

Navigating the regulatory wave: How CDSCO's oversight could transform India's nutraceutical landscape

03 December 2024 | News

Herbochem's vision for quality, innovation, and compliance amid stricter regulations



Herbochem's vision for quality, innovation, and compliance amid stricter regulations

The Indian nutraceutical sector stands on the brink of transformative change as it prepares for the potential regulatory oversight of the Central Drugs Standard Control Organization (CDSCO). With implications for product development, consumer trust, and global competitiveness, this move could redefine industry standards. In this exclusive interview with NUFFOODS Spectrum, Karthik Kondepudi, Partner at Herbochem shares insights on adapting to stringent regulations, driving innovation through R&D, and ensuring sustainable growth in a rapidly evolving market.

1) What impact do you foresee from the potential move of the nutraceutical sector under the regulatory oversight of the CDSCO? How might this affect product development and industry growth?

Integrating the nutraceutical sector under the regulatory umbrella of CDSCO can be a landmark phase change for the industry. Subjecting nutraceuticals to a standardized framework of regulation will usher in practices typically associated with drugs into this industry. Products from each of the constituent companies will be more clearly consistent, transparent, and on a higher plane, thus fostering consumer goodwill and a new standard of excellence for the industry as a whole.

This would imply that manufacturers such as Herbochem should adapt to something more or less in the same spirit as drug development strategies: quality assurance is very stringent, ingredients are carefully sourced, and safety tested thoroughly. By stiffening the manufacturing and quality control systems, these companies should treat nutraceuticals with a similar seriousness as pharmaceutical-grade substances should. This move may be trying at first since adherence to the new laws would delay the time of launching the product as well as increase the cost of operations. The firms would need to invest in sophisticated testing equipment, research infrastructure, and professional workers to meet the new requirements.

Long-term impact would be very positive though the demand up front would be very high. Only then would the nutraceutical industry be able to compete globally because all the CDSCO-manufactured products would be held up to international standards of quality. This might help in finding new markets for export and international partnerships where Indian nutraceuticals will come to be traded as reliable, guaranteed international products.

Adoption of such high standards would perhaps nudge the sector to try new innovation as the need is well upheld by the organizations to go for advanced formulation techniques, improvement of extraction processes, and furthering new research. Thus, quality and safety-consciousness in the industry at large will likely result in nutraceuticals that are better working and reliable products for the end-customers. In the long run, the growth of the nutraceuticals sector under CDSCO regulation would not only support sustainable development but also a stable, matured industry ready to meet future demands and expand to new markets.

2) How do you think the stricter regulatory framework could enhance consumer trust and safety standards in the Indian nutraceutical market? Could this also position Indian products more competitively on the global stage?

Stricter regulations would undoubtedly reveal to a large extent the advantages that such will have for the nutraceutical industry-increased consumer confidence and better-quality products. Increasingly health-conscious and better-informed Indian consumers are looking for products that have proved their track record in terms of safety and efficacy. Such a proper regulatory framework would give such consumers a sense of security because they would trust only products that have stood the test of time at quality checks. This transparency and accountability in product manufacturing will not only attract the new customer but also long-term loyalty and brand trust among existing consumers.

This can be the key basis the international market uses to position Indian nutraceuticals as premium products equated with global standard benchmarks - pharmaceutical grade. This will also open doors to new export markets where regulatory standards are more stringent and often mirror North America, Europe, or parts of Asia. Since nutraceuticals from India will be made to meet the international quality and safety standards regulations, this can enhance the global attractiveness of Indian nutraceuticals to consumers and potential partnering people abroad. Dependability and high standards can spur significant export growth, and India may become a hub for preferred suppliers from around the world.

These regulatory changes can also lead to better access for Indian firms to partnerships with international firms. The international nutraceutical and wellness brands are usually picky about the source of the ingredients and alliances, and Indian firms compliant with strict standards are very attractive for partnerships. This can be a reason to increase the attraction towards the influence of technology transfer, shared R&D initiatives, and co-development of innovative products.

3) Given the potential regulatory changes, do you anticipate increased R&D investments from nutraceutical companies to meet higher compliance standards? How could this shift influence innovation in the industry?

Of course, more R&D outlays would be required to keep up with changing regulatory compliance and therefore challenge corporations to be even more innovative along all fronts. She would consider this shift as an opportunity to tap into research and development not only to keep abreast of regulatory compliance but be the leading edge in the development of new and innovative product formulations. Herbochem would then lead the nutraceuticals industry since advanced scientific capabilities are married with natural ingredients and traditional knowledge.

The industry will be driven further toward innovations, such as formulation techniques, extraction processes, and more rigorous testing protocols for safety. This drives the efficacy and sophistication of nutraceuticals to new and higher levels of quality and consistency. To the consumer, this translates into having access to nutraceuticals that do not just come in safer forms but also more potent and reliable forms. This will boost consumer confidence and maintain the industry dynamic and competitiveness around the world.

Long term, this focus on high standards and innovation will help to establish a more sustainable trajectory for the nutraceuticals growth but with companies like Herbochem leading the way through examples of best practice that advance quality and safety of products.

4) What are some of the challenges smaller nutraceutical manufacturers might face with the proposed CDSCO regulations, particularly in terms of compliance costs and operational adjustments?

To small-scale nutraceutical manufacturers, potential CDSCO regulations would likely present a sizable challenge primarily due to the financial and structural adjustments that they entail to achieve full compliance. It would require huge inputs towards the adoption of quality control measures since these are to be undertaken by small-scale manufacturers so that they meet the resultant strict standards on product safety, efficacy, and consistency. This is because compliance will expose firms to costly certification processes, regular quality checks, and record documentation required by the regulations, making it rather

expensive to the small firms who are well-restrained.

Besides financial pressures, this change will also make smaller companies adapt to new operations. Issues such as upgrading the factories to improved standards, increased equipment for quality testing, and larger production steps compliant with regulatory approval are some of the issues that need to be solved. Training employees on best practice, manufacturing, quality control, and preparation of compliance documents are also bound to fill these skill gaps.

In theory, of course, such adjustments can be challenging, but at the same time, they also provide an opportunity for smaller participants to adjust and further strengthen their processes by achieving higher standards of compliance, thereby enhancing their reputation and perhaps also increasing the reliability and quality of the products in new markets opened up for new customers. The regulatory landscape may therefore generate pressure through consolidation within the sector, with the more minor players in other ways forming alliances or partnerships with major players through shared resource bases, knowledge, and distribution networks. Alliances will emerge among smaller manufacturers to further keep compliance costs down while driving quality up among nutraceuticals. There will be both more cohesion and competitiveness on the national and international fronts.

5) With rising consumer awareness and demand for natural health products, how do you see the evolving regulatory landscape affecting market accessibility and product diversity for end-users?

The evolving regulatory landscape is likely to enhance product accessibility and diversity by creating a well-regulated, transparent market. As consumer demand for natural health products grows, the standards enforced by CDSCO will ensure that only products meeting verified quality and safety standards reach consumers. This will likely lead to a broader array of safe and effective products for end-users, further fueling trust in the nutraceutical market. For Herbochem, such standards align with our commitment to quality and innovation, allowing us to better serve our consumers with verified and reliable products.

6) Considering your experience and Herbochem's focus on blending traditional practices with modern science, how do you plan to navigate these regulatory changes while maintaining product quality and innovation?

Herbochem remains uniquely positioned to navigate and profit from future regulatory changes for its commitment to quality, innovation, and high standards in science. Its success is founded on ancient herbal knowledge allied with the best of scientific research into the latest discoveries, enriching the product lines and positioning the company to meet new compliance standards. This commitment allows us to craft products that truly reflect the highest standards of safety, effectiveness, and customer satisfaction.

As we move towards an even more regulated environment, we have a forward-looking approach focused on continuous investment in R&D. With R&D as the top priority, we look forward to moving from the mere science of botanical extracts into innovative new formulations that can meet the growing demands of consumers and regulatory groups. Such commitment to R&D helps us design formulations to achieve maximum bioavailability, efficacy, and safety and thus create products that continue to meet the health needs of our customers in respect of very stringent quality standards.

Modernization of our manufacturing processes is also part of our commitment to compliance. Investing in the latest technology, advanced testing equipment, and facilities ensures our improved capabilities in production will meet the world's current standards. The improved facilities give us the ability to maintain consistency in terms of the quality product, traceability, and GMP compliance that are increasingly necessary in the nutraceutical industry.

We also regard our staff as the backbone that keeps drawing us closer to the finish. Therefore, we invest in training and upskilling at all levels. This is through targeted training programs and constant education so that our staff are adept at observing regulatory compliance, quality control, and industry best practices. It equips us with a culture that aligns us with the evolving landscape of regulatory compliance.