

Daily News

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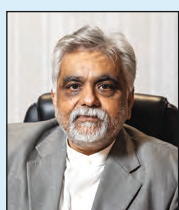
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Regulatory reliance & pharmacopoeia convergence: iPHEX 2025 advances global quality agenda

LAXMI YADAV, MUMBAI

THE second day of the 11th International Exhibition for Pharma and Healthcare (iPHEX 2025) was a vivid demonstration of how regulatory cooperation, market access strategy, and pharma-

copoeia convergence are shaping the future of global pharmaceuticals.

Under the theme "Regulatory Reliance: Pathways to Global Recognition & Collaboration", the day's agenda moved seamlessly from country specific regulatory briefings to strategic trade discus-

sions and a landmark pharmacopoeia convergence dialogue.

Organised by the Pharmaceuticals Export Promotion Council of India (Pharmexil) under the Ministry of Commerce & Industry, Government of India, iPHEX 2025 (September 4-6)

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India needs to streamline patenting, regulatory systems & strengthen clinical validation infra to become global R&D hub for nutra: Dr Agrawal



DR. SANJAY AGRAWAL, a distinguished pharmaceutical consultant and scientific advisor at Alkomex GBN Pharma Group USA in talk with **LAXMI YADAV**, PharmaClick, discusses the significant economic and public health contributions of the nutraceutical industry, emphasizing the critical need for clinical validation of product claims and the importance of aligning Indian nutraceutical standards with global benchmarks to enhance India's nutraceutical exports.

Dr. Agrawal further elaborates on the country's pivotal role in meeting the increasing global demand for organic, clean-label, and plant-based nutraceuticals. He underscores the necessity for India to bolster regulatory clarity, streamline its patenting system, and invest in clinical validation infrastructure to position itself as one of the top five global research and development hubs for nutraceuticals, by integrating both traditional knowledge and modern scientific rigour.

1. How is the nutraceutical industry contributing to India's economic growth and public health?

Dr Sanjay Agrawal: The Indian nutraceutical industry today represents a critical intersection of food, health, and medicine, driving both economic momentum and better public health outcomes. Economically, the industry is currently valued at over \$10 billion and is projected to cross \$20 billion by 2030, reflecting a growth trajectory fuelled by increased consumer awareness, expanding middle-class purchasing power, and global demand. This sector generates employment across multiple verticals, agriculture for raw material cultivation, pharmaceutical and food technology research, manufacturing, packaging, logistics, and fast-moving consumer goods (FMCG). It also benefits rural economies by increasing demand for specific crops such as herbs, pulses, and oilseeds that are used as nutraceutical ingredients. Simultaneously, nutraceutical hubs in urban centres are becoming

innovation engines, fostering new product development, export capabilities, and start-up ecosystems.

On the public health front, nutraceuticals are making a substantial contribution to preventive healthcare. With India facing an epidemic of lifestyle-related diseases such as diabetes, cardiovascular conditions, obesity, and micronutrient malnutrition, nutraceuticals are offering cost-effective solutions that emphasize prevention rather than cure. Affordable Indian nutraceutical products are accessible to a wide socioeconomic spectrum, reducing reliance on expensive pharmaceutical interventions and lowering long-term healthcare costs. By addressing nutritional gaps, improving immunity, and promoting overall wellness, the industry not only improves the quality of life for millions of Indians but also helps ease the burden on an overstretched healthcare system.

2. What are some key trends you're seeing in the development and use of

nutraceuticals in India?

Dr Sanjay Agrawal: The nutraceutical industry in India is undergoing a rapid transformation, with several clear trends shaping its trajectory. One of the most significant is the rise of personalized nutrition, where AI-driven health analytics and genomic insights are being used to develop customized supplement regimens based on an individual's genetic profile, lifestyle, and dietary habits. This is moving consumers away from generic, one-size-fits-all supplements toward precision-based nutrition.

Another major trend is the integration of Ayurveda and modern science, producing nutraceuticals that combine time-tested herbs like ashwagandha, turmeric, and giloy with clinical validation. This hybrid approach not only appeals to domestic consumers who trust traditional medicine but also enhances global credibility. Plant-based proteins are also gaining traction, particularly with the rise of veganism and flexitarian diets among health-conscious consumers, offering alternatives to animal-derived proteins.

Food fortification remains a cornerstone of India's efforts to combat malnutrition and micronutrient deficiencies. Essential nutrients such as iron, vitamin B12, and vitamin D are increasingly being added to staples like rice, wheat, and dairy products to address widespread deficiencies in the population. Simultaneously, digital health platforms are embedding nutraceutical recommendations within telemedicine, fitness, and wellness apps, making supplementation more integrated into lifestyle management.

Finally, India's export potential is expanding rapidly. Demand for organic, clean-label, and plant-based nutraceuticals is surging in North America, Europe, and Southeast Asia, positioning India as a reliable global supplier of affordable, high-quality nutraceuticals.

3. How is the nutraceutical industry in India regulated, and are there any gaps in the current regulatory framework? According to you, what steps can be taken to ensure quality control and standardization of nutraceutical products in India?

Dr Sanjay Agrawal: The Indian nutraceutical industry is primarily regulated by the Food Safety and Standards Authority of India (FSSAI), which treats nutraceuticals as foods rather than pharmaceuticals. While this ensures that nutraceuticals are subject to food safety standards, the current framework leaves several important gaps. A major challenge is the lack of mandatory clinical validation for product claims. Unlike pharmaceuticals, where extensive clinical trials are required, nutraceuticals often reach the market without strong scientific backing, raising questions about efficacy and credibility.

Another regulatory gap lies in the ambiguity of categorization. The overlap between dietary supplements, traditional Ayurvedic formulations, and pharmaceutical products often creates confusion, both for manufacturers and consumers. Enforcement also remains weak, as spurious or mislabelled products still flood the market, undermining consumer trust.



India needs to streamline patenting...

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To strengthen the framework, several steps are essential. India must mandate clinical validation for health-related claims, particularly for products marketed for disease prevention or management. Developing clear and harmonized standard operating procedures (SOPs) for composition, dosages, labelling, and safety testing is critical for consistency. Expanding regional quality-testing laboratories would help verify safety and efficacy before products reach the market. Finally, aligning Indian nutraceutical standards with global benchmarks such as Codex Alimentarius, the European Food Safety Authority (EFSA), and the US FDA would not only ensure global credibility but also boost India's exports in the sector.

4. How does India compare to other countries in terms of nutraceutical

research and development?

Dr Sanjay Agrawal: When it comes to nutraceutical research and development, India lags behind advanced markets such as the United States, Japan, and the European Union, which lead in clinical validation, intellectual property filings, and investment in innovation. These countries have established ecosystems with strong academia-industry linkages and strict regulatory oversight that encourage sustained R&D.

India, however, possesses unique comparative advantages. Its biodiversity and Ayurvedic heritage provide access to an unparalleled variety of bioactive compounds that can be studied and adapted into modern nutraceuticals. Additionally, India has a cost advantage, with lower R&D and manufacturing expenses compared to Western counterparts, making it an attractive partner for global nutraceutical

companies. Growing public-private partnerships between universities, research institutes, and start-ups are also beginning to fuel innovation.

If India strengthens regulatory clarity, streamlines its patenting system, and invests in clinical validation infrastructure, it has the potential to emerge as one of the top five global R&D hubs for nutraceuticals, leveraging both traditional knowledge and modern scientific rigor.

6. Are there any specific nutraceuticals or functional foods being developed by you to address prevalent health issues in India?

Dr Sanjay Agrawal: Yes, the development of nutraceuticals in India is closely tied to addressing its most pressing health challenges. For diabetes, which affects over 70 million Indians, nutraceutical formulations using herbal extracts like fenugreek,

bitter melon, and cinnamon are being developed to support blood sugar regulation and improve insulin sensitivity. For cardiovascular health, omega-3 enriched oils, plant sterols, and antioxidants are formulated to support heart health and manage cholesterol.

To address widespread malnutrition and anaemia, particularly in women and children, iron and vitamin-fortified foods such as fortified rice and wheat flour are being deployed as part of both private and government initiatives. The growing concern around digestive and immune health has spurred innovation in probiotics, prebiotics, and synbiotics, which not only aid digestion but also enhance immunity and reproductive health. Meanwhile, immunity boosters such as turmeric curcumin, ashwagandha, and vitamin C-enriched formulations have surged in popularity, particularly

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ly after the COVID-19 pandemic, both domestically and internationally.

These nutraceuticals not only address India's domestic health issues but also serve as highly marketable products globally, reinforcing India's positioning as both a consumer and exporter of high-value nutraceuticals.

6. Could you shed light on challenges faced by nutraceutical researchers/firms while seeking patents for their products in India? What could be done to improve the ecosystem for accelerating nutraceutical research in India?

Dr Sanjay Agrawal: Securing patents for nutraceuticals in India remains a challenging task. One major issue is the lengthy approval process, with backlogs in patent offices delaying commercialization. Another challenge lies in the traditional knowledge exclusion, where formulations based on Ayurveda or indigenous herbs are often denied patents because they fall under common knowledge, even if firms have invested in modernizing and clinically validating them. The high cost of international patent filings further limits Indian firms, especially start-ups, from securing global IP protection. Moreover, there is a shortage of specialized patent professionals with expertise in nutraceutical formulations, which differ significantly from pharmaceuticals.

To improve this ecosystem, India must create specialized IPR cells dedicated to nutraceuticals, with experts trained in this niche domain. Establishing fast-track approval mechanisms for novel formulations can accelerate innovation. Additionally, government support in the form of grants, sub-



sidies, and legal assistance can help smaller firms and start-ups secure both domestic and international patents. Finally, fostering stronger collaborations between academia, industry, and regulators would ensure that research translates more smoothly into market-ready, patent-protected products.

7. How is the Indian nutraceutical industry embracing technology and sustainable practices to optimize resources and improve outcomes?

Dr Sanjay Agrawal: The Indian nutraceutical industry is rapidly adopting advanced technologies and sustainable practices to optimize operations while minimizing environmental impact. Artificial intelligence and big data analytics are being used to discover new bioactive compounds and create personalized nutrition recommendations, enabling companies to design more effective products. In agriculture, IoT-driven systems help farmers monitor soil quality, irrigation, and crop yields for nutraceutical ingredients, ensuring traceability and

quality right from the source.

Blockchain technology is increasingly being deployed for transparent supply chains, allowing consumers to trace products from raw material to final packaging, thus strengthening trust and reducing counterfeits. On the manufacturing side, companies are adopting green extraction techniques, renewable energy use, and biodegradable packaging to lower their ecological footprint. Circular economy approaches are also gaining ground, where agricultural and food waste, such as fruit peels and vegetable by-products, are repurposed into bioactive nutraceutical ingredients.

These sustainable practices are not only ethical but also commercially advantageous, as global consumers are increasingly seeking nutraceuticals that are environmentally responsible, clean-label, and ethically sourced.

8. What are the key areas where India needs to focus its efforts to become a global leader in nutraceutical research? What kind of scientific advancements do you anticipate in the

field of nutraceuticals over the coming years?

Dr Sanjay Agrawal: For India to achieve global leadership in nutraceutical research, several priority areas need attention. The foremost is robust clinical validation, which would lend scientific credibility to products and counter skepticism about efficacy. Global harmonization of standards is also crucial, ensuring that Indian nutraceuticals can seamlessly enter regulated international markets. Investment in cutting-edge R&D infrastructure such as biotech innovation hubs, advanced laboratories, and centres of excellence is essential to accelerate discovery and testing. Furthermore, India must pioneer research in nutrigenomics, which explores the interaction between genes and nutrition, to deliver truly personalized nutraceutical solutions.

Looking ahead, several scientific advancements are expected to redefine the sector. AI-driven nutraceutical discovery platforms will accelerate the identification of novel bioactive compounds from India's biodiversity. Smart nutraceuticals with targeted delivery systems will ensure that nutrients are absorbed more effectively in the body. Integration of wearable health devices with nutraceutical interventions will allow real-time monitoring of nutrition impact. Finally, we may see next-generation functional foods such as 3D-printed supplements that are personalized to an individual's metabolism, lifestyle, and genetic makeup.

By aligning tradition with technology and focusing on evidence-based innovation, India is well-positioned to transition from being a low-cost manufacturer to a global innovation hub in nutraceuticals.

