Joint expert committee deliberates on long pending issue to classify products as ‘nutraceutical’ or ‘drug’

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To help determine efficacy of a product either as ‘nutraceutical’ or as ‘drug’, experts from Central Drugs Standard Control Organisation (CDSCO) and the Food Safety and Standards Authority of India (FSSAI) are currently deliberating on the long pending issue more so as pharma firms have also been marketing drugs as food supplements to escape the price control.

A senior CDSCO official however says that the regulatory authorities wants a science based evaluation on the matter which is taking time.

The expert committee is expected to clear the confusion whether the labelling on products is a marketing gimmick or is proper as per the requirements for its intended use to be defined as a drug or food.

Drugs Controller General of India has also sought clarity on the matter with reference to examining the validity of claims made on the labels of some vitamin supplements. There were some borderline issues with claims that these multi-vitamin products are not properly labelled. In order to expedite the case, some new experts have also been appointed in the committee to arrive at science based evaluation.

The blurred line between drug and food supplements surfaced in 2009 when the drug price regulator National Pharmaceutical Pricing Authority (NPPA) said that pharma firms are marketing drugs as food supplements to escape the price control.
The joint expert committee of CDSCO and FSSAI formed is meant to ascertain whether the products and ingredients marketed are labelled on the basis of their intended effects on the human body and further to be classified as drugs, vitamins or food.

Submissions made by the industry, however, say that vitamins need to be allowed both in health and nutritional supplements if they are within the recommended dietary allowance (RDA) stipulated by Indian Council of Medical Research (ICMR). It further elaborates that the issue is more of recognizing RDA as the basis and not the ceiling in daily intakes of nutrients.

If vitamins are removed from health supplements, it will have far reaching effects on the health of the consumers. The submission recommends that vitamins should be allowed both in food as well as drug, depending on the dosages employed.