

Nutraceutical in India: How big is the market? Are they really beneficial?

Lack of medical aid, a general scepticism about allopathic medicines and food fads make nutraceuticals extremely popular. No wonder the market is booming, with new products launched everyday. But do we really need them?

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It's a controversy that refuses to die down. In July, the Food and Drugs Administration in Maharashtra ordered an inquiry into the sale of the Patanjali product, Divya Putrajeevak Beej, after complaints were raised in the state assembly that the product "promises the birth of a male child". It's not the first time that the product, which categorises itself as a food supplement, has been at the centre of such a controversy. In 2015, the Madhya Pradesh government, too, had imposed a ban on it till the name was changed. The same year, the Uttarakhand government also formed a committee to examine the herbal product produced by Divya Pharmacy, which is owned by yoga guru Baba Ramdev's Patanjali.

Divya Putrajeevak Beej, however, continues to be available in every market as do controversies surrounding it. "It's a political gimmick. We are used to being at the centre of controversies now," says Acharya Balkrishna, CEO, Patanjali. "We don't claim Putrajeevak Beej to be a medicine and neither say that it will help in the conception of a male child. This is a supplement

for women for infertility issues. How can it claim to be for sex selection when male chromosomes determine the sex of the foetus and this is for consumption by women?" he questions, adding, "We have retained the compound's original name, which is 'Putrajeeva'... It's a reputed herb in Ayurveda. Will you ask someone named Suryaprakash to be Sun? It's unwarranted."

While he may be right, there's no denying that most people fall for the name, only to be disappointed. This is a classic example of how nutraceuticals can knowingly or unknowingly mislead the public.

No panacea this

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The nomenclature and regulatory classification of nutraceuticals may vary from country to country, although, generally, these products are treated as a class of foods. Nutraceuticals can be classified as dietary supplements (including vitamins and minerals), functional foods and beverages (such as energy and sports drinks, probiotics, products fortified with omega-3 fatty acids and herbal formulations). India, in fact, is one of the largest suppliers of herbal extracts and raw material for the dietary supplement market worldwide. According to a 2018 Assocham Knowledge report, the Indian nutraceuticals market is expected to grow from \$4 billion in 2017 to \$18 billion in 2025.

"People take allopathic medicines till they get relief, but nutraceuticals are used to prevent sickness and, therefore, need to be taken on a regular basis. So it will not be surprising if their usage exceeds that of pharmaceuticals in the future," says Ajit Singh, president, Health Foods and Dietary Supplements Association (a national non-profit association, which represents the interests of manufacturers of health foods, dietary supplements, etc), and chairman, ACG Associated Capsules, a pharmaceuticals company.

Adds Anshu Budhraja, CEO, Amway India, an FMCG company: "In the absence of requisite nutrition through food—due to irregular eating habits, pesticides in food, adulteration, etc—supplementation of the diet with nutraceuticals is important." As per market research firm Euromonitor, the vitamins dietary supplements (VDS) market size in 2017 was estimated to be at `9,400 crore, while the multivitamin market size was worth `780 crore. It's not surprising then that the country is one of the top 10 markets by sales for Amway.

But not everybody needs nutraceuticals and not every such product is beneficial.

Even though there are several herbal supplements that aid good health, in a recent study, published in British Journal of Clinical Pharmacology, it was noted that it's very important to evaluate the safety of nutraceuticals and the mechanism of their action on the body before prescribing them. "People consume health supplements or drinks thinking these are health promoters, but don't know that these can be just tall claims made by the makers," says Arun Gupta, convenor, Nutrition Advocacy in Public Interest, a Delhi-based national thinktank on

nutrition. In a small survey conducted in June by the organisation (among a sample size of 51 people from Delhi), it was found that 41.7% people in the age group of 15-25 years consumed health drinks daily. Around 44.44% people said health drinks are essential because they provide necessary nutrients—22.22% believed they provide immunity. "This is based on misleading advertisements, which claim your child, or you, will become taller by consuming such health drinks. On top of it, the Advertising Standards Council of India, set up as a voluntary regulation exercise, mostly defends the industry," Gupta adds.

Safety, hence, remains as much of a concern as the indiscriminate use of these products, which are sold over the counter. Take, for instance, Delhi-based Sunita Kaushik. Having suffered from osteoporosis for around two decades, the 65-year-old has, over the years, tried almost every medicine available in the market. Besides undergoing extensive allopathic, homeopathic and Ayurvedic treatments, Kaushik is also a consumer of 'non-traditional' medicines—her medicine cabinet is lined with nutritional supplements, herbal pills and homemade concoctions. "At least there won't be any side-effects. If not helpful, they will not harm either," she believes. For the past two years, though, she has been suffering from chronic digestive problems, something her doctor blames on an over-dosage of supplements. "Though there is no conclusive proof yet, my doctor believes that the long self-medication of supplements has harmed me. But how can anything herbal be harmful?" she asks.

A belief many in the medical fraternity frown upon. "The indiscriminate usage of nutraceuticals is a worldwide phenomenon, but in India, besides nutraceuticals of established companies, locally-made nutritional supplements of dubious quality are also consumed. We notice this daily in our clinic," says Anoop Misra, chairman, Fortis C-DOC (Centre of Excellence For Diabetes, Metabolic Diseases and Endocrinology) Hospital, Delhi. "Most people think these are effective and without any side-effects, and, hence, superior to allopathic drugs," he adds.

He is right. In a paper published in The Medical Journal of Australia in 2017, researchers from the University of Adelaide found that herbal medicines can cause kidney failure and liver damage in some consumers because these contain toxic chemicals or heavy metals, or react harmfully with other drugs. Earlier this year, British Journal of Clinical Pharmacology published a study that highlighted the danger of mixing herbal supplements, including common ones like ginkgo biloba, ginseng and green tea, with prescription drugs. "By self-prescribing, patients think they have helped themselves without seeing doctors, thus saving time and money. The mindset of these patients is influenced by elders who say any 'natural' product is better than that developed by chemical means," points out Misra.

Fake vs real

In a 2015 study conducted by Assocham and market research service provider RNCOS, it was noted that about 60-70% of dietary supplements being sold across India are fake, counterfeit, unregistered and unapproved. It's a concern that hasn't gone unnoticed by the regulator as well as the industry.

While companies maintain that product quality is of utmost importance, some like Ayurvedic company Jiva Ayurveda go a step ahead and carry out extensive tests in multiple sample sizes across different demographics before sending their products for necessary regulatory approvals. "Before launch, our products undergo numerous tests with respect to stability and quality parameters," says Partap Chauhan, director, Jiva Ayurveda. His biggest

concern is related to fakes that flood the market. "A variety of products have flooded the market, which may carry the 'Ayurvedic' moniker, but these are not necessarily Ayurvedic... awareness among consumers about this has to increase," he adds.

Another big concern is herbal security, especially for products that use low-quality herbs or wrong substitutions for classical herbs. "Ayurveda talks of 'Pratinidhi Dravya', or herb replacements, which can be used for preparing classical formulations, where a herb may have become extinct or is very rare. That said, these traditional concepts are not commonly known or practised by most product manufacturers," points out Chauhan.

Marketing is also a challenge that manufacturers are facing. "To give an example, we may get an Ayurveda licence for our honey, but a competitor may sell honey with the label 'FSSAI (Food Safety and Standards Authority of India)-approved'. It creates confusion among people who think that we aren't selling a quality product," says Balkrishna of Patanjali.

Budhraja of Amway adds: "We follow stringent global standards, which are more than just about meeting the mandatory regulatory requirements of the government." The company's processes also involve documentation of all aspects of the ingredients, including soil and water management, seeds, nutrients, and harvesting and post-harvesting practices. "Our agricultural experts and over 1,000 scientists from across the globe work together to optimise the nutrients gathered from the most powerful plants nature has to offer," he says.

Not surprisingly, the FSSAI has called for self-regulation of the industry to increase the trust factor among consumers. Industry body Health Foods and Dietary Supplements Association (HADSA) says the regulatory scenario in the nutraceutical sector is ever evolving, with several new notifications/orders (for instance, products should carry detailed information about their composition, claims, etc) coming in. "The industry is collaborating with the FSSAI for a smooth transition and compliance with these regulations. But these changes are so rapid that, at times, it becomes difficult to keep up with the pace of implementation required," rues Singh of HADSA.

In 2016, the FSSAI had amended regulations to fix loopholes in the definition of proprietary food, which includes nutraceutical and health supplements. Some of these regulations have been inspired by WHO guidelines. The new rules, which were implemented from January this year, maintain that products sold under this category should not contain hormones, steroids or psychotropic ingredients, but may use approved colours and additives. The quantity of nutrients added should not exceed the recommended daily allowance as specified by the Indian Council of Medical Research and accepted by the FSSAI.

The regulator also roped in the Confederation of Indian Industry (CII) to establish a Resource Centre for Health Supplements and Nutraceuticals (ReCHaN)—in partnership with the International Alliance of Dietary/Food Supplement Associations (IADSA)—

to further ensure there are no glitches. ReCHaN will contribute to capacity-building initiatives, develop guidance documents, manuals and the Food Safety Management System guidelines that will ensure safe practices. It will also look after the training of professionals in the sector and create consumer awareness through various initiatives.

Manufacturers, on their part, are happy for an international standard to be set for the usage of these products. "We acknowledge an opportunity to align with established international standards like the Codex/WHO guidelines... for instance, the adoption of upper tolerable limits for vitamins/minerals in the health supplement category, so that consumers can benefit from supplementation along with a regular diet," says Budhraja of Amway. The Codex Alimentarius is a collection of internationally-recognised standards, codes of practice, guidelines and other recommendations relating to foods, food production and food safety.