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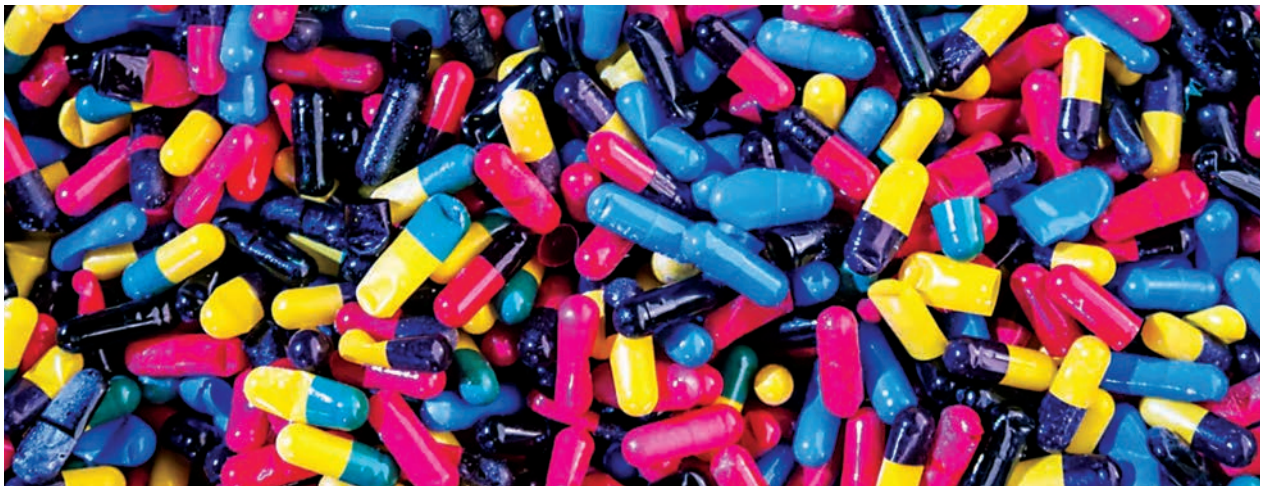
"Our priorities will include identifying and understanding the challenges while engaging regularly with industry leaders to address their concerns"

– K Raja Bhanu, Director General, Pharmaceuticals Export Promotion Council of India (Pharmexcil)



Are Nutraceuticals DRUGS? Examining a Needless Regulatory Tussle

The news has been around for a while which has put a big question mark ahead of the Indian nutraceuticals industry. The news is about changing rules, it is about switching regulations and even about reimagining the entire identity of nutraceuticals. The talk is about moving nutraceuticals from one existing regulatory body to another. Very recently, government has formed a panel to examine the possibility of bringing nutraceuticals under the ambit of the apex drug regulator, Central Drugs Standard Control Organisation (CDSCO) instead of the food regulator Food Safety and Standards Authority of India (FSSAI) to address regulatory challenges and promote consumer safety. This step taken by the centre towards nutraceuticals products has been receiving mixed reactions from the industry players and associations. According to our research, along with nutraceuticals producers, pharma players also have their own say on this particular development. Based on this, it can be said that bringing nutraceuticals under the jurisdiction of the CDSCO rather than the FSSAI could have significant implications, both positive and negative. Let's explore the numerous implications for the nutraceutical industry and the stakeholders involved.

The committee formed by the government has Secretary, Ministry of Ayush; Secretary, Ministry of Food Processing Industries; Secretary, Department of Pharmaceuticals; Chief Executive Officer (CEO), FSSAI; Drugs Controller General of India (DCGI); Director General (DG), Indian Council of Medical Research (ICMR) and Director General of Health Services (DGHS) as members. Presently, the FSSAI regulates the usage of health supplements and nutraceuticals under the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022. This regulation covers food items that are specially processed or formulated for specific nutritional or dietary purposes.

Why this step and why now?

During a surveillance drive to curb the menace of spurious nutraceuticals manufactured by nutraceutical companies operating in Himachal Pradesh (HP) in June 2023, FSSAI issued a stern warning to the firms to strictly follow the regulations as according to the reports, industrial area in HP has become a hub for producing spurious vitamins, syrups, and drugs in the name of food supplements. Having said that, quality has always been one of the topics of debates in the Indian nutraceuticals

CDSCO is one of the complex regulatory bodies of India. The CDSCO's drug approval process is more rigorous and time-consuming than FSSAI. This could slow down the introduction of new nutraceutical products, potentially stifling innovation in the sector. Most of the nutraceuticals are quite simple formulations unlike others in the market. Hence putting all of them into one single basket of CDSCO would not work.

Another factor that needs to be considered is increased regulatory burden. More stringent CDSCO regulations could lead to a higher regulatory burden on nutraceuticals manufacturers. This might increase the cost of bringing nutraceuticals to market, potentially affecting pricing and availability. This will ultimately affect the government's agenda of making nutraceuticals affordable, leaving the decision purposeless.

While sharing his thoughts on this particular move by the government, ***Shaheen Majeed, Global CEO & Managing Director, Sami-Sabinsa Group*** said, "Independently, the FSSAI through its FSS Act 2006 and FSS Regulations 2022 has streamlined the fast-growing nutraceutical sector and aligned it to global markets' requirements. We feel, more stringent regulations in terms of GAP, GMP, label claims, dosage etc. ensuring the safety and efficacy of products are required to strengthen it further. Shifting nutraceuticals from FSSAI to CDSCO will be a setback to the sector as it may lose its identity and potential, suppress the growth of nutra industry and exports, kill MSMEs fearing hard time to meet market demands during the transition period, and shift global customers to other countries and make us less competitive."

Moreover, if not clearly delineated, there could be confusion or overlap in regulatory responsibilities, especially for products that straddle the line between food and drug categories. This might lead to legal and operational challenges for companies.

"While, there are both positives and negatives in bringing the nutraceuticals under the ambit of the drug regulator, we need to examine both aspects. We should also look at global practices in this regard. India tends to lose out in this burgeoning market for food supplements and nutraceuticals if we do not align it with global practices. The weaknesses in the regulation of the nutriceuticals can be addressed by keeping it under FSSAI itself," said ***Pawan Agarwal, former CEO FSSAI and Secretary to the Government of India.***

Prioritising growth and consumer safety

The move to bring nutraceuticals under CDSCO could enhance consumer safety and regulatory clarity, but it also brings challenges related to regulatory burden and market dynamics. The effectiveness of this change will depend on how well the transition is managed and whether the regulatory framework can balance safety with industry growth and innovation.

Sandeep Gupta, Director & CEO, Nutraworks, said, "I believe Government of India and industry should come together to discuss and deliberate, understand the background of what has been designed so far for Nutraceutical Regulations and to understand what kinds of value these regulations can bring in and put Indian nutra industry on the Global Map. The Government should involve the 'Right Expert' panel, Standard Review Group (SRG), FSSAI and bodices like Expert Nutraceutical Advocacy Council (ENAC), Association of Herbal and Nutraceutical Manufacturers of India (AHNMI), Indian Drug Manufacturers' Association (IDMA), Confederation of Indian Industry (CII), Federation of Indian Chambers of Commerce & Industry (FICCI) and other such relevant groups."

Ahead of all this, prioritising voluntary self-regulation as a means of setting higher industry standards is the need of the hour. Voluntarily adhering to codes and guidelines, surpassing legal requirements to ensure the highest quality products reach consumers can enhance regulatory compliance and overall safety in the dietary supplement industry.

"Every industry player should self regulate and not over claim , and ensure effective and quality products. A $100 billion industry is the dream of the nation, government and industry needs a consensus approach. Imploring all industry stalwarts and startups alike including different bodies to align and show an united front is important at this stage," commented ***Shriram Balasubramanian, Director, Commercial and Business Development, Zuventus Healthcare.***

Moving a category from one regulatory body to another is not an overnight thing. Things will take time and execution even more. If activities start getting serious at some point, will it be a wrap for the Indian nutraceuticals industry or will it be the dawn of a new sunrise sector? What do you think? BS

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