Government panel to review if nutraceuticals should be brought under apex drug regulator CDSCO

This regulation covers food items that are specially processed or formulated for specific nutritional or dietary purposes, official sources said.

New Delhi: The government has formed a panel to examine the possibility of bringing nutraceuticals under the ambit of the apex drug regulator CDSCO instead of the food regulator FSSAI to address regulatory challenges and promote consumer safety

Presently, the Food Safety and Standards Authority of India (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, official sources said.

Nutraceuticals are products derived from food sources that are believed to provide extra health benefits besides the basic nutritional value found in foods

The sources said that the challenges in uniform implementation and enforcement, interchangeable usage of the same nutrient/ingredient at different doses for pharma and nutraceutical use and overlap in phylactic and therapeutic usage along with disease risk reduction claims were discussed with the Central Drugs Standard Control Organisation (CDSCO) officials in a recent meeting.

"Several issues were discussed following which a high-level committee under the chairmanship of Secretary, Ministry of Health has been constituted to review the regulatory challenges in nutraceutical and drugs to ensure consumer safety," a source said.

The committee has as its members Secretary, Ministry of Ayush, Secretary, Ministry of Food Processing Industries, Secretary, Department of Pharmaceuticals, Chief Executive Officer (CEO), FSSAI, Drugs Controller General of India, Director General, Indian Council of Medical Research and Director General of Health Services (DGHS) as members.

The nutraceutical market in India is estimated to reach USD 18 billion by the end of 2025 as compared to USD 4 billion in 2020, according to industry data.

During the meeting some officials noted that many health supplements like probiotics, vitamins, minerals and botanicals also have therapeutic usage and due to unclear demarcation, many companies are shifting from CDSCO to FSSAI for approval of ingredients which are akin to drugs such as melatonin and zinc carnosine.

Some officials said several supplements are marketed with disease management/disease risk reduction claims considering that the same ingredients are permitted in both drugs and nutra regulations, the sources stated.

"Besides, there is no mandatory medical supervision for products covered under nutra regulations as a result people might consume it for longer duration and/or in higher doses which might prove harmful," the sources said.

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Officials said due to unsupervised usage of supplements, people at the same time consume supplements along with drugs which might interact with each other and may cause adverse effects on the health of the consumer.

Due to availability of health supplements over the counter there are chances of consuming multiple nutrients whose action might be antagonistic to each other like calcium from a multi-mineral supplement might affect the absorption of iron.

"The committee will identify the feasibility of regulating probiotic/prebiotic in food formats and drug formats. It will also examine if there is a need and possibility of bringing nutraceuticals and health supplements under the ambit of the CDSCO," another official source said.

The panel will also explore the feasibility of price control for categories covered under nutraceutical regulations, besides, examining the feasibility of GMP provisions and certification for nutraceuticals and similar products in alignment with schedule M of drugs.

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