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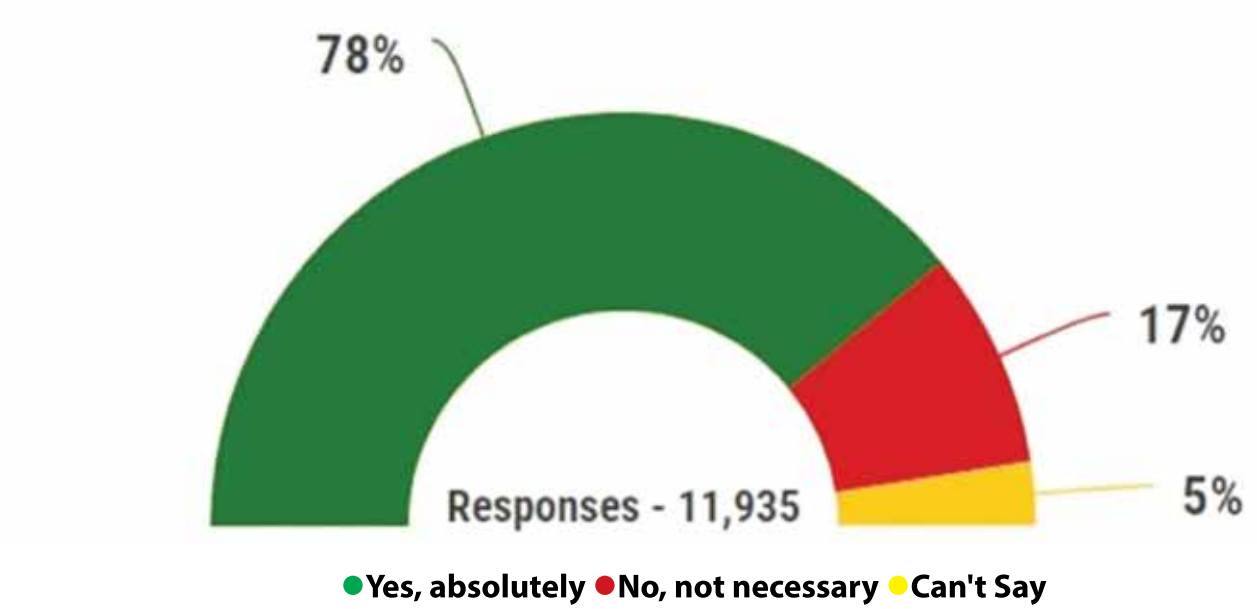
Are Nutraceuticals DRUGS?

Examining a Needless Regulatory Tussle

Should the Government cap prices of vital nutraceuticals like Vitamin A, Vitamin C and other immunity boosters?



rather than CDSCO for ingredients that have drug-like properties, such as melatonin and zinc carnosine.

In summary, today, in 2024, nutraceuticals have become a lifestyle consumer product and at this stage, some rigid steps were the need of the hour which the government has been trying to address with such actions recently.

Positives

Moving nutraceuticals from the umbrella of FSSAI to CDSCO can have its own set of positives and negatives. Let's first have a look at some favourable outcomes.

The term 'nutraceutical' was coined from 'nutrition' and 'pharmaceutical' in 1989 by DeFelice and was originally defined as, a food (or part of the food) that provides medical or health benefits, including the prevention and/or treatment of a disease. A nutraceutical may be a naturally nutrient- rich food such as spirulina, garlic, soy or a specific component of a food like omega-3 oil from salmon. They are also known as medical foods, functional foods, nutritional supplements and dietary supplements. It ranges from isolated nutrients, dietary supplements, genetically engineered foods, herbal products, and processed products such as cereals and soups. Owing to all such terms used to describe nutraceuticals, currently, the distinction between food supplements and drugs is sometimes blurred. Under CDSCO, nutraceuticals might be better classified based on their intended use and potential health impact, leading to more clarity for consumers and manufacturers.

Nutraceuticals, often marketed as dietary supplements, have significant effects on health. Under

Proposed Shifts in Regulatory Framework of Nutraceuticals

Way back in July 2012, the Report of the 44th Meeting of the Drugs Consultative Committee was released (the Report) which raised the issue that various non-pharmaceutical companies are manufacturing supplements with vitamins that fall in the quantity specified under the Schedule V of the Drugs Rules, 1945 (the Drugs Rules). The Report went on to state that the supplements that are manufactured as per the dosage defined in the Drugs Rules should be licensed under the Drugs Rules (Drug License) instead of the FSS Act making the regulation of nutraceuticals more stringent. However, no shift in regulatory framework was implemented based on the Report.

Recently, in February of 2024, the Central Government formed another committee to analyse specifically whether nutraceuticals should be regulated by FSSAI or by the CDSCO.

Source: Lexology (global legal intelligence platform)

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 industry 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.

"Whether nutraceuticals fall under CDSCO or FSSAI, whoever leads this sector must prioritise both industry growth and consumer safety. The key issue, actually, is regulatory oversight and the pressing need to address the lack of coordination among bureaucratic departments. The government should focus on regulating false advertising practices and misleading claims within the industry. Products making such claims must be withdrawn. To achieve this, we don't just need the CDSCO—we need adequately trained staff and a dedicated department for nutraceuticals. Establishing this dedicated department would also streamline communication with government bodies and other industry stakeholders, which is crucial for supporting the industry's R&D efforts and ensuring product quality. The government and industry must work closely together to overcome these challenges," commented Sanjaya Mariwala, Executive Chairman and Managing Director of OmniActive Health Technologies.

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? NS

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"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."

- Shaheen Majeed,
Global CEO & Managing Director, Sami-Sabinsa Group

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