae, aloe vera, seaweed, and wheatgrass, alongside teas and herbs such as ginseng and Echinacea, continues to flourish and expand steadily.

Detailed findings including clinical data on nutraceuticals are shown in the table below.

Nutraceuticals	Bioactive Molecule	Dosage	Formulation	Duration of Study	Action
Omega-3	Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA)	60 mg/kg/day	Capsule	12 months	Cystic fibrosis
Aloe vera	aloe-emodin, aloin, aloesin, emodin, and acemannan	-	Gel	2 months	Acute dermatitis
Seaweed	polysaccharides, proteins, lipids, and polyphenols	2000 mg/day	Extract	12 weeks	High-density lipoprotein (HDL) cholesterol
Wheatgrass	vitamins, (A, B, C and E), minerals such as iron, calcium, magnesium, benzo(a)pyrene, ferulic, gallic, caffeic, syringic and p-coumaric acid	100 cc/day	Juice	1 month	Active distal ulcerative colitis
Ginseng	ginsenosides	100 mg twice a day	Capsule	12 weeks	Psychomotor functions
Echinacea	polysaccharides, glycoproteins, alkamides, cichoric acid, caftaric acid and chlorogenic acids	20 mg or 40 mg twice a day	Powder	6 weeks	Anti-anxiety and anti-depressant



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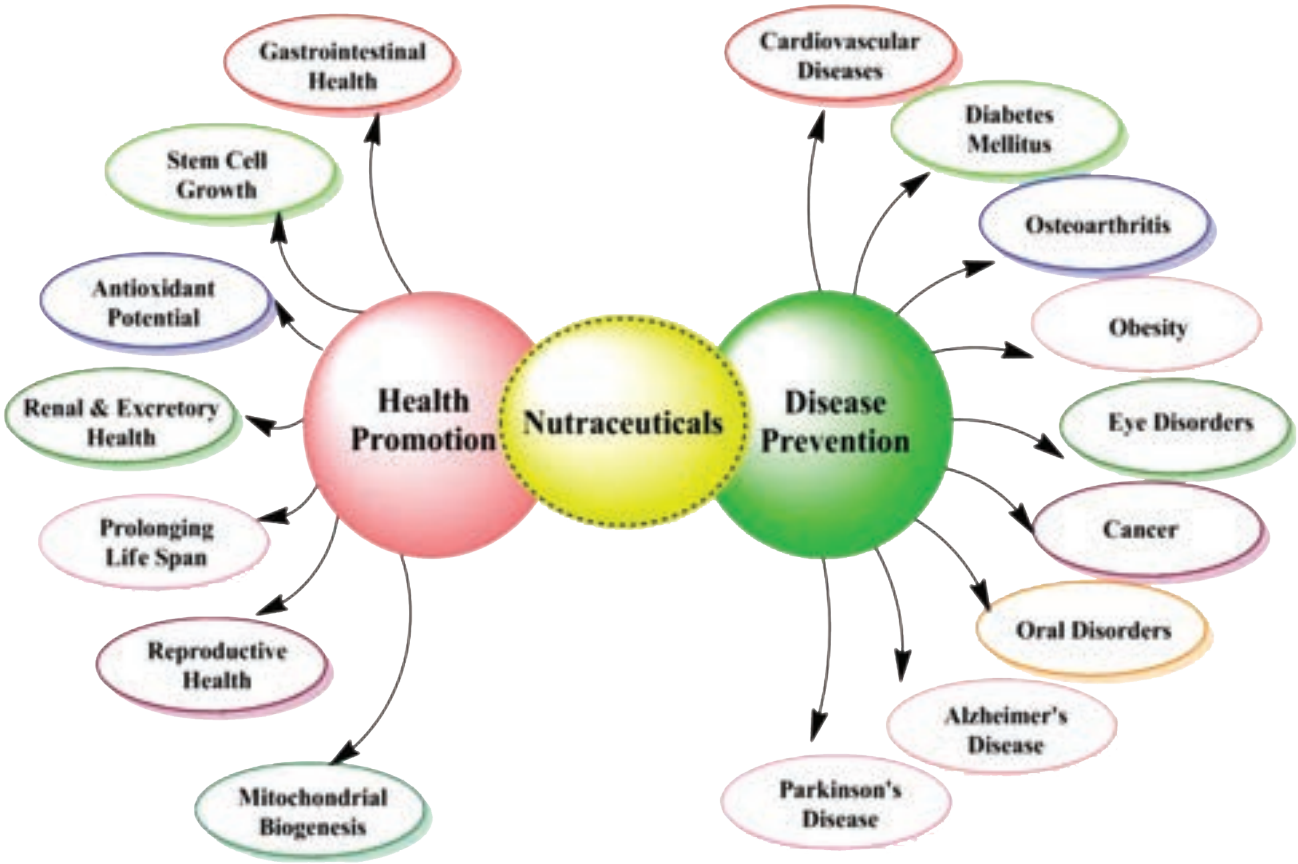
5. https://pubmed.ncbi.nlm.nih.gov/3528672/
6. https://pubmed.ncbi.nlm.nih.gov/34217960/

Nutraceuticals offer a broad spectrum of therapeutic benefits across various areas such as cough and cold relief, anti-arthritis properties, digestive aid, sleep improvement, and assistance in treating conditions like cancer, depression, diabetes, high cholesterol, blood pressure, and pain management. Research and development efforts in the nutraceutical sector are currently at their peak, aiming to explore the potential significance of various nutraceuticals in the pharmaceutical industry. Meeting the scientific demands for nutraceuticals involves standardizing their constituents, carefully developing protocols, and conducting clinical studies, which are crucial for consumer health and the success of nutraceutical companies. Over the past decade, there has been a significant increase in awareness regarding nutraceuticals and their role as potent therapeutic supplements. Nutraceutical medicine has gained acceptance as a part of Complementary and Alternative Medicine (CAM), leading to its integration as a distinct branch of CAM.



Classification of Nutraceuticals

Nutraceuticals cover a broad spectrum of items sourced from food that provide potential health advantages extending beyond simple nutrition. These comprise functional foods, carotenoids, collagen hydrolysate, probiotics, and other similar products.

FUNCTIONAL FOODS

Contain antioxidant compounds that help prevent diabetes, in addition to providing us with nutrients.

PHYTOCHEMICALS

Active compounds that work on balance inside the body and nervous activity can decrease cancer. Lutein and lycopene are two of the most important of these compounds.

FATTY ACIDS

The building blocks of the fat in our bodies. They have biological activities that act to influence cell and tissue metabolism, function, and responsiveness to hormonal and other signals.

DIETARY FIBRE

Non-starchy, poorly digestible vegetable carbohydrates are found in vegetables, fruits, wheat bran, and oats. Diets rich in fibre have a positive effect on the digestive system and can reduce Crohn's disease and ulcerative colitis.

COLLAGEN HYDROLYSATE

It is secreted from skin, bone, cartilage, and tendons and is the most important human protein. It has multiple medicinal properties.

CARETINOIDS

Pigmented compounds such as α carotene, β-carotene, and β-cryptoxanthin have antioxidant and anti-inflammatory properties. They are used to improve vision, prevent cancer, and strengthen the immune system.

HERBS

Plants that do not have a wooden bowl are called non-woody plants. These plants have antioxidant properties. For example, garlic extracts and ginger are used in the treatment of cholesterol, wound healing, and anti-ulcer.

PROBIOTICS

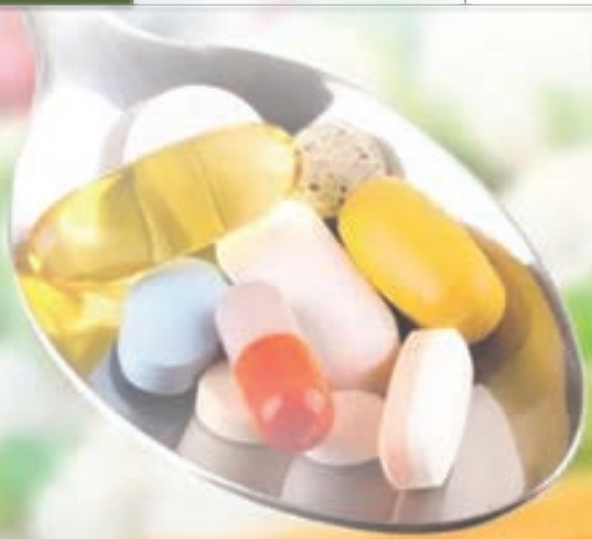
Microbes are considered to have many uses in the medical field and human health. They are found in milk products and have antioxidant properties. They also regulate the movement of the digestive system and work to regulate the growth of gut microbiota.

The Necessary Steps to Consider When Developing a New Nutraceutical

India is known for its traditional medicinal systems—Ayurveda, Siddha, and Unani. Ayurveda, also known as the "science of longevity," provides a holistic approach to leading a prolonged and healthy life. It furnishes comprehensive programs aimed at revitalizing the body through dietary practices and nutritional strategies. Additionally, it presents therapeutic techniques to address various common ailments like food allergies, for which modern medicine offers limited solutions. While food serves as a primary means of meeting nutritional requirements, the increasing pace of modernization has led to the abandonment of certain traditional practices.

Impact of modern food concept in required nutrition.

Nutrients	Intake by traditional ways	Intake by modern ways	Effect on nutrient intake
Water soluble vitamins (vitamins B and C) and minerals	Vegetables used for cooking were/are fresh	Freezing and packaging of the cut vegetables	Loss of ascorbic acid, water soluble vitamins, and minerals
Proteins, minerals, and vitamin B complex	Manual processing of cereals, without polishing	Milling and polishing of cereals	Reduces protein, minerals, and vitamin B complex
Calcium, iron, thiamine, and niacin	Fresh grinding at home	Heavy milling and poor storage conditions	Loss of calcium, iron, thiamine, and niacin
Iron	Cooking in iron pot	Food generally cooked in cookware like nonstick and Teflon-coated utensils	The benefit of organic iron from the conventional iron pot is not obtained by using modern cookware
Copper	Storing of water and cooking use of copper vessels	Stainless steel utensils and plastic wares	Copper required in minor amount which is not gained from modern utensils used today. Deficiency is known to cause chronic Diarrhea, malabsorption problems, and reduce immunity. Use of plastic containers is also harmful

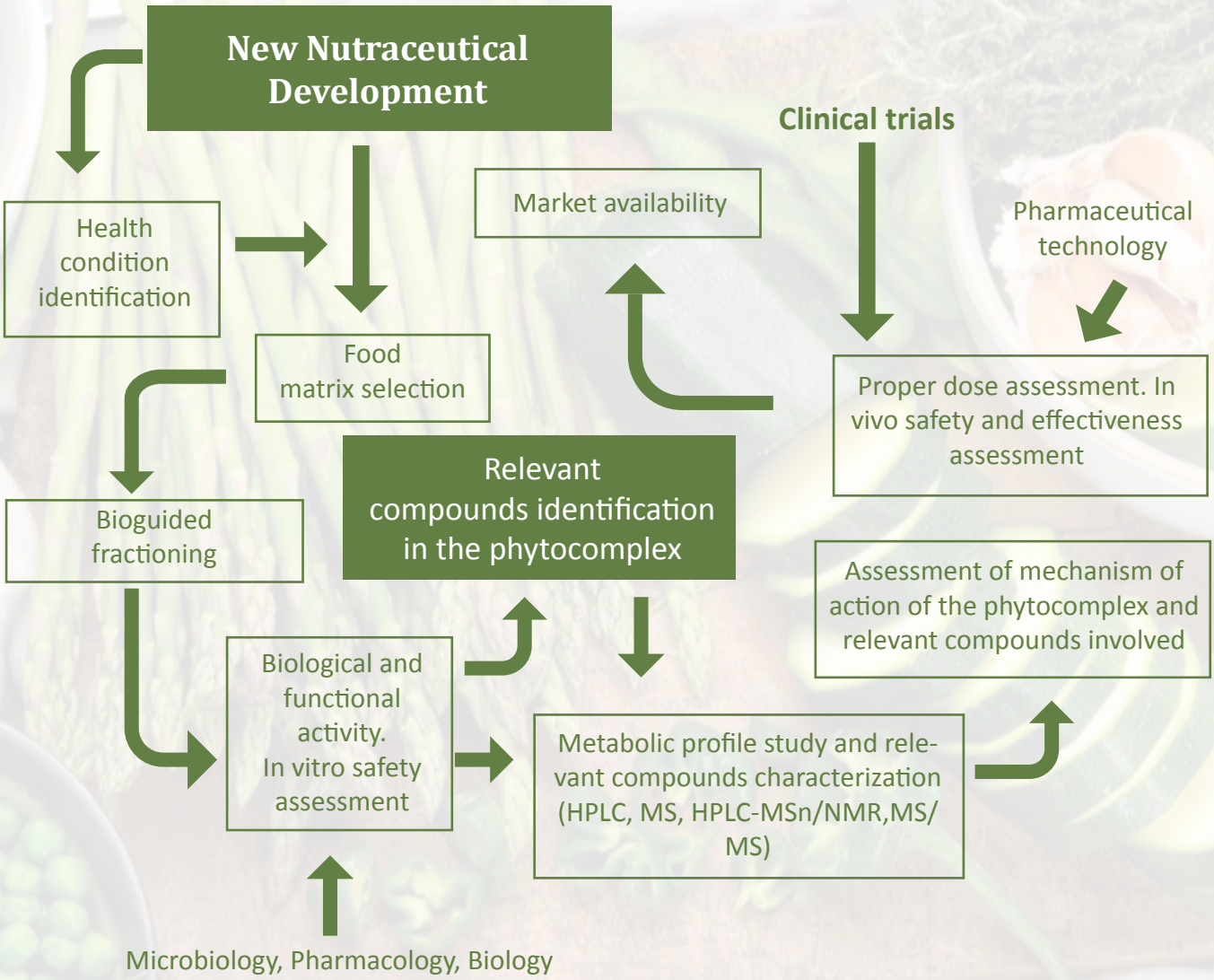


The nutraceutical market in India has seen a significant expansion since 2020, with the emergence of products such as ashwagandha and herbal kaadha, which are designed to promote strong immunity. In 2021, Bio-Botanical Inc. produced an herbal supplement, designated as "Ashwagandha 5404ST", to preserve and enhance the skin's health. This herbal supplement can be utilized for a variety of purposes, including skin care, mental health support, and immunological enhancement. Products like herbal honey or chwyawanprash have become a huge success as they are extensively used in jams, chocolates, cheesecakes and capsules as a general health supplement. For instance, in Aril 2021, Amway, the parent company of the renowned Nutrilite brand, declared the official launch of chwyawanprash, a high-quality blend of 32 herbs that have been verified through DNA fingerprinting. The blend is composed of 16 certified organic components and does not contain preservatives. Motivated by traditional Indian recipes, the main purpose of Nutrilite Chwyawanprash is to boost immunity, rejuvenate the body, increase strength, and endurance besides fight common infections. Additionally, in April 2018, Amway India, country's one of the leading direct-selling FMCG company launched its Nutrilite Traditional Herbs range. This range was specifically developed using Indian traditional herbs keeping in mind the nutritional requirements of Indian consumers.

Consequently, contemporary dietary habits are disrupting the attainment of balanced nutrition. This disparity in nutrient consumption is resulting in what was once considered a normal lifestyle becoming increasingly abnormal. Nevertheless, the rise in the affluent working population, coupled with shifting lifestyles and the escalating costs associated with healthcare, both in terms of time and finances, are compelling individuals to reconsider their approach to well-being. Manufacturing nutraceuticals is a multifaceted process with numerous intricacies. To guarantee adherence to standards and maximize safety, it's essential to devise a comprehensive plan spanning from initial research to production. While meticulous attention is necessary at every stage, certain junctures within the production process hold greater significance. Choices regarding raw materials, sourcing strategies, and implementation of controls significantly influence the success of the final product. Whether launching a new nutraceutical or enhancing an existing one, several crucial factors merit consideration before commencing. While each manufacturer has distinct processes and protocols, understanding these tasks is imperative before starting a project. Here are five primary considerations:

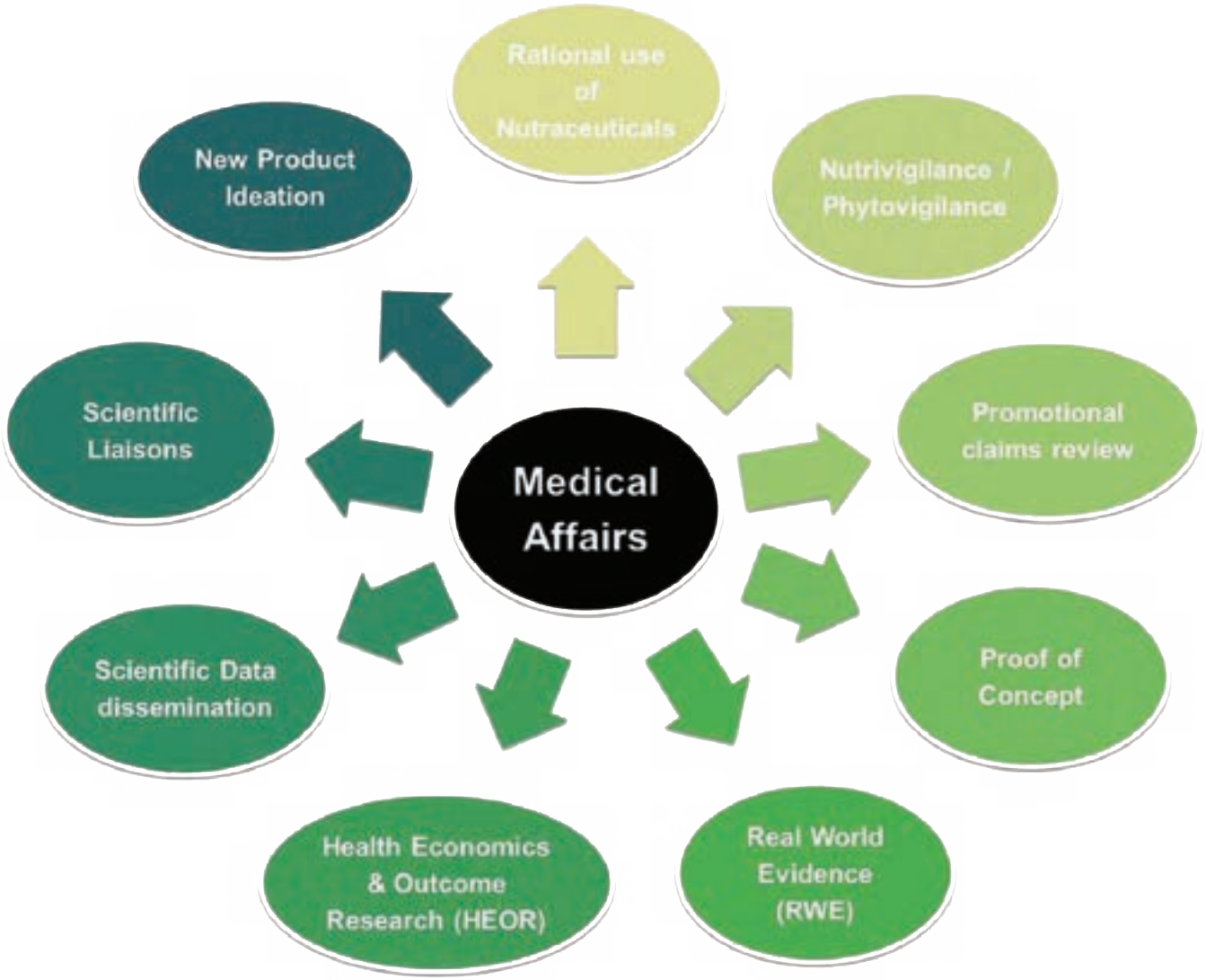
The quality of raw materials and components plays a pivotal role in determining the excellence of the end product. Manufacturers must prioritize the utilization of top-tier materials to ensure superior outcomes. For instance, when incorporating herbal ingredients into a nutraceutical, opting for pure, uncontaminated herbs devoid of impurities is imperative. Similarly, for minerals, vitamins, oils, and other constituents, sourcing from authentic, high-quality suppliers is crucial.

The quality of raw materials and components	The choice of raw materials and components utilized in the manufacturing process significantly influences the end product. It is imperative for manufacturers to prioritize the use of top-notch raw materials and components to ensure the quality of their products.
Manufacturing process and condition	Producers ought to meticulously choose the site for producing their nutraceutical goods, evaluating its suitability and ensuring it meets the necessary conditions for the manufacturing process.
Schedule for manufacturing and packaging processes	Manufacturers are required to adhere to a precise timetable when producing their nutraceutical items. They need to adhere to a predetermined schedule tailored to the specific product type and its processing needs.
Equipment for the manufacturing process	Prior to producing any nutraceutical item, manufacturers need to evaluate the equipment, tools, and machinery necessary for the manufacturing process.



Evolving Role of Medical Affairs/Pharmaceutical Physician for Nutraceuticals and Consumer Health Products

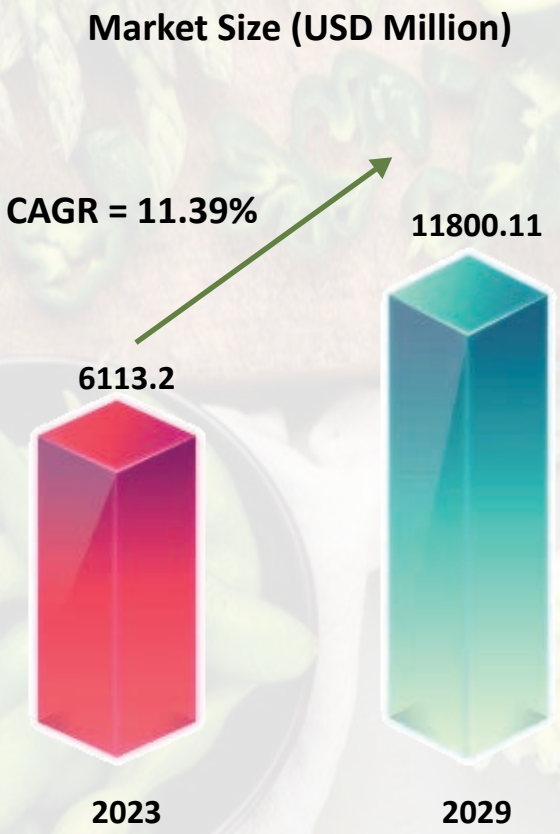
The medical affairs function serves as a vital bridge between various commercial teams, such as sales and marketing, and research and development, as well as external stakeholders like healthcare professionals and the public. Its primary role involves disseminating scientifically valid information about nutraceutical products to both internal and external stakeholders. This includes engaging with key opinion leaders to understand unmet needs and convey key scientific messages related to the products. With tightening regulatory norms governing the promotion and use of nutraceuticals, the role of medical affairs becomes even more crucial. They play a pivotal role in ensuring that promotional materials and product claims are supported by rigorous scientific evidence. Medical affairs also contribute to generating real-world data on product usage and justifying the value proposition of products through health economics and outcomes research (HEOR) data. Additionally, they guide the future development of innovative products by understanding unmet needs and continuously evaluating new formulations and delivery mechanisms. Ethically disseminating evidence-based data on nutraceutical products and promoting their rationale use are key responsibilities of the medical affairs function, which also encompasses nutrivigilance.


Medical Affairs
Rational use of Nutraceuticals
Nutrivigilance / Phytovigilance
Promotional claims review
Proof of Concept
Real World Evidence (RWE)
Health Economics & Outcome Research (HEOR)
Scientific Data dissemination
Scientific Liaisons
New Product Ideation

Exploring India's Growing Nutraceutical Market: Drivers and Challenges - India Nutraceutical Market

The India nutraceuticals market stood at USD 6,113.20 million in 2023 and is expected to register a CAGR of 11.39% and reach USD 11,800.11 million by 2029 . The rising consumer awareness regarding health and sedentary lifestyle-associated issues, growing awareness for nutraceutical benefits, and growing consumer preference towards plant-based and organic health supplements are some of the major trends in the Indian nutraceuticals market. Additionally, rising consumer focus towards preventive healthcare is another primary trend propelling the nutraceuticals industry's growth in the country. The market is hampered by factors, such as the growing adoption of ayurvedic formulas for health and immunity boosts, the high cost of branded nutraceuticals, and the lack of stringent regulatory policies for nutraceuticals. Moreover, the availability of several look-a-like products with fake ingredients in the nutraceutical market is affecting the consumer trust and thus, hindering the market growth. The Indian government has implemented policies and regulations such as the 'Make in India' campaign and the establishment of the Food Safety and Standard Authority of India (FSSAI) to promote the nutraceutical industries and to build the quality, safety, and standards of nutraceutical products.

India Nutraceuticals Market Size, By Value (USD Million), 2019-2029F



7. *https://www.techsciresearch.com/report/india-nutraceuticals-market/14150.html*

Market Drivers

Rising Incidence of Chronic Diseases and Geriatric Population

The rise in health issues like diabetes, obesity, thyroid disorders, and cardiovascular diseases in India has led to a surge in the use of nutraceuticals and dietary supplements. According to WHO, in 2016, around 54.5 million adults in India had cardiovascular diseases, with an estimated 4.77 million deaths in 2020. To tackle this, India is emphasizing the consumption of supplements and dietary products as they significantly influence the development and mortality rates of chronic diseases. Aging populations are more susceptible to these conditions due to declining organ function over time. Consequently, the increasing prevalence of geriatric populations, lifestyle changes, and rising chronic diseases have spurred interest in nutraceuticals, particularly those tailored for better health, emphasizing low fat, low cholesterol, high protein, and weight management.

Intensification of Preventive Healthcare

In India, the use of nutraceuticals is increasing, particularly for preventive healthcare, as people seek to enhance their immune systems and overall well-being. By 2025, the preventive healthcare sector is projected to reach USD 197 billion, growing annually at 22%. There's a notable rise in the consumption of essential vitamins like A, D, C, folate, and minerals such as selenium and zinc to boost immunity. Nutraceuticals, devoid of additives and artificial agents, are preferred by consumers, prompting the industry to integrate science and healthy food for public health benefits. Personalized nutrition is gaining traction as individuals recognize diverse nutritional requirements influenced by age, gender, genetics, and lifestyle. India's FMHG sector, capturing 1-2% of the global market share, presents significant growth prospects, with functional foods dominating 60% and dietary supplements 40%. Companies like Abbott and Nutrilitius are innovating to address nutritional deficiencies and promote health, launching products like PediaSure and Nutraceuticals Capsules, respectively, catering to various health needs while emphasizing affordability and quality through certifications like FDA, Non-GMO, Make in India, and Startup India.

Bend Towards Ayurvedic Legacy

India has a vast array of plants known for producing medicinal and nutritional products, highly valued globally. Amid the COVID-19 pandemic, there was a heightened focus on bolstering immunity using natural herbs and plants. This led to a surge in demand for ayurvedic innovations. The nutraceutical market in India has witnessed notable growth since 2020, with products like ashwagandha and herbal kaadha gaining popularity for their immunity-boosting properties. In 2021, Bio-Botanical Inc. introduced "Ashwaganda 5404ST," an herbal supplement aimed at improving skin health, mental well-being, and immune function.

Market Challenges

Counterfeit Products

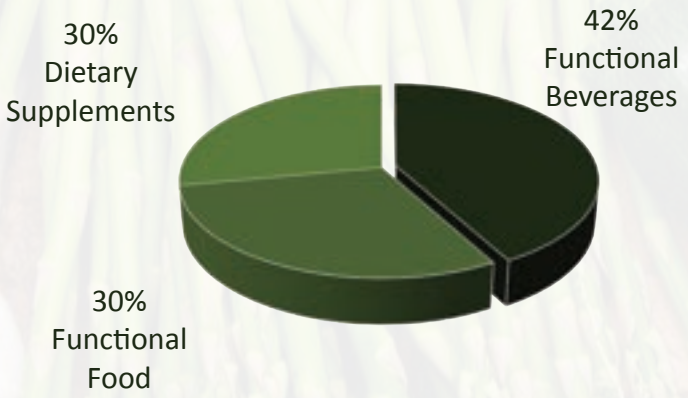
As the demand for dietary supplements rises, so does the prevalence of counterfeit nutraceuticals. The packaging of genuine and fake products often looks very similar, making it hard for consumers to differentiate between them. Counterfeit supplements are typically produced in unhygienic conditions and may lack active ingredients, posing health risks due to potential inclusion of harmful chemicals. Counterfeiting significantly harms supplement brands' reputation, leading to revenue loss and loss of consumer trust. To combat this, dietary supplement manufacturers can employ Neuro-Tags' effective anti-counterfeiting solution to safeguard their brand and protect consumers from fraudulent products.

Variation in Prices

Nutraceuticals have been in high demand for quite some time, yet their uptake in the Indian market is hindered by their high cost. Manufacturers aim to recover their R&D expenses quickly by setting high prices, but in a price-sensitive market like India, this approach faces challenges due to either high production costs or high profit margins. Additionally, the introduction of GST has led to a significant increase in taxes, with nutraceuticals and health supplements now subjected to an 18% tax rate (some even taxed at 28%), further raising the prices of these products. The high taxes also pose a barrier to entry for new players in the market, as they would need to launch their products at lower prices to remain competitive.

Insights from Nutraceuticals Survey: Unveiling India's Market Potential

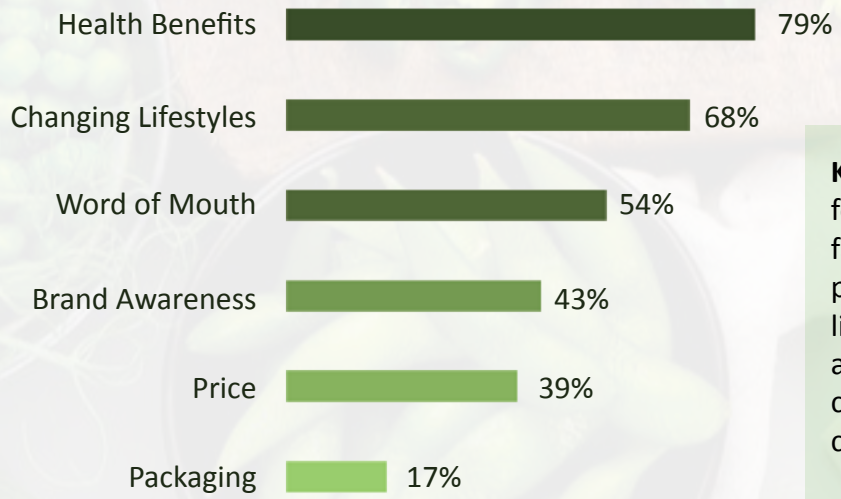
1. Preference for Nutraceuticals, By Category, 2023



Key Takeaway: Majority of the respondents preferred functional beverages over functional food and dietary supplements. This is majorly because the respondents feel that it is better to consume functional beverages than any other aerated drink or beverage.

Note: 1. Respondents who have purchased nutraceuticals in past nine months were considered for this survey.
2. The respondents were asked to select a single option to answer the question.

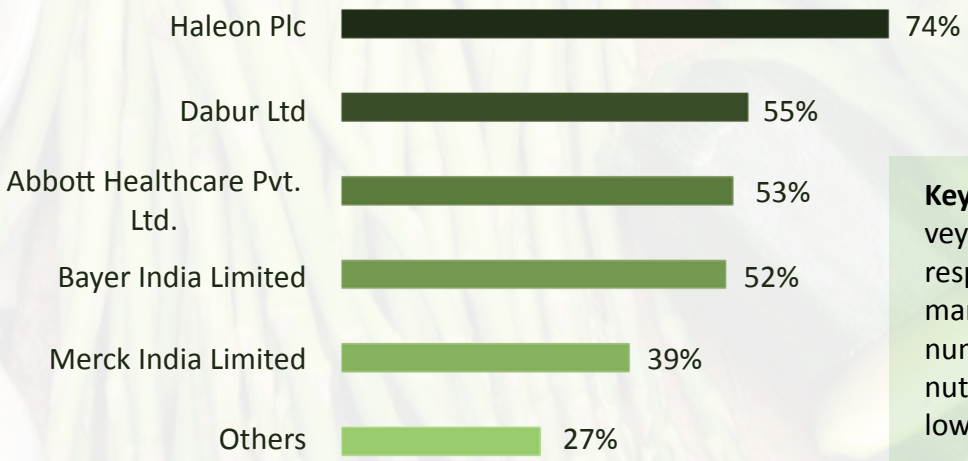
2. Factors Influencing Purchase Decision, 2023



Key Takeaway: Health benefits offered by nutraceuticals are the key factor that influences consumers to purchase nutraceuticals. Changing lifestyle, word of mouth, and brand awareness are other major factors considered while purchasing nutraceuticals in India.

Note: 1. Respondents who have purchased nutraceuticals in the past nine months were considered for this survey.
2. The respondents were asked to select multiple options to answer the question.

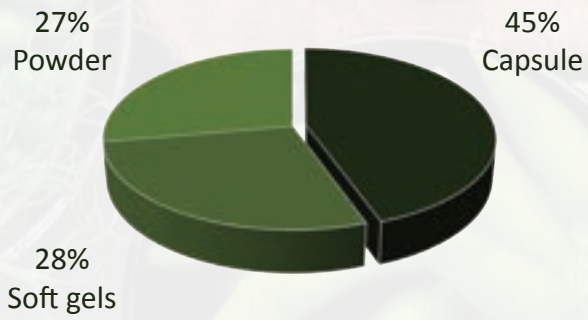
3. Brand Awareness, 2023



Key Takeaway: As per the survey conducted, most of the respondents were aware and marked Haleon Plc. as the number one known brand of nutraceuticals in India, followed by Dabur Ltd.

Note: 1. Respondents who have purchased nutraceuticals in the past nine months were considered for this survey.
2. The respondents were asked to select multiple options to answer the question.
3. Others include Wockhardt Ltd, Baidyanath Group, Himalaya Wellness Company, etc.

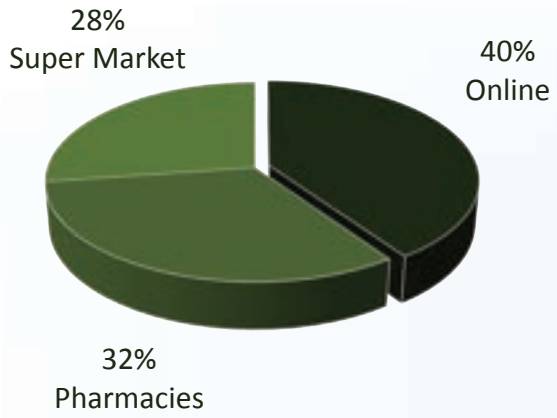
4. Preference for Nutraceuticals, By Form, 2023



Key Takeaway: The majority of the respondents preferred capsule form over soft gels and powder. The Capsules allow for precise dosage control, as the amount of active ingredient in each capsule can be accurately measured and standardized. This ensures consistency in dosing, which is important for achieving desired health benefits and avoiding potential overdosing or underdosing.

Note: 1. Respondents who have purchased nutraceuticals in past nine months were considered for this survey.
2. The respondents were asked to select a single option to answer the question.

5. Preferred Mode of Purchase for Nutraceuticals, 2023



Key Takeaway: The majority of the respondents preferred an online mode of distribution channel. Shopping online for nutraceutical products offers convenience as consumers can make purchases at any time of the day without the need to visit a physical store.

Note: 1. Respondents who have purchased nutraceuticals in past nine months were considered for this survey.
2. The respondents were asked to select a single option to answer the question.

Micronutrient Deficiencies in India: A Public Health Emergency

Hidden hunger, also termed micronutrient deficiencies (MiNDs), refers to the insufficiency of vital vitamins and minerals necessary for normal cellular and molecular functions. According to the World Health Organization (WHO), micronutrients are compounds needed in small quantities (< 100 mg/day). Globally, over one-third of individuals lack one or more micronutrients, with more than two billion people affected by MiNDs, with almost half of them residing in India. The situation in India is particularly severe, with widespread risks of deficiencies in calcium, vitamin A, B12, and folate affecting over 80% of the population, along with more localized deficiencies in iron, zinc, and vitamin B6. Serum zinc deficiency prevalence exceeds 20% in India, signifying a significant public health concern. Vitamin D deficiency and inadequate calcium intake contribute to the high rates of osteoporosis, especially among Indian women . Female Indians exhibit higher MiNDs due to lower nutrient consumption compared to males. Studies indicate significantly lower intake of various vitamins and minerals among Indian women compared to men, with a large percentage of pregnant women falling below recommended intakes for iron, calcium, and folic acid. Healthcare professionals note that urban Indians' micronutrient intake falls below recommended levels, with over 62% of urban and semi-urban adults affected by MiNDs due to poor dietary habits, inadequate nutrition, and prevalent Anemia leading to multiple micronutrient inadequacies .

Causes of inadequate micronutrient intake via poor diets

Micronutrient Loss in Food

- Farming techniques and food processing results in plant micronutrient loss Cooking leads to a loss of vitamins (25%-40%).

Daily Diet Inadequacy

- Due to reduced bioavailability in plant sources, vegetarian diets provide an inadequate nutritional intake of omega-3 fatty acids, vitamin B12, and minerals.
- Insufficient intake owing to the weight-reducing and imbalanced diets, and wrong dietary and modern eating habits.
- Increased consumption of junk food leads to unhealthy snacking habits Eating disorders, emotiona l and/or physiological stress.

Optimizing Cognitive Function: The Potential of Multivitamins and Minerals

Given the crucial role micronutrients play in bolstering immunity, it's logical to consider supplementing them to replenish levels, especially following an infection or during recovery, to support immune function. Vitamin A supplementation has been associated with decreased morbidity and mortality linked to its deficiency . WHO/UNICEF advocates for zinc supplementation during diarrheal episodes and severe malnutrition treatment. Research indicates a potential preventive effect of micronutrient supplementation (including vitamins A, B12, C, D, iron, and zinc) against viral respiratory infections. Micronutrients aid immune function, with zinc supplementation notably reducing infection frequency and severity. Additionally, maintaining optimal bone density is crucial for preventing osteoporotic fractures later in life. Vitamin D and calcium supplementation have proven beneficial in achieving peak bone densities. A majority of healthcare providers (HCPs) support micronutrient supplementation as a complementary therapy post-infection or surgery, dispelling the misconception that only malnourished individuals are nutritionally deficient. Obese individuals, too, often lack essential nutrients, with vitamin D deficiency being a notable concern. Similarly, the elderly, individuals with gastrointestinal absorption issues, and those with various chronic conditions like diabetes, hypertension, COPD, asthma, or cardiovascular diseases require micronutrient supplementation. Recent research highlighted the efficacy of folic acid, alone or combined with vitamin B12, in reducing elevated homocysteine levels in Indian patients with vascular disease .

8. *https://www.sciencedirect.com/science/article/pii/S0002916523280260#:~:text=Vitamin%20D%20deficiency%20or%20poor,8%2C%209%2C%2010).*
9. *https://www.ipinnovative.com/journal-article-file/17329*
10. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7589163/#:~:text=Micronutrients%20(i.e.%2C%20vitamins%20and%20nutritionally,increasing%20the%20susceptibility%20to%20infections*
11. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2716415/#:~:text=Although%20combined%20folic%20acid%20and,generally%20fallen%20short%20of%20expectations.*

Chapter 2

Navigating the Regulatory Maze

The Regulatory Landscape of Nutraceuticals in India

Regulatory Landscape

Regulatory journey of food products in india

1990s	Eight separate food laws including Prevention of food adulteration (PFA) act, mainly focussing on curbing the adulteration in food products.
2006-2008	Introduction of Food safety and standard (FSS) act and establishment of Food safety and standard authority of India (FSSAI).
2011-2015	Major activity started with implementation of six key regulations from 05 August 2011 and FSSAI logo with license number was made mandatory on all food product labels
2016	Introduction of regulations of functional food and nutraceuticals.
2017-2018	Introduction of import regulations and organic food regulations and implementation of functional fooda nd nutraceuticals regulations.

Future road map

In India, nutraceuticals are overseen by the Food Safety and Standards Authority of India (FSSAI) through various regulations such as the Food Safety and Standards Act, 2006, along with subsequent amendments and regulations including those about health supplements, organic foods, food standards, packaging, advertising, contaminants, and import. These regulations cover the production, sale, marketing, and import of nutraceuticals, requiring compliance from all involved Food Business Operators (FBOs).

Nutraceutical Regulations apply to products intended for individuals over 2 years old, aiming to support health maintenance. These products may include various ingredients, extracts, and formulations presented in different formats approved by FSSAI. However, formulations for infant nutrition are regulated separately. Foods in their natural state, like vegetables and fruits, are excluded from these regulations, as are conventional foods with naturally occurring ingredients. Nutraceutical products must contain specified ingredients/additives within prescribed limits, and organic ingredients are permissible. However, ingredients of animal origin must comply with regulations, and genetically modified ingredients are presently not allowed. Labels on nutraceutical products must include specific information regarding their purpose, target consumers, usage instructions, and precautions.

FBOs must provide scientific rationale for their product formulations, based on peer-reviewed literature. They can make certain health-related claims within the scope of regulations but claims resembling drug properties are prohibited and fall under the jurisdiction of the Drugs Controller General of India. Any unproven claims or those involving novel ingredients require prior approval from FSSAI. Licensing requirements are governed by the FSS (Licensing and Registration of Food Businesses) Regulations, 2011. In the competitive nutraceutical market, intellectual property considerations, including patents, trademarks, and copyrights, are crucial for protection and differentiation. Patents safeguard research, development, and product usage, while trademarks build consumer trust and prevent unauthorized use. Copyrights come into play for product launches, marketing, and branding. Although legal standards for infringement are similar to pharmaceutical products, nutraceutical IP rights remain a key focus for industry players.

India's varied climate supports the growth of a wide range of fruits and vegetables. Despite being the second largest producer of fruits and vegetables globally, trailing only China, India lags in processing agricultural products compared to the United States, the largest market for nutraceuticals worldwide. This discrepancy is primarily attributed to the absence of stringent regulatory frameworks and insufficient awareness regarding the health benefits of food processing, including the development of health supplements and nutraceuticals. The regulatory landscape governing food products in India has changed over time. Before the 1990s, there was no centralized national authority responsible for food product regulation. Instead, regulations were fragmented across various laws governing different aspects such as vegetables, mineral oils, and animal products, comprising numerous state regulations alongside eight central laws.

1. The Prevention of Food Adulteration Act (PFA), 1954.
2. The Fruit Products Order (FPO), 1995.
3. The Meat Food Products Order (MFPO), 1973.
4. The Vegetable Oil Product (Control) order, 1947.
5. The Edible Oil Packaging (regulation) Order, 1998.
6. The Solvent Extracted Oil, De-oiled Meal, and Edible Flour (Control) Order, 1967.
7. The Milk and Milk Products Order, 1992.
8. Any other order under the Essential Commodities Act, 1995 relating to food.

By the time of 1930s, adulteration of food products was very much widespread and required comprehensive legislation. There were several local laws for the prevention of food adulteration, but they lacked uniformity, and then in 1937, a committee pointed out by the Central Advisory Board of Health recommended introducing the Prevention of Food Adulteration (PFA) Act. The PFA Act was introduced on 29 September 1954 and came into force on 01 June 1955. All the above-mentioned acts or orders including PFA (1954) were inclined towards curbing the adulteration in food products and maintaining sanitation/hygiene at the manufacturing sites. However, none of these acts or orders laid any guidelines to check the food safety i.e. possible side effects of food products (as the food products were considered safe from the belief that they have been used for long periods without serious toxicities). Furthermore, there was no information to mark the scope of processing of food products to gain health benefits.

Current Regulatory Framework for Nutraceuticals in India

India is the second largest producer of fruits and vegetables; however, India is lagging in terms of processing of these food products. The term 'nutraceuticals' was not even introduced in the Indian regulatory structure of food products till 2015. The draft for regulations of Health Supplements and Nutraceuticals was made available to the public on 11 September 2015 and was finally notified in the official gazette of India in 2016. Under these regulations for nutraceuticals and health supplements:

1. In-depth definitions of all categories of functional foods were laid down as per their content and use.
2. The criterion of acceptance for the safety, efficacy, or health claims of these products was specified.
3. A list of approved ingredients and excipients was made available to the manufacturers along with the minimum or maximum permissible levels.
4. Requirements of quality, labeling, and packaging of nutraceuticals and health supplements were also specified.

After the introduction of nutraceuticals regulations in 2016, one year was given by FSSAI to the food product manufacturers in India to comply with these regulations; hence, the effective date of these regulations was finalized as 01 January 2018. As these regulations have recently come into force, the impact of these regulations on the quality of nutraceutical products and the nutraceutical market of India is yet to be seen.

Road Map to the Future

Currently, the Indian nutraceutical market is growing at a rapid pace and is expected to grow more than double of current market within the next five years, considering the significant annual growth rate. Moreover, with growing awareness regarding the benefits of nutraceuticals in health and fitness, people are getting more inclined towards nutraceuticals. This enormous growth is also bringing propositions for food, agriculture, and nutraceutical industries. Although the continuous advancements in the FSS Act have provided a sound platform for food safety and standards in India, a lot is still required to inspire trust and to assure the availability of healthy and nutritious food. A robust FSSAI system should have unequivocal safety standards based on a strong approach to risk assessment with an unbiased compliance verification system through proper inspections. A major requirement for a robust system would be to have reliable food testing laboratories to ensure the highest standards of food products, which are safe and efficacious. In addition, global guidelines can be studied, and the best approaches can be adopted in our system. Further, for an uninterrupted improvement, regular surveys can help assess the degree of improvement. This goal can be achieved with proper implementation, strategy, and a clear roadmap. A future roadmap could consist of the following:

1. An accountable and transparent governance along with an effective administrative system.
2. A comprehensive review of the existing standards based on the reviews from expert review groups and consumers. In addition, a robust risk assessment system should be introduced to monitor any food hazards and any adverse events associated with food products.
3. A simplified and easily understandable guidance documents and registration system to support food business operators.
4. Development of a more stringent audit and inspection system.
5. Well-equipped analytical laboratories with experienced and qualified staff to check the quality standard of food products.
6. To emerge as a reliable collaborator in the global food safety network and present the country's interests and plans on a worldwide platform through multilateral and bilateral engagements.
7. Bringing social and behavioural changes by reaching out to workplaces, eating joints, and schools through nutritional campaigns and developing a culture of safe and wholesome food.
8. Focus on technical and scientific areas of mutual interest, exchange of scientific information, implementing international best practices, capacity building through visits of scientists/technicians, and organizing workshops and training.

FSSAI Labelling Provisions for Nutraceuticals in India

The Food Safety and Standards (Health Supplements, Nutraceutical, food for special dietary use, food for special medical purpose, functional food, and novel food) regulations, 2016 facilitate the given labeling provisions for nutraceuticals.

- The labeling on the nutraceutical-based food items shall not claim that the packed food items offer medicinal benefits or treat any chronic disease.
- The statement by the manufacturer related to the function or structure or the general well-being of the body may be permitted by the FSSAI if the legitimate scientific data support the statement.
- Every package of nutraceutical-based food shall enclose the given details on the label, namely:
  - the word "NUTRACEUTICAL".
  - the common name of the nutraceutical;
  - A declaration about the amount of each nutraceutical ingredient available in the product that either has a physiological or nutritional effect;
  - Where it is necessary, the nutrient's quantity shall be reflected in terms of % of the relevant advisable daily allowances as recommended by the Indian Council of Medical Research even when the nutrient is a mere addition to the nutraceutical and shall have an advisory warning – 'not to exceed the stated recommended daily usage';
  - an advisory warning stating- 'recommended usage
  - an advisory warning 'stating 'NOT FOR MEDICINAL USE.'
  - an advisory warning in cases where excess consumption could be fatal for the end-users;
  - Precautions to be taken during consumption
  - Known side-effects, if any.
  - Product-drug interactions, as applicable;
  - A statement reflecting that the product should not be placed near children;
- No FBO shall utilize additives for nutraceutical formulation except those cited in Schedule VA or Schedule VE or Schedule VF.

Significance Of Labelling Provisions from The Consumer's Viewpoint

Ensuring food safety isn't solely the duty of one individual, regulatory bodies, or the food industry alone. Rather, it's a collective responsibility shared among the government, producers, industry, and consumers. Food labeling stands as a crucial legal requirement aimed at providing consumers with a clear comprehension of the products they're consuming. Serving as a vital means of communication between manufacturers and consumers, labels should uphold truthfulness, and transparency, and accurately depict the contents of the package being purchased. Consumers play a significant role by diligently examining labels before purchasing food items. It's imperative to possess the knowledge and skills to decipher the information provided on labels to grasp the nature of the food being consumed.

Date Markings: Date labels on food packaging serve to inform consumers about the safety and freshness of the product. The terms 'Use By' or 'Expiry Date' indicate the deadline by which the food remains safe for consumption, emphasizing that consuming it beyond this point could pose health risks. Conversely, 'Best Before' denotes the date after which the food may begin to lose its optimal quality in terms of taste, aroma, or nutrients, though it may still be safe to eat. Relying on sensory cues such as taste, smell, and appearance can help determine the edibility of food beyond its Best Before date. To combat food waste, the Food Safety and Standards Authority of India (FSSAI) now requires food labels to include both the Manufacturing Date and Expiry/Use by Date, while the inclusion of a Best Before date is at the discretion of the manufacturer. Certain products, such as whole fruits and vegetables, wine, chewing gum, vinegar, alcoholic beverages with over 10% alcohol content by volume, and sugar-boiled confectionery, are exempt from displaying an expiry date on their labels.

12. https://www.fssai.gov.in/upload/media/FSSAI_News_Guidance_FNB_09_06_2020.pdf
13. https://main.icmr.nic.in/

Ingredients and Allergen Declaration: Date markings provide crucial information on food product labels, detailing ingredients in descending order by weight or volume, including additives indicated by INS or E numbers. Emphasized percentages of ingredients are also disclosed. These labels are particularly vital for individuals with food allergies or intolerances, as consuming undisclosed allergens can lead to severe health consequences. The Food Safety and Standards Authority of India (FSSAI) designates cereals containing gluten, crustaceans, milk, eggs, fish, peanuts and tree nuts, soybeans, and sulphite as the eight major allergens requiring declaration on labels. Some labels include a "May Contain" statement, indicating potential cross-contamination with allergens, highlighting the importance of scrutiny for those with allergies .

Nutrition Labelling and serving sizes: Nutrition labels serve as a valuable tool aiding consumers in making informed choices about their food intake. They provide detailed information on the nutrient content per 100 grams or millilitres of the product, as well as its contribution to the Recommended Dietary Allowance (RDA). The % RDA indicates the recommended daily intake or limit of various nutrients, aiding in understanding the food's composition and managing calorie consumption while regulating sugar, salt, fat, saturated fat, trans fat, and cholesterol, and prioritizing protein and other essential micronutrients. Additionally, it's crucial to pay attention to the serving size indicated on the packaging. Often, these serving sizes are smaller than typical consumption patterns, potentially misleading consumers into perceiving the product as lower in sugar, calories, or fat. For instance, a 500-gram package may list one biscuit as a serving size. To accurately assess nutritional intake, consumers must multiply the stated serving size by the number of servings consumed.

14. FSSAI – https://fostac.fssai.gov.in/fostac/doc/EDIBLE%20OIL%20&%20FATS.pdf

The Most Common Symbols on Packaging

Veg-

The emblem comprises a green circle enclosed within a green square, symbolizing the product's full adherence to vegetarian standards, indicating the absence of any non-vegetarian components or substances.

Non-Veg-

The non-vegetarian food logo has been updated by FSSAI, shifting from a brown circle to a brown triangle. This alteration aims to aid individuals with colour blindness in distinguishing it from the brown hue typically indicating non-vegetarian food. Colour-blind individuals often inadvertently purchase items with brown logos instead of green ones, intending to buy vegetarian products. The introduction of the triangle shape simplifies the process of determining whether a product is suitable for vegetarians. Any shape, including circles and triangles, will be swiftly recognized, with the triangle emblem signalling that the contents are not suitable for vegetarians.

Gluten-Free-

The Gluten-Free Certification Organization (GFCO) develops the Certified Gluten Free emblem, ensuring that the contents of the package are devoid of gluten and have not been subject to cross-contamination. Consumers seek out this logo as a guarantee, understanding that products labelled as gluten-free might still contain gluten traces unless they meet GFCO's stringent testing standards.

Jaivik Bharat -

The Jaivik Bharat emblem serves as a consolidated symbol for organic food products, backed by official government certification. It serves to distinguish organic items from conventional ones, with the slogan 'Jaivik Bharat' underscoring their origin from India. This emblem signifies the product's organic nature and mandates that any manufacturing, packaging, selling, marketing, distribution, or importation of organic food must include a comprehensive and truthful label indicating its organic status.

15. *https://foodregulatory.fssai.gov.in/agmark-certification#:~:text=AGMARK%20is%20a%20certification%20mark,Grading%20Marking)%20Act%2C%201937.*

AGMARK -

AGMARK is a certification emblem denoting agricultural products that conform to grade standards established by the Ministry of Agriculture and Farmers Welfare through the Agricultural Produce (Grading and Marking) Act of 1937 . The AGMARK on food packaging, signifies that the enclosed product is indeed an agricultural item that has undergone rigorous certification and laboratory testing. This emblem assures consumers that the product is unaltered and free from adulteration, thus ensuring its high quality.

Vegan -

In 2022, the FSSAI officially introduced the national vegan symbol . Vegan food denotes food devoid of any animal-derived ingredients, additives, flavourings, carriers, enzymes, or processing aids in its production or processing. The emblem showcases a 'V' enclosed within a square, topped with a small plant, and labelled with the word "vegan" at the base. The green leaf signifies plant-based components or products, while the "V" denotes vegan status. To locate vegan-friendly food items, keep an eye out for this emblem.

Food Irradiation Logo -

The radura serves as a globally recognized symbol denoting food products that have undergone irradiation. Typically, green and resembling a plant, this emblem features a dashed upper half within a circle. Perishable items like fruits necessitate preservation for prolonged storage, requiring atomic radiation and additional measures to ensure safety. Hence, the presence of this emblem on the packaging signifies that the enclosed goods are preserved and safe for human consumption.

Licensing

Every food business operating within the country must obtain authorization from India's FSSAI. The procedures and requirements for obtaining licenses and registrations are outlined in the Food Safety and Standards (Licensing and Registration of Food Business) Regulation of 2011. FSSAI has introduced an online platform called the Food License and Registration System to streamline the application process for FBOs in India, making it simpler to apply for licenses or registration certificates and allowing them to track their submissions as they are processed.

Requirements for Eligibility

1. Yearly Revenue Turnover should be twelve lakhs to twenty crores for a food company. Including units for milling of grain; cereals; and pulses.
2. For the Central License- Yearly Revenue Turnover should be more than twenty crores for a food company. And functioning in two or more States.

16. *https://www.fssai.gov.in/cms/standards-vegan-food.php*

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Chapter 3

Exploring the Evolving Landscape

Emerging Trends in Nutraceuticals

Emerging Nutraceutical Trends: A Forecast for the Year Ahead

In an era marked by heightened effectiveness and individual responsibility for health, there is a notable surge in the popularity of oral health supplements or nutraceuticals. Nutraceuticals refer to dietary or oral supplements designed to provide a concentrated dose of biologically active substances to improve overall health or address specific health concerns. Whether it's a blend for improving sleep, boosting immunity, or supporting an active lifestyle, these supplements play a vital role in dietary habits. This surge in usage has resulted in significant expansion within the nutraceutical industry.

1. **NAC supplement:** a forthcoming favourite for the medication collection, with a tongue-twisting name - N-Acetyl Cysteine (NAC), an important supplement for various reasons, is expected to gain significant popularity. Glutathione replenishment, assistance with respiratory and fertility issues, kidney and liver detoxification, immune system strengthening, and maintenance of healthy blood sugar levels are among its benefits. A rise in health consciousness among the Indian urban population has led to the opening up of a market for the massive growth of the nutraceutical industry in India. As a result of this increased awareness, new and unique ways to inform customers about products and their benefits are constantly being developed by these companies and marketers. With new initiatives being undertaken by the industry, an increase in transparency and greater innovation is also anticipated.
2. **Hydration Products:** According to studies, it is expected that the market for hydration products will experience a significant increase in the forthcoming years . It is evident that electrolytes and similar hydration options, which also incorporate other health-promoting ingredients, are predominantly chosen in this category. These hydration products are comprised of various components including vitamins, minerals, and essential electrolytes, among others, to facilitate optimal hydration and rehydration in the body. Additionally, electrolyte balance within the body is supported by added minerals such as chloride and potassium.
3. **Multifunctional sleep supplements all-in-one support:** Several goals are targeted by multifunctional sleep supplements while also aiding in falling asleep. It means that a single product can be found that not only supports a sleep routine but also assists with skin or joint problems. Unlike regular multivitamins, these supplements are designed to work together to address specific issues rather than focusing on overall well-being.
4. **Greater demand for plant-based protein:** Concerns about whether or not the required amount of protein is being provided by a vegan diet are often heard. With an increase in veganism and plant-based diets over the years, alternatives to animal products and plant-based items, especially daily plant-based protein, are continuing to gain popularity day by day, even in the nutraceutical industry. A large number of vegan and plant-based protein powders have been introduced in the market over the past few years, and massive growth is predicted to be faced by this market by 2025.
5. **Addressing sleep issues:** Good sleep is struggled with by many people today, and chronic issues like sleeplessness and insomnia are faced by them. There can be several reasons behind one's sleeplessness, which are linked to other problems such as stress. Mental health problems and a weakened immune system can be caused by this, in turn. A good night's sleep can be achieved with the help of nutraceutical aids, especially melatonin, which is available in a variety of forms like gummies, drinks, or tablets.

17. *https://www.fao.org/fileadmin/templates/wsfs/docs/expert_paper/How_to_Feed_the_World_in_2050.pdf*

6. **Desire for non-pill options:** For several years, supplements in the form of pills have been sold by the nutraceutical industry. Due to changes in consumer preferences, many non-pill formats of supplements have emerged, with effervescent tablets and gummies being among the most popular ones. Effervescent tablets are favoured because they can be dissolved in water or fruit juice, making them often preferred over regular tablets due to their better taste. Conventional tablets, which dissolve slowly, result in reduced absorption rates. In contrast, effervescent tablets dissolve quickly and completely, ensuring that the full benefits from the ingredients are received. Gummies are regarded as a less intimidating means of consuming supplements, especially for those new to such products who may feel overwhelmed by pills and tablets. Now, with the assistance of gel, powder, and liquid multivitamins and supplements, the way the body is nourished can be altered.
7. **Evolution of sports nutrition:** The consumption of supplements like amino acids and proteins for enhancing strength in athletic performance is entailed in sports nutrition. It is made easier for individuals to attain their health objectives, achieve rapid muscle recovery, and experience increased strength through the utilization of nutraceuticals. Due to the significant growth witnessed in the sports industry in recent years, there has been a gradual increase in the demand for these supplements.
8. **Herbal extracts:** The increasing popularity of herbal extracts is attributed to the consumer's trust in traditional remedies as solutions to modern-age issues. Steady growth is observed in the demand for plant-based protein supplements. To further explain the concept of new formats, creatine, typically found in the market as either powder or tablet, has been introduced by Steadfast Nutrition in effervescent form, and liquid form has been adopted for carnitine, which is commonly available as powder.

The growth and modernization of the Nutraceutical industry are being fueled by the emergence of five essential pillars of positive growth and change:

Formulation Ecosystem

- A vast number of world-class GMP facilities are present in India, stemming from India having the largest FDA-approved contract manufacturing facilities globally. Additionally, high-end nutraceutical manufacturing facilities, usually audited by pharmaceutical companies, further contribute to India's potential to become a global contract manufacturing hub in nutraceuticals. Furthermore, pharmaceutical delivery technologies can be applied to churn out bio-available, disruptive nutraceutical formations.

Medicinal Plant Farming

India's rich potential in active nutraceutical ingredients is being tapped into, with over 1,700 medicinal plants from Ayurveda being accessed. This resource base alone has the potential to propel India into the 200-billion-dollar league.

The Start-Up Ecosystem

India's 7,400 nutraceutical start-ups, supported by high-end incubation hubs such as CCMB, IITs, and other institutions, are leading a technological revolution across the entire ecosystem.

Medicinal Plant Farming

The creation of a fingerprinted, raw material supply chain is being driven by India's 52 Agro-Climatic zones, coupled with an improved biodiversity Act, and the utilization of IT Applications in conjunction with blockchains.

Academia

Nutrify Today Academy is closely collaborating with Centurion University to launch nutraceutical industry-specific post-graduation courses, the first of their kind. Moreover, universities are partnering with the industry to develop industry-specific courses and programs.

Navigating the Digital Frontier: E-commerce Trends in the Nutraceutical Industry

The e-commerce landscape in India has experienced remarkable growth in recent years, offering lucrative opportunities for nutraceutical businesses. India had over 700 million active internet users aged 2 years and above as of December 2022, according to Nielsen's India Internet Report 2023 . This growth in the nutraceutical sector is propelled by heightened health awareness and evolving consumer preferences. E-commerce platforms have transformed the way people buy dietary supplements in India, offering convenience, diverse product selections, and competitive prices. As a result, they've become the preferred choice for health-conscious consumers. India's e-commerce market is expected to reach USD 200 billion by 2026 . To excel in this competitive environment, sellers of nutraceuticals must optimize their product listings and descriptions. By leveraging statistical data and market insights, they can create compelling content that highlights the unique advantages of their products, driving sales and fostering customer loyalty.

Influencer marketing has emerged as a powerful strategy for promoting dietary supplements in India. Collaborating with influencers who specialize in health and wellness can significantly enhance brand visibility and credibility. Projections indicate that influencer marketing in India could generate USD 24.1 million in revenue by 2025 . Localized marketing is crucial for connecting with Indian consumers. Understanding and catering to the diverse preferences and cultural nuances across different regions is essential. Analysing regional data enables businesses to tailor their marketing efforts and product offerings effectively. Reliable logistics and secure delivery are vital for ensuring customer satisfaction and repeat business. Partnering with reputable logistics providers and implementing robust packaging solutions is essential for success in the e-commerce landscape. Customer satisfaction with delivery currently stands at 92% in the Indian market. Establishing trust with consumers is paramount when selling dietary supplements online. Highlighting product quality, authenticity, and safety through certifications and transparent communication can inspire confidence in potential buyers.

In recent times, there has been an exponential surge in the demand for E-pharmacy services, particularly amplified by the ongoing pandemic. Several E-pharma companies have emerged as crucial resources, tirelessly providing their services to the public. Projections indicate that the market is poised to grow at a compounded rate of 44 percent, reaching USD 4.5 billion by 2025 . Currently, India boasts over 50 startups in the E-pharmacy sector, catering to approximately 5,000,000 patients per month nationwide with quality and affordable medication. The proliferation of internet access, propelled by the widespread availability of internet-enabled smartphones and high-speed broadband connectivity, has significantly increased internet penetration across both rural and urban India. This trend is expected to continue, leading to an exponential growth in the number of internet users. The Government of India (GoI) and the Ministry of Health and Family Welfare (MoHFW) have introduced various public health initiatives utilizing information and communication technologies to facilitate easy access to government healthcare services for residents. Some of these initiatives include:

- National health portal
- Online registration system
- E-hospital@NIC
- SUGAM

Here are some key players specifically in the health and wellness e-commerce segment in India:

1. **HealthKart:** HealthKart is one of the leading e-commerce platforms for health and wellness products in India. It offers a wide range of dietary supplements, fitness equipment, personal care products, and health food and drinks to cater to diverse customer needs.
2. **Tata 1mg:** 1mg is a popular e-pharmacy platform that allows users to order medicines, book diagnostic tests, consult doctors online, and purchase health and wellness products. It provides a comprehensive range of healthcare products, including OTC medications, health devices, and personal care items.
3. **Netmeds.com:** Netmeds is an online pharmacy and wellness platform that offers a wide variety of prescription medications, generic drugs, OTC products, and healthcare devices. They provide doorstep delivery of medicines and have a user-friendly interface.
4. **PharmEasy:** PharmEasy is an online medicine delivery platform that offers a range of healthcare products. Along with prescription medicines, they also provide wellness and personal care products, nutritional supplements, health devices, and more.
5. **Healthmug:** Healthmug is an e-commerce platform that specializes in providing Ayurvedic and natural health and wellness products. They offer a vast range of Ayurvedic medicines, herbal supplements, personal care items, and organic foods.

18. *https://indbiz.gov.in/india-had-over-700-mn-active-internet-users-by-dec-22-report/#:~:text=India%20had%20over%20700%20million,areas%2C%20with%20295%20million%20users.*
19. *https://www.ibef.org/industry/ecommerce*
20. *https://economictimes.indiatimes.com/news/how-to/how-influencer-marketing-works-and-what-are-its-advantages/articleshow/94699501.cms?from=mdr*
21. *https://www.investindia.gov.in/team-india-blogs/e-pharmacies-bridging-gap-indian-healthcare*

Revolutionizing Health: Cutting-Edge Technological Advancements in the Nutraceutical Industry

Incorporating cutting-edge technologies has sparked a revolution in the research and development (R&D) sector of the Indian nutraceutical industry. Utilizing high-throughput screening methods coupled with robotics and AI algorithms expedites the process of discovering and creating new nutraceutical compounds. Computational Modeling and simulation, enhanced by sophisticated software and algorithms, empower researchers to explore interactions between nutrients and biological systems, facilitating quicker optimization of formulations and targeted development of products. The rise of genomics and personalized nutrition has stimulated the growth of genetic testing services and personalized nutraceutical interventions. These advancements in R&D fuel innovation, enhance effectiveness and ensure the safety of Indian nutraceutical products.

Artificial Intelligence

The nutraceutical industry is booming thanks to the popularity of supplements and functional foods for health benefits. NutrifyGenie, an AI engine, streamlines product development from ideation to market, reducing time by 50%. NutrifyGenie Clicks, a gamification platform, enhances learning and simplifies processes. In April 2020, BhookhaHaathi launched personalized nutrition using AI, predicting users' health conditions. In May 2019, Nestlé India introduced NINA, an AI assistant, to provide nutritional guidance through AskNestle for parents. These innovations aim to transform product development, compliance, and consumer engagement in the nutraceutical industry.

Robotic Process Automation (RPA)

Implementing Robotic Process Automation (RPA) effectively can boost productivity, enhance operations, cut expenses, and accelerate product launches. RPA also has the potential to uncover valuable insights into market dynamics, customer behaviours, and industry trends, paving the way for delivering superior services and outcomes.

3-D Printing Trends

In the nutraceutical industry, the utilization of 3-D printing techniques has sparked the emergence of new business opportunities. These ventures leverage the technology to enhance the delivery of nutraceutical drugs. This advancement allows for the utilization of customizable ingredients, facilitating the creation of tailor-made products with food components. The customization enabled by 3D Food Printing holds promise in meeting specific dietary needs, potentially reducing complications and hospitalizations. Certain sugar substitutes, like maltitol and xylitol, are popular among diabetics. Consequently, a chocolate-based 3D-printed food item containing a blend of these artificial sweeteners and functional polysaccharides was developed. This cutting-edge technology also serves a distinct role in providing personalized nutritional supplements. Through personalized supplement printing, essential nutrients are promised to be released at the appropriate times, aligning with individual needs and daily routines.

Synthetic Biology

Synthetic biology applied to plant systems holds promise for enhancing human health through the creation of plants capable of synthesizing pharmaceuticals, nutrients, and nutraceuticals. However, the ca-

pacity to develop plants that yield beneficial small molecules is impeded by technological obstacles.

Virtual Reality and Augmented Reality

Virtual reality (VR) and augmented reality (AR) streamline manufacturing and processing by offering clear, step-by-step guidance, thus minimizing the learning curve. The incorporation of AR holograms and 3D elements enhances the product experience, while the introduction of AR dietitians into consumers' homes makes product information easier to understand and readily available.

Nanonutraceuticals

Nanonutraceuticals surpass conventional nutraceutical formulations due to their ability to (a) improve the solubility and stability of natural bioactive compounds they encapsulate and (b) enhance absorption and effectiveness while reducing off-target release and minimizing potential side effects. According to recent scientific findings, nutraceuticals play a diverse role in preventing and treating various health issues. Nanonutraceuticals have broadened their health applications, ranging from providing antioxidant, antimicrobial, anti-inflammatory, wound healing, pain relief, and immunomodulatory effects to addressing age-related neurodegenerative diseases like Alzheimer's and Parkinson's, cancer, diabetes, skin conditions, and more recently, pre- and post-COVID-19 infections .

Some Recent Research (April 2021 to March 2022)

- **Microbiological safety and quality of commonly consumed herbal drugs:** Ashwagandha, Shatavari, aloe vera, and amla are the commonly consumed herbal drugs. Over 112 herbal drugs were collected. These included solid, semisolid, and liquid samples for microbiological analysis. Microbiological contamination in solid herbal drug samples was found to be more compared to semisolid and liquid herbal drug samples.

- **Assessment of nutritional status of below 12 years children of Muzaffarpur District, Bihar - A rapid nutritional assessment:** A rapid study was carried out to assess the nutritional status of the children in litchi growing areas of Muzaffarpur district of Bihar, where an outbreak of Acute Encephalitis Syndrome (AES) was reported. It was found that the children were subsisting on inadequate diets, both quantitatively and qualitatively. The same was reflected in their nutritional status - the prevalence of underweight (AES: 31.6% & non-AES: 25.1%) and stunting (AES: 47.7% & non-AES: 38.7%) among children under 5 was high. Anaemia was high among 3-5 years children (47.7%) and children below 3 years (76.4%). The prevalence of B12 deficiency was 45.4% in children 3-5 years and 58.6% in children below 3 years. All the deceased children were from underprivileged or marginalized communities. Most children reportedly consumed Litchi fruits and were exposed to hot sun during summer. Litchi fruits contain hypoglycin A or Methylene cyclopropylglycine (MCPG) known to cause hypoglycemia and metabolic derangement. Therefore, parents were sensitized not to allow their children to skip the night meal and play outdoors in the hot sun.

- **Development of prebiotic noodles containing galactooligosaccharides:** The study aimed to develop prebiotic (such as galactooligosaccharides) formulated noodles. Twelve different formulations of noodles were prepared and subjected to nutrient and sensory evaluation. The nutritional analysis showed an increase in the protein content in the formulation containing Maida (74%) + Defatted Bengal Gram (DFBG) (20%) + galactooligosaccharides (5%) +1g Micronutrients (MN). The percent of carbohydrates was high in the formulation [Maida (95g) + galactooligosaccharides (5g)]. The results showed 75% acceptability for Maida noodles compared to 22% for Maida (74%) +DFBG (20%) + galactooligosaccharides (5%) +1g Micronutrients (MN)], 26% for wheat (95%) galactooligosaccharides (5%), 52% for Maida (95%) galactooligosaccharides (5%).

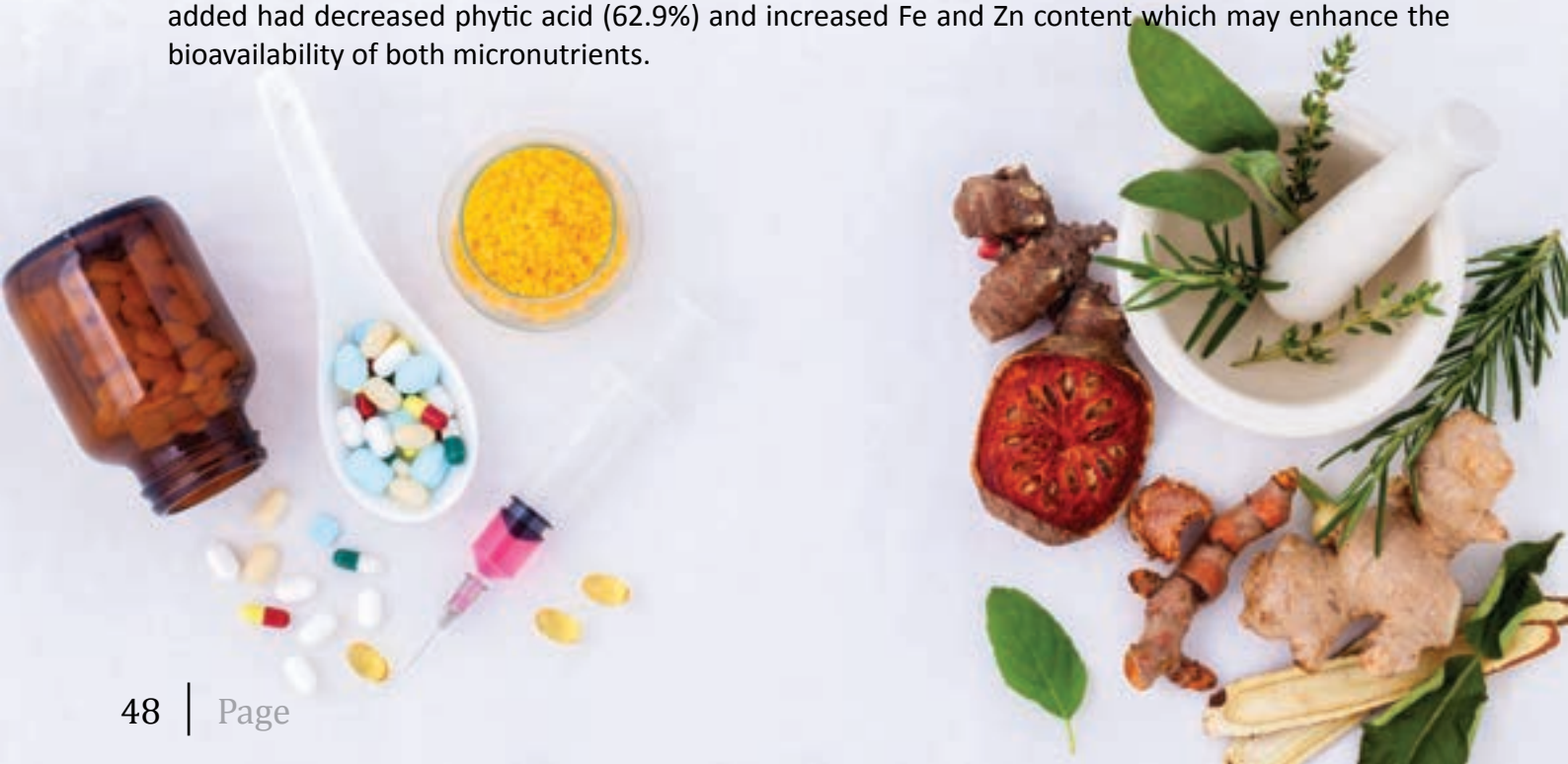
- **Consumption pattern of artificial sweeteners used in food products and as tabletop sweeteners among normal, overweight, obese, and type II diabetes individuals located in major metropolitan cities of India:** This study examined the consumers' knowledge of artificial sweeteners and quantifying levels of high-intensive sugars present in various food products available. The survey on the consumption pattern of artificial sweeteners among type II diabetic subjects indicated that 86% of individuals consumed tabletop sweeteners. The preference for these artificial sweeteners was 27% saccharine, 25% sucralose, 23% aspartame, 10% stevia, and 4% acesulfame K. About 74% of dieticians did not recommend using artificial sweeteners, while 26% recommended AS for weight management and glycemic control. Among the Artificial sweeteners, stevia (28%) and sucralose (15%) were most recommended by the dieticians. The content of sweeteners in various food products quantified using HPLC and TLC indicated that they were following Acceptable daily intake (ADI).

22. *https://www.sciencedirect.com/science/article/abs/pii/S1773224720311278*
23. *https://pubmed.ncbi.nlm.nih.gov/35186674/*
24. *https://main.icmr.nic.in/*

- **Development of α-crystallin mini chaperone peptides as therapeutic molecules for diabetic ocular diseases:** The protective and therapeutic effects of individual α-crystallin peptides and their combination in a 3:1 ratio in diabetic cataract and retinopathy were investigated in a rat model and cell lines. Even though systemically administered, αcrystallin peptides did not prevent hyperglycemia, however, they delayed cataract progression and preserved retinal function in the diabetic rats. Furthermore, α-crystallin peptide administration reduced the aggregation and solubilization of protein. Additionally, hyperglycaemia-induced oxidative and ER stress were also attenuated upon α-crystallin peptides administration. α-Crystallin peptides alleviated the hyperglycaemia-induced apoptosis by reducing the caspase-3 activity and Bax levels.

- **Anticancer effect of cinnamon extract and its active component procyanidin B2 in a rat model of prostate cancer:** This project studied the chemopreventive efficacy of cinnamon and its bioactive compounds in a rat model of prostate cancer. Histopathological changes such as hyperplasia and Prostate Intraepithelial Neoplasia [PIN] induced by the combination of chemical carcinogen and testosterone in the prostate were reversed by cinnamon and its bioactive compounds. Similar to chemo-preventive drugs, cinnamon (concentration) and its bioactive compounds led to inhibition of cell proliferation, induction of apoptosis, inhibition of oxidative stress and angiogenesis, proteasome inhibition, and inhibition of metastasis in prostate tissue. The data demonstrates that 4 cinnamon and its bioactive compounds have a beneficial effect against carcinogen-induced prostate carcinogenesis.

- **Effect of traditional cooking on phytonutrient content and radical scavenging activity in cereals and millets:** Traditionally processed sorghum, pearl millet, and finger millet (viz. cooking, fermentation with curd, fermentation without curd, the addition of curd to fermented millets) were analysed for their nutritional and anti-nutritional properties. Protein content was significantly higher in the cooked and fermented with curd sorghum (20.57±0.37 g/100g) and pearl millet (20.27±0.27 g/100g). Phytic acid content in millet flours ranged from 4.77±0.07 (pearl millet) to 8.6±0.15 mg/g (sorghum) and a sharp reduction (3.28±0.09 mg/g) was observed in sorghum after it was cooked and fermented overnight and mixed with curd. Nutrient retention of water-soluble vitamins increased in all the traditionally processed millets. The millets when traditionally cooked, overnight fermented, and then added had decreased phytic acid (62.9%) and increased Fe and Zn content which may enhance the bioavailability of both micronutrients.



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Chapter 4

Exploring Contemporary Developments in Ayush Practices

Emerging Trends and Innovations

Emerging Trends in Ayush

The AYUSH market, including Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy, was valued at USD 10 billion in 2020 and is projected to grow by 50% in the next five years. India's AYUSH sector, supported by a dedicated ministry since 2014, encourages foreign investment, especially during public health crises. With over 3000 hospitals and 500 colleges, India leads globally in AYUSH medicine. The country's emphasis on AYUSH is evident in the establishment of wellness parks and the widespread use of Ayurvedic remedies in rural areas, ensuring nearly equal penetration in both rural and urban regions.

Increased budget allocations and standardization efforts have boosted growth, as evidenced by successful companies like Dabur, Himalaya, and Patanjali. India's favourable business environment and moderate market saturation facilitate market entry. With a young and diverse workforce and a large pool of STEM graduates, India is primed for research and development. As the world's second-largest exporter of alternative medicine, India meets the rising global demand for practices like yoga and acupuncture. Success in the AYUSH sector also benefits the healthcare and cosmetics industries, catering to the demand for non-chemical solutions worldwide. India actively promotes exports through the AYUSH Research and Export Council.

Challenges persist, including stigma in Western markets, necessitating efforts to destigmatize AYUSH practices. However, India's blend of ancient wisdom and modern approaches positions it as an attractive destination for investment and industry growth, supported by a growing domestic market and government initiatives. Overall, India presents a compelling opportunity for foreign investment in the AYUSH sector.

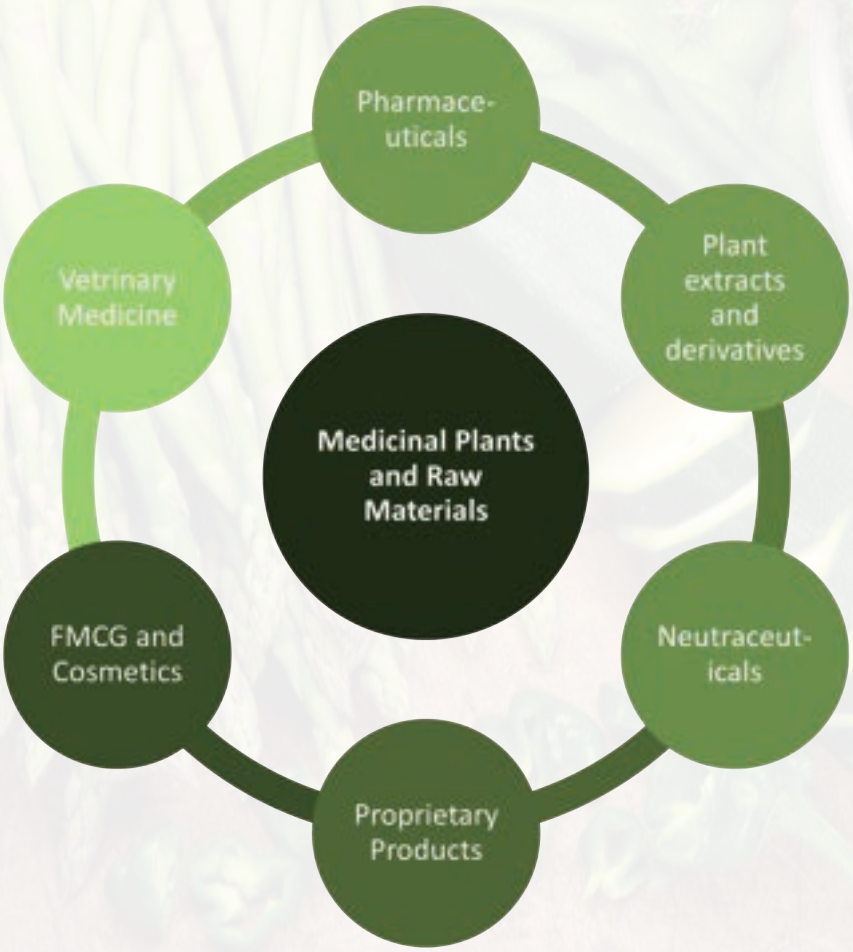
The Ministry of Ayush has taken the following steps to push exports globally :

The ministry has signed 24 Country-to-Country MoUs for Cooperation in the field of Traditional Medicine and Homoeopathy with foreign nations.

- 40 MoUs have been signed with international institutes for undertaking Collaborative Research / Academic collaboration.
- 15 MoUs have been signed with international institutes for setting up Ayush Academic Chairs in foreign nations.
- The Ministry of Ayush has provided support for the establishment of 39 Ayush Information Cells in 35 foreign nations.
- The "Ayush Export Promotion Council" has been registered under section 8(4) of the Companies Act 2013 on 04.01.2022 under the Ministry of Ayush in support of the Ministry of Corporate Affairs to tackle the obstacles to the registration of Ayush products abroad, the undertaking of market studies, and research activities abroad.
- MoUs have been signed with the London School of Hygiene & Tropical Medicine (LSH&TM), UK, and Frankfurter Innovationszentrum Biotechnology GmbH (FIZ), Frankfurt Germany for clinical research studies on the mitigation of Covid-19 through Ayurveda. WHO-GMP (COPP) has been given to 31 Ayurvedic Drug manufacturers to facilitate the export of Ayurveda, Siddha, and Unani & Homoeopathy Drugs.

25. *https://www.investindia.gov.in/team-india-blogs/growth-potential-ayush-india*
26. *https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1909096*

Various components of AYUSH Industry in India



Industrial Growth

AYUSH products have shown a broad acceptability in the Indian market due to which, in the last few years, leading pharmaceutical and FMCG firms have entered the market with proprietary and herbal products. Firms like Dabur and Patanjali whose major focus has been on AYUSH products, market themselves as Ayurvedic firms. Big FMCG and pharmaceutical firms who have entered the AYUSH market owing to its profitability and potential for growth such as Lupin pharmaceuticals, have started a subsidiary of Lupin-Life (OTC) products derived from Ayurveda, though these are not classical Ayurveda products. Hindustan Unilever, a major FMGC firm offers products under the brand "Lever AYUSH".

27. https://www.ris.org.in/sites/default/files/Publication/Ayush%20Study-Public%20Policy%20and%20Economic-FINAL%20REPORT%2028%20OCT_0.pdf

Leading AYUSH Firms

Company Name	AYUSH Segmentation (%)
Dabur India Ltd.	80.2
Patanjali Ayurved Ltd.	52.8
Glaxosmithkline Pharmaceuticals Ltd.	38.5
Marico Ltd.	15.5
Hindustan Unilever Ltd	7.8
Lupin Ltd.	2.2

Biodiversity Act Modification

The Biological Diversity Amendment Bill, 2021, introduced in the Lok Sabha on December 16, 2021, aimed to revise the existing Biological Diversity Act, 2002, addressing concerns raised by stakeholders since its inception. After a month-long public feedback period, receiving 1,217 comments, the Bill underwent scrutiny by a Joint Parliamentary Committee (JPC). In August 2022, the JPC submitted its recommendations. The government accepted most suggestions, leading to a revised version of the Bill presented in the Lok Sabha on July 20, 2023. The Lok Sabha approved it on July 25, 2023, followed by the Rajya Sabha on August 1, 2023. The President signed it into law on August 3, 2023.

The amendments proposed various changes, including exemptions for codified traditional knowledge users and AYUSH practitioners from benefit-sharing obligations. However, the term "Codified traditional knowledge" lacked clarity. Additionally, the Bill sought exemptions for specific research activities from benefit-sharing and aimed to decriminalize offenses under the Act. The JPC recommended refining the Bill to protect local communities' interests, streamline resource access, and clarify terminology. They suggested defining "Codified Traditional Knowledge" and refining wording to focus solely on knowledge directly linked to biological resources. However, the definition overlooked local communities' traditional knowledge.

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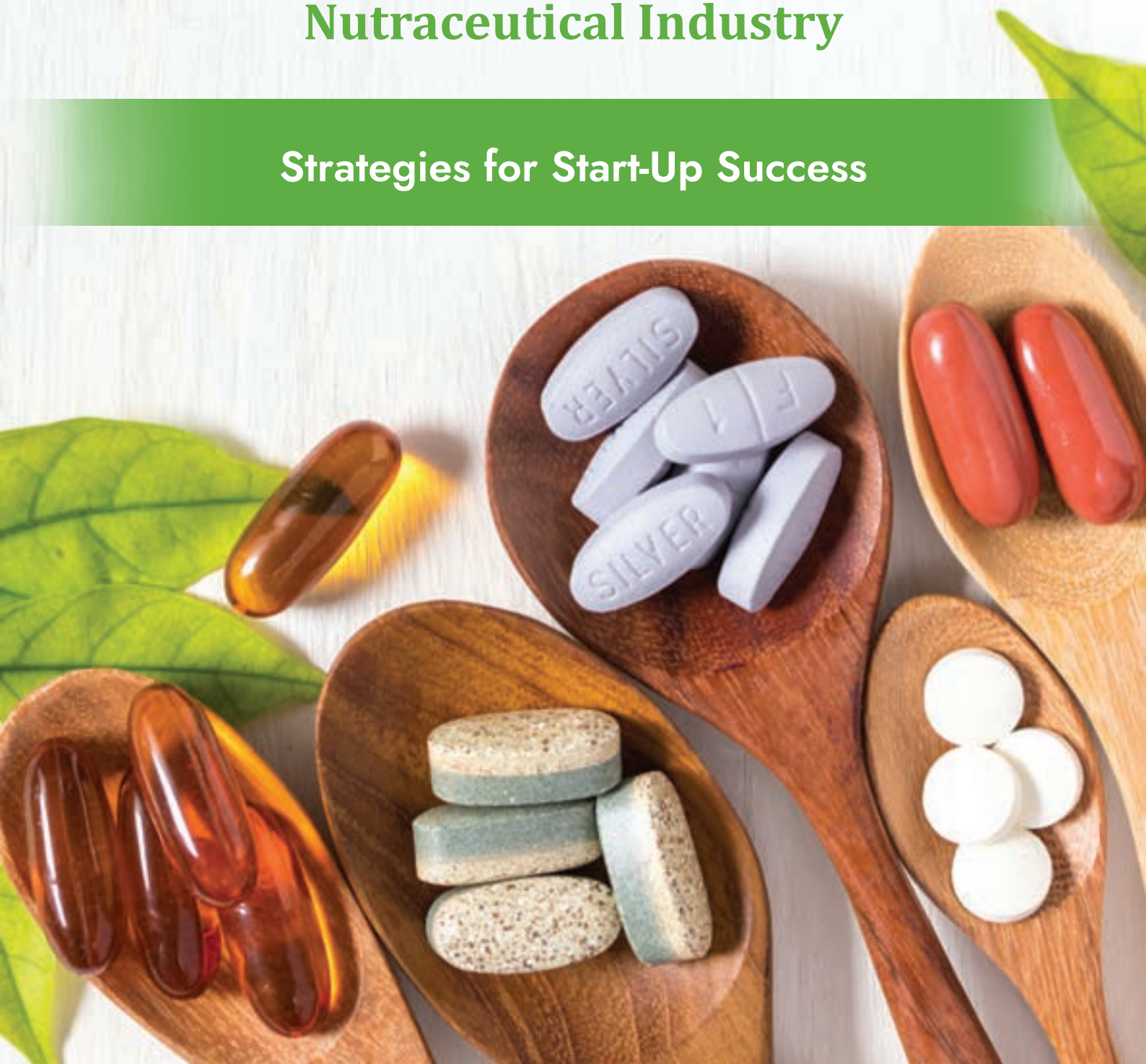
Chapter 5

Navigating Trademark Challenges in the Nutraceutical Industry

Strategies for Start-Up Success



Trademark challenges faced by nutraceutical start-ups and possible solutions

With the nutraceutical industry experiencing swift expansion, there's an increasing emphasis on investing in intellectual property (IP) assets. For a nutraceutical enterprise, trademarks serve as crucial IP assets by distinguishing their products and fostering confidence among consumers and industry partners. A trademark encompasses elements such as brand names, logos, slogans, taglines, and even the overall appearance and packaging of products.

1. **Conflict with existing brand owners:** It's not uncommon for companies to select a brand for their nutraceutical product, dedicate significant time, energy, and resources to promote it, and introduce it to the market, only to be served with a cease-and-desist notice by a prior owner of a similar or identical trademark, or face a court injunction prohibiting the use of the mark.
   To mitigate the aforementioned risks, it is advisable to perform a trademark clearance search before launching a brand, to ascertain the following:
   - Whether the intended brand is available for use.
   - Whether the intended brand is defensible against existing third-party marks.
   - Whether there are any identical or similar trademarks already in existence.

   The Indian Trademarks Office (TMO) offers a searchable database on its website, enabling users to search for trademarked words, brands, and images. It is recommended to cross-reference domain names and conduct thorough internet searches, encompassing popular search engines, social media platforms, e-commerce sites, the Registrar of Companies website, and the TMO's list of well-known marks. Conducting a clearance search helps prevent costly repercussions such as infringement lawsuits, the need for product and logo redesigning, rebranding efforts, and the disposal of manufactured goods. Additionally, it assists in addressing objections stemming from prior pending or registered trademarks.

Searching for an international non-proprietary name (INN) is essential when checking the trademark availability for nutraceuticals. It's important to avoid using an INN that cannot be registered or enforced, such as BIOTIN, when branding the product.

2. **Trademark infringement/passing off:** Another obstacle encountered by brand proprietors involves the unauthorized adoption or utilization of an indistinguishable or comparable symbol by external parties, resulting in the erosion of the trademark's uniqueness. Registering a trademark serves as the primary safeguard against such appropriation.

   In India, pharmaceuticals and medications are governed by the Drugs and Cosmetics Act of 1940, whereas nutraceuticals fall under the regulation of the FSS Act of 2006 and the corresponding FSS regulations. However, the criteria for assessing the similarity of trademarks remains consistent for both, as established by the Delhi High Court in the case of Sun Pharma Laboratories v Ajanta Pharma, CS (COMM.) 622/2018. The court recognized that nutraceuticals:
   - Are subject to stringent regulation.
   - Cannot be produced without proper licensing; and
   - Require approval from the FSSAI for various aspects including the product itself, packaging, labeling, specific disclaimers, etc.

   Both pharmaceuticals and nutraceuticals are commonly recommended by healthcare professionals to target specific conditions and promote overall well-being.

3. **Counterfeiting on e-marketplaces**: A study carried out by the social networking site Local Circles and released in 2018 revealed that 38% of customers had encountered fake items they had bought from an online marketplace . Considering the widespread use of e-marketplaces and the anonymity of sellers, brand owners should closely monitor these platforms. It is recommended that trademark owners establish a monitoring service and a protocol for removing counterfeit and infringing items to maintain a counterfeit-free environment.

4. **Product disparagement**: Due to the rapid expansion of the nutraceutical sector, companies may encounter challenges related to comparative advertising, potentially leading to the disparagement of their products by competitors. It is advisable for brand owners to exercise caution when crafting advertising strategies and to stay informed about the guidelines established by the Advertising Standards Council of India concerning unfair advertising practices.

Nutraceutical Product Development Challenges

Nutraceuticals are different from functional foods and present regulatory challenges that cross both food and pharmaceutical frameworks. Due to varying national regulations and the lack of international consensus on labeling standards, regulatory ambiguity, and label reliability concerns are prevalent in the nutraceutical industry. The nutraceutical sector is hindered by communication gaps, which make it difficult for companies to promptly identify compounds with medicinal properties in the numerous plants found in India. Bioactive components also face challenges, such as limited solubility, stability, and gastrointestinal permeability, which can affect their effectiveness. Encapsulation technologies, such as probiotics encapsulation technology (PET), aim to address these challenges, but careful consideration of biomaterial selection and solvent toxicity is required. Despite innovations in drug delivery systems, their adoption in the nutraceutical sector remains slow due to complexity and cost, which means reliance on conventional forms persists. Challenges arise from crystalline-free phytosterols, which can affect food texture and organoleptic properties. Educating the public about healthy dietary choices is crucial, underscoring the importance of informed decision-making in driving food market expansion.

28. *https://economictimes.indiatimes.com/small-biz/startups/newsbuzz/a-third-of-ecommerce-buyers-get-counterfeit-products/*

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Chapter 6

Addressing Challenges in the Indian Nutraceuticals Industry

Strategic Solutions for Growth and Sustainability

The nutraceuticals industry in India has witnessed significant growth in recent years, fueled by increasing health consciousness among consumers and a growing demand for natural and preventive healthcare solutions. However, like any rapidly evolving sector, the Indian nutraceuticals industry faces its share of challenges. From regulatory hurdles to supply chain issues and consumer education gaps, addressing these challenges is crucial for the sustainable growth of the industry.

1. **Harmonization and Streamlining Regulations:** Currently, nutraceuticals are regulated under various laws and regulations, including the Food Safety and Standards Authority of India (FSSAI) regulations, the Drugs and Cosmetics Act, and the Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homoeopathy (AYUSH) guidelines. This fragmented regulatory landscape often leads to ambiguity and inconsistency in compliance requirements, hindering industry growth.

   To address this challenge, there is a pressing need for the harmonization and streamlining of regulations governing the nutraceuticals industry. This involves collaboration between regulatory bodies such as FSSAI, AYUSH, and the Ministry of Health to develop a unified regulatory framework that provides clarity and consistency in standards, labeling requirements, and product categorization. Moreover, regulatory agencies should engage with industry stakeholders to ensure that the regulations are pragmatic, science-based, and conducive to innovation while safeguarding consumer safety.

2. **Quality and Safety Standards:** To address quality and safety concerns, industry players must prioritize the implementation of stringent quality assurance measures across the entire supply chain – from sourcing raw materials to manufacturing, packaging, and distribution. This includes adherence to Good Manufacturing Practices (GMP), Hazard Analysis and Critical Control Points (HACCP) systems, and robust testing protocols for raw materials and finished products. Collaboration with accredited testing laboratories and certification bodies can further enhance transparency and credibility in the marketplace.

3. **Consumer Awareness and Education:** Many consumers are sceptical due to misinformation or misconceptions surrounding nutraceuticals, while others may not fully comprehend their role in supporting overall health and wellness. Industry stakeholders, including manufacturers, retailers, and industry associations, should invest in comprehensive education and communication initiatives to raise awareness and enhance consumer understanding of nutraceuticals. This involves disseminating accurate information about the science behind nutraceuticals, their potential health benefits, proper usage guidelines, and the importance of incorporating them into a balanced lifestyle. Leveraging digital platforms, social media, and collaborations with healthcare professionals can help reach a wider audience and debunk myths surrounding nutraceuticals.

4. **Market Access and Distribution:** Limited availability of retail outlets, logistical constraints, and complex distribution networks often hinder the reach of nutraceutical products, especially in remote or rural areas. To overcome these challenges, nutraceutical companies need to adopt a multi-channel distribution strategy that encompasses traditional retail channels, e-commerce platforms, direct-to-consumer models, and partnerships with pharmacies and healthcare providers. Investing in infrastructure development, cold chain logistics, and last-mile delivery solutions can improve accessibility and enable penetration into underserved markets. Additionally, strategic alliances with local distributors and regional players can facilitate market expansion and enhance brand visibility across diverse geographies.

Solutions

The regulation and marketing of nutraceuticals vary greatly worldwide due to challenges in classification, the absence of a suitable regulatory framework, and differing views on what constitutes sufficient scientific evidence of their efficacy. A unified approach could establish a universally accepted definition. India recently posted its definition on the FSSAI site, while the FDA and EU have implemented regulatory changes. When employing the ethnobotanical approach to drug development, it's crucial to share information gathered from traditional knowledge holders while respecting the intellectual property rights of cultural groups, tribes, or local communities where plants are sourced based on their ethnomedical expertise. This can enhance understanding and identify new sources effectively.

The utilization of nanotechnology in pharmaceutical applications offers a new avenue for enhancing the stability, solubility, or permeability of challenging nutraceuticals, aiming to support health and well-being as global life expectancy rises. While the introduction of generic alternatives may lower prices for some nutraceuticals, the growing reliance on these products and their expanding market presence suggests that market growth will remain steady. Another solution is the implementation of advanced food processing technologies and analytical studies to ensure the quality and safety of nutraceutical ingredients. Investment in new manufacturing methods and sophisticated analytical procedures is also necessary to scale up production without compromising product quality. Furthermore, interfacial engineering approaches, such as the use of emulsions as delivery systems, can

enhance the dispersibility, stability, and bioavailability of nutraceuticals in functional food. Implementing robust quality control and assurance measures throughout the manufacturing process is essential for ensuring product safety, consistency, and compliance with regulatory standards. This includes sourcing high-quality raw materials, conducting rigorous testing for purity and potency, and adhering to good manufacturing practices (GMP). Furthermore, incorporating sustainable sourcing and manufacturing practices into nutraceutical product development can enhance brand reputation, minimize environmental impact, and meet growing consumer demand for ethically sourced and eco-friendly products. This includes sourcing organic and responsibly harvested ingredients, minimizing waste and energy consumption, and adopting eco-friendly packaging solutions.

December 2023

The Central Marine Fisheries Research Institute (CMFRI) has brought to market two seaweed-derived nutraceuticals with patented technologies. One aims to enhance antiviral immunity, while the other targets high cholesterol or dyslipidemia. These products are slated to be available within six months through Pioneer Pharmaceuticals.

April 2020

A study published, showed that amendments of gut microbiota may improve the Autism spectrum disorder symptoms and revealed the beneficial impact of probiotic supplementation on the improvement of symptoms of Autism spectrum disorder, which suggest that probiotics can be used as a potent adjuvant therapeutic agent for neurodevelopmental disorders such as Autism spectrum disorder. In addition, studies have suggested that the dietary regulations may strengthen the therapeutic advancement in autism spectrum disorder treatment.

November 2019

Bharathiar University bagged a patent for a method of manufacturing a dietary supplement from the seed embryo of palmyrah (Borassus flabellifer). The method not only helps develop a potent dietary supplement rich in anti-stress properties but also brings a change in the socio-economic status of farmers.

Chapter 7

Realizing the Promise

Concluding Insights on Nutraceuticals in India

Conclusion

India's potential to emerge as a global export and manufacturing centre under the 'China plus one' strategy hinges on various critical factors. India can thrive in specialized nutraceutical markets by drawing on its extensive heritage in Ayurveda and herbal medicine, setting itself apart from China's dominance in mass markets. Vital investments in robust transportation, logistics, and digital infrastructure are necessary for efficient goods movement, along with precision-oriented manufacturing facilities and farms. Simplifying trade regulations and enhancing the ease of doing business will entice foreign investors.

Promoting sustainability-focused innovation across sectors will yield high-value, globally competitive goods. The convergence of scientific progress, cultural traditions, and technological advancements promises advancements in healthcare and individual well-being. Acknowledging India's rich legacy in traditional medical systems such as Ayurveda, Siddha, and Yoga emphasizes the holistic approach to health, viewing food as both sustenance and medicine. Blending traditional wisdom with modern science offers a unique opportunity to customize interventions to individual needs and preferences, fostering better health outcomes.

India's potential to become a global export and manufacturing hub under the 'China plus one' strategy relies on several critical factors. Leveraging its rich heritage in Ayurveda and herbal medicine, India can excel in specialized nutraceutical markets, distinguishing itself from China's dominance in mass markets. Crucial investments in robust transportation, logistics, and digital infrastructure are essential for efficient goods movement, alongside precision-oriented manufacturing facilities and farms. Streamlining trade regulations and improving the ease of doing business will attract foreign investors. Prioritizing sustainability-focused innovation across sectors will yield high-value, globally competitive goods.

The fusion of scientific advancements, cultural traditions, and technological progress promises breakthroughs in healthcare and individual well-being. Recognizing India's legacy in traditional medical systems like Ayurveda, Siddha, and Yoga underscores a holistic health approach, where food is seen as both sustenance and medicine. Integrating traditional wisdom with modern science presents a unique opportunity to tailor interventions to individual needs and preferences, fostering improved health outcomes.
Technology plays a vital role in personalized nutrition and medicine. Wearable devices, mobile apps, AI, and big data enable access to personalized health insights. Digital platforms help healthcare providers deliver tailored recommendations, track progress, and facilitate real-time feedback, promoting a more proactive and preventive approach to healthcare.

The promise of nutraceuticals in India lies in a convergence of tradition, innovation, science, technology, culture, and commerce. By fostering collaboration and embracing a multidimensional approach, we can unlock their full potential in promoting health and enhancing quality of life. As this transformative journey is embarked upon, let it be guided by the principles of integrity, inclusivity, and compassion, ensuring that the benefits of personalized nutrition and medicine are equitably shared by all.

The development of the Nutraceutical market can be the epitome of the 'MAKE IN INDIA' imitative and this can create new opportunities in the field of Biotechnology. In December 2023, USV and Biogenomics launched Insuquick, a rapid-acting insulin biosimilar aimed at transforming diabetes treatment. USV will continue to prioritize cardiology and diabetes as key focus areas, with plans to introduce nutraceuticals to complement diabetes care. This "Make in India" product, available in major cities as well as tier I/II cities, marks the first biosimilar in the rapid-acting insulin category. In the fight against the COVID-19 pandemic, the term 'immunity' has gained significant attention, leading to a surge in global demand for nutraceutical products. Given our nation's rich heritage in Ayurveda and abundant resources of herbs and spices, there exists a promising opportunity to establish ourselves as a leading Nutra-Hub. However, this requires additional incentives and promotional efforts to further develop and promote the nutraceutical sector.

About ASSOCHAM

The Associated Chambers of Commerce & Industry of India (ASSOCHAM) is the country's oldest apex chamber. It brings in actionable insights to strengthen the Indian ecosystem, leveraging its network of more than 4,50,000 members, of which MSMEs represent a large segment. With a strong presence in states, and key cities globally, ASSOCHAM also has more than 400 associations, federations and regional chambers in its fold.

Aligned with the vision of creating a New India, ASSOCHAM works as a conduit between the industry and the Government. The Chamber is an agile and forward looking institution, leading various initiatives to enhance the global competitiveness of the Indian industry, while strengthening the domestic ecosystem.

With more than 100 national and regional sector councils, ASSOCHAM is an impactful representative of the Indian industry. These Councils are led by well-known industry leaders, academicians, economists and independent professionals. The Chamber focuses on aligning critical needs and interests of the industry with the growth aspirations of the nation.

ASSOCHAM is driving four strategic priorities - Sustainability, Empowerment, Entrepreneurship and Digitisation. The Chamber believes that affirmative action in these areas would help drive an inclusive and sustainable socio-economic growth for the country.

ASSOCHAM is working hand in hand with the government, regulators and national and international think tanks to contribute to the policy making process and share vital feedback on implementation of decisions of far-reaching consequences. In line with its focus on being future-ready, the Chamber is building a strong network of knowledge architects. Thus, ASSOCHAM is all set to redefine the dynamics of growth and development in the technology-driven 'Knowledge-Based Economy. The Chamber aims to empower stakeholders in the Indian economy by inculcating knowledge that will be the catalyst of growth in the dynamic global environment.

The Chamber also supports civil society through citizenship programmes, to drive inclusive development. ASSOCHAM's member network leads initiatives in various segments such as empowerment, healthcare, education and skilling, hygiene, affirmative action, road safety, livelihood, life skills, sustainability, to name a few.

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