Guidelines to regulate the ‘nutraceutical’ industry have led to mixed reactions

A doctor at a public hospital in Hyderabad became concerned when a middle-aged man being treated for jaundice reported puffiness of the face during treatment.

The doctor noticed that the patient had been taking a branded herbal preparation for months, given to him under the guise of it being a food supplement for general well-being. Suspicious, the hospital’s clinician sent a sample of the supplement for testing at the National Institute for Nutrition (NIN), Hyderabad. Scientists at the premier facility’s drug toxicology labs were not surprised to find lead in the formulation. The patient was then treated for heavy metal poisoning.
Varied claims
Reports of patients experiencing adverse events during the course of medical treatment, accompanied by samples for testing, often land at the NIN’s doorstep. Obesity pills, diet regimens and shakes sold with exaggerated benefits, as well as preparations — often adulterated with corticosteroids — that promise anything ranging from enabling pain relief to easing chronic conditions such as arthritis — are frequent suspects. Supplements sold to improve sexual potency are another group of products frequently assessed by scientists when an adverse reaction is reported.

New directions
Until recently, a system to verify and notify adverse reactions from products other than those recognised as ‘drugs’, under the Drugs and Cosmetics Act, did not exist. With the framing last year, of guidelines by the Food Safety and Standards Authority of India (FSSAI) to regulate products recognised as ‘nutraceuticals’ — or supplements and foods that aren’t drugs but purported to contain ingredients essential to well-being, the need to report adverse reactions was felt and the Hyderabad-based NIN was selected to run the centre.

“It was set up earlier this month. We plan to start functioning by carrying out [a] sensitisation campaign for doctors practising all systems of medicine, to report adverse events in a prescribed format,” says B. Dinesh Kumar, who heads the Drug Toxicology Division at NIN and is a coordinator for the recently-inaugurated facility. Called the ‘National Coordination Centre – Pharmacovigilance Programme of India, the body’s mandate also involves monitoring advertised and marketed claims of products classified as ‘foods’, adds Dr. Kumar.

Reporting mechanism
On receiving reports of adverse reactions, the NIN centre will discuss with reporting clinicians the specific case to make an assessment. The adverse event is then tagged to the Indian Pharmacopoeia Commission (IPC) for notification to the product manufacturer.
the centre has been envisaged as a part of India’s larger efforts to regulate ‘nutraceuticals,’ a category that didn’t exist until recently. In a 2017 report, the Associated Chambers of Commerce and Industry of India estimated the global nutraceutical industry to be growing by about $15 billion annually. In India alone, it says the industry is worth more than $2 billion.

The new rules formulated by FSSAI are set to become effective in January next year. Though exhaustive, there is scepticism — mostly legal — in the food and drug industry over whether the new set of rules can effectively regulate nutraceuticals.

The Indian Council of Medical Research has recommended that dietary supplements such as multivitamins can remain out of the ambit of the Drugs and Cosmetics Act if they are within the recommended dietary allowance in a product. Recently, the government’s reported attempts to amend the Drugs and Cosmetics Act to make a distinction between drugs and dietary supplements has seen the industry aver that vitamins should have the benefit of being defined as both a drug and food.

**Reactions**

Scientists at the IPC caution that the NIN’s role should not be interpreted as an assault on an industry. On the contrary, they suggest that adverse reactions, as in the case of drugs, can often result unexpectedly and be specific to a small group of individuals, without necessarily being a result of nutraceutical intake.

“A person’s genetic make-up or the conditions under which a substance is taken can lead an individual to experience an adverse reaction while another may not. Additionally if a person takes two substances together despite being explicitly told not to, an adverse reaction can occur,” a senior scientist at IPC said, asking not to be named.