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FSSAI's draft guidelines on nutraceuticals evoke mixed response from pharma & herbal sectors

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Food Safety Standards Authority of India's (FSSAI) draft guidelines on health supplements, nutraceuticals, foods for special dietary uses and special medical purposes have evoked mixed response from pharmaceutical and herbal sectors.

While one part of the industry experts sees the norms to open up ample growth opportunities for market expansion, the other part pinpoints omission of herbals and plant extracts used in a number of formulations and lack of product testing infrastructure at FSSAI.

Under Schedule V and IX, many extracts used in a number of formulations are omitted. Description of the products whether they are raw materials or extracts is not clearly defined. Many plant extracts are not included in the Schedules which indicate a lack of clarity on whether an industry should seek FSSAI consent to include such commonly used plants, according to experts.

"Presently, India does not have any kind of regulatory guidelines for the approval or monitoring of the products under this segment. Interestingly, a lot of ayurvedic products in the country are sold as nutraceuticals or dietary supplements. Nutraceuticals are natural or bioactive chemical compounds that are promoted and marketed globally, claiming to be health promoting and disease preventing products with some medicinal properties. This category comprises vitamins, minerals, herbal supplements and certain animal products. Nutraceuticals also include functional foods claimed to offer a specific health benefit based on their ingredients," said pharmaceutical consultant Dr Sanjay Agrawal.

Dr Agrawal appealed to FSSAI to come up with safety norms for nutraceuticals and dietary supplements. "Around 70 per cent dietary supplements in the nutraceuticals market, which has potential to grow to about USD 12.2 billion in the next five years, are fake and such unregistered and unapproved products should be recalled from the markets," he said.

A panel constituted by the Food Safety Authority of India to regulate the category of special food items such as nutraceuticals and dietary supplements has submitted its recommendations to the FSSAI in April 2015. The recommendations comprise guidelines for approval of dietary supplements and nutraceuticals that are manufactured and marketed across the country.

Once these recommendations get approval from FSSAI, all the manufacturers in the country falling under this category will have to get a no objection certificate and approval from the Centre prior to manufacturing and marketing the products.

Talking about the issue of labeling mandated in the draft guidelines, Dr Agrawal said "The need to provide too many details eventually results in an unreadable typeface and point size will be futile."

Another expert on condition of anonymity pointed out lack of adequate, qualified and dedicated workforce at FSSAI resulting in delay in clearing applications.

The stark reality is that applications, which are submitted to FSSAI after paying a huge fee per dosage form is a non-refundable fee, he said.

Welcoming the draft guidelines, healthcare expert Anshu Yadav said "India has taken a lead in the international market to put in place the draft guidelines for the Food Safety and Standard Regulations for food or health supplements, nutraceuticals, foods for special dietary uses, foods for special medical purpose, functional foods, and novel foods. This is expected to give a big boost to the Indian traditional foods based on medicinal plants and herbs."

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