Policy & Regulations

Industry seeks clarity on dual control of nutraceuticals and drugs by DCGI and FSSAI

Shardul Nautiyal, Mumbai
Monday, February 1, 2021, 08:00 Hrs [IST]

Amidst growing confusion about effectively regulating dietary supplements, multi-vitamins and drugs, industry has once again sought Centre's intervention and clarity on the dual control of nutraceuticals and drugs by Drugs Controller General of India (DCGI) and Food Safety and Standards Authority of India (FSSAI).

This is following the Drugs Technical Advisory Board (DTAB)'s recommendations to amend Drugs and Cosmetics (D&C) Rules, 1945 for effective regulatory regime in the country.

The DTAB having recently examined the Indian Council of Medical Research (ICMR)'s recommendation has suggested that vitamins with doses of up to one recommended dietary allowance (RDA) should be regulated under Food Safety and Standards (FSS) Act.

Other vitamin preparations having prophylactic and therapeutic claims should be regulated under the D&C Act, 1940 and Rules, 1945 including Schedule V of the D&C Rules. Schedule V stipulates standards for patent or proprietary medicines, containing vitamins for prophylactic, therapeutic or paediatric use.

DTAB proposed that necessary review of doses specified under Schedule V may be undertaken subsequently. Board was apprised that a proposal has been received from FSSAI proposing that D&C Rules, 1945 may be amended to delete the preparations containing the prophylactic doses under Schedule V considering the provisions of doses under Section 22 of FSS Act, 2006 especially products formulated in tablets, capsules, liquids, etc. meant for oral administration.

It was deliberated at the recent DTAB meet that as per Section 22 of FSS Act, 2006, it is evident that the products in drug type matrix (i.e. tablets, capsules etc.) covered under FSS Act which are containing vitamins below RDA also fall under prophylactic and some of the therapeutic doses prescribed in Schedule V of the D&C Rules, 1945.

DCC in its 52nd Drugs Consultative Committee (DCC) meeting held on September 18, 2017 had also deliberated the proposal and recommended that a provision may be incorporated in D&C Rules, 1945 especially in Schedule V and Schedule K to exclude multivitamin preparations containing vitamins in a strength which is lower than RDA for Indians as recommended by ICMR and FSSAI, from the provisions of D&C Rules, 1945.

Industry expert Dr Sanjay Agrawal has argued that as per the D&C Act, drug is defined as "All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes. On the other hand, nutraceuticals are used for the prevention and treatment of diseases which are regulated by FSSAI. The question here arises why there are two regulatory authorities for prevention of disease."

Industry had earlier made submissions that vitamins need to be allowed both in health and nutritional supplements if they are within the recommended dietary RDA stipulated by ICMR.

Echoing similar views pharma consultant Anshu Yadav, "Multivitamins were very well managed 10 years ago when it was controlled by drug regulators. At present there is lot of confusion. Nutraceutical industry is highly mismanaged at this point of time and requires clear cut guidelines and management."

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 evade price control.

Printer-Friendly Version | Email This Article

<< BACK

Submit Reset