REGULATION OF VITAMINS – GOVT PLANNING TO AMEND SCHEDULE V OF D&C RULES 1945

Govt Planning to amend Schedule V of D&C Rules 1945 for regulation of vitamins.This is following the Drugs Technical Advisory Board (DTAB) having recently examined the Indian Council of Medical Research (ICMR) recommendations.

The Union Health Ministry has proposed to amend provisions of Schedule V of the Drugs and Cosmetics Rules 1945 to ensure the vitamins and minerals with doses up to one recommended dietary allowance (RDA) value to be regulated under the Food Safety and Standards Authority of India (FSSAI) regulations. Other vitamin preparations having prophylactic and therapeutic claims should be regulated under the Drugs & Cosmetics Act 1940 and Rules 1945 including Schedule V of the D&C Rules. **This is following the Drugs Technical Advisory Board (DTAB) having recently examined the Indian Council of Medical Research (ICMR) recommendations.**

“Drugs Technical Advisory Board proposed that necessary review of doses specified under Schedule V may be undertaken subsequently. The Board was apprised that a proposal has been

received from Food Safety and Standards Authority proposing that Drugs and Cosmetics Rules 1945 may be amended to delete the preparations containing the prophylactic doses under Schedule V considering the provision of doses under Section 22 of Food Safety and Standards Act 2006 especially products formulated in tablets, capsules, liquids, etc. meant for oral administration," stated a recent report in the public domain. The Section 22 of Food Safety and Standards Act 2006, noted vitamin drugs as tablets, capsules covered under FSS Act below recommended dietary allowance also come under prophylactic and some of the therapeutic doses prescribed in Schedule V of the Drugs and Cosmetics Rules, 1945.

This essentially means, pharmaceutical companies manufacturing nutraceuticals in various forms like capsules and tablets etc with no therapeutic dose claim will now have to approach a new regulator, the FSSAI, since the Drugs Controller General of India will no longer license these products, according to industry experts. **The autonomous body under the Ministry of Health & Family Welfare of India (FSSAI) has also proposed amending the Schedule K (10) to revise the scope of substances used both as food and drugs so that same are exempted from the provisions of Chapter IV of the D&C Act and Rules.**

According to industry experts the government's move would require coordination and accurate data submission to the new regulatory authority. It is a good step in the right direction. It will bring in the required clarity to both the pharmaceutical and food industries and also to consumers. The industry experts view that there was a need for clarity for vitamin and mineral preparations and they had suggested that a very old notification like Schedule V of the Drugs and Cosmetics Ruleswas required to be amended.

To comment whether the government's move is good or bad for industry is premature unless and until we have clarity on the details of the draft regulations.Pharmaceutical companies, which presently had limited interaction with the food regulator, will have to adapt to this new standards. Only time will tell what the advantages and disadvantages are. For successful implementation,

close coordination between the industry, Drugs Controller General of India and the apex food regulator will be required.

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

The Drugs Technical Advisory Board further deliberated the matter in its 78th meeting held on February 12, 2018; the DTAB discussed and opined that the matter may be referred to directorgeneral of Indian Council of Medical Research for their recommendations. The said matter was then referred to director general and a reply in the form of letter dated June 10, 2019 addressed to the DCGI was received along with comments from director general of ICMR. Further, Indian Council of Medical Research had made another communication vide letter dated October 14, 2019 to the FSSAI on the same matter.

In July, 2018 the FSSAI banned use of 14 ingredients under Nutraceutical Regulations and directed the food business operators involved in manufacturing of health supplements and nutraceuticals, foods for special dietary use and for special medical purposes , functional and novel foods, governed under the Nutraceutical Regulation, to stop using these ingredients lacking scientific data for safe usage.

The directive by the country's apex food regulator asked the food business operators to discontinue the use of raspberry ketone, silica, angelica sinensis, paullinia cupana, saw palmetto, notoginsing, chlorella growth factor, pine bark extracted to pinus radiate, pine bark extracted from pinus pinaster, vitamin D3-veg,

chaga extract, oxalobacter formigenes, phytavail iron and tea tree oil.

The directive also added that food business operators were directed to discontinue the use of ingredients such as para amino benzoic acid, vanadium, prenolit and selenium dioxide, used for the product category under the Nutraceutical Regulations, with immediate effect. Food business operators were also directed to withdraw any product containing these ingredients immediately.

The order also baned the use of D-ribose in health supplements and nutraceuticals, while for foods for special medical purpose and dietary use, approval from the authority was needed. Besides, the use of ipriflavone and polypodium leucotomos was also prohibited as they exhibited the properties of drugs.

In recent time the apex food regulator defined recommended dietary allowance value of methylcobalamin. The nutraceuticals industry opined it was dual standards of FSSAI on recommended dietary allowance value as methylcobalamin is very important nutrient for overall health immune system of human body based on scientific evidences.

In a representation made to Union Ministry of Chemicals and Fertilizers, the nutraceuticals industry has also recommended DCGI to be given the sole authority for implementation of nutraceutical policies and regulations citing FSSAI and ICMR as toothless bodies giving reference that ten years back nutraceuticals sector was under DCGI only and it was properly regulated.

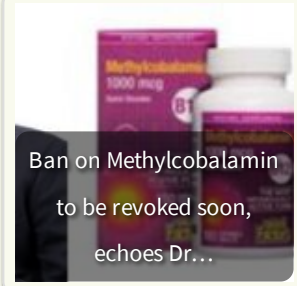
Nutraceutical and drug industry have alleged that FSSAI has been turning a blind eye to the contentious issues raised with reference to recommended dietary allowance values of vitamin C and other micro-nutrients which are vital for boosting immunity, mental health and other co-morbid chronic ailments.

The government has also recommended 1**000 mg of vitamin C as prophylactic use against COVID-19 cases whereas its recommended**

dietary allowance value is only 40 mg due to poor regulatory and policy interventions from apex authorities.

Dr Sanjay Agrawal
Leading Pharmaceutical Consultant
Editor-in Chief of IJMToday

Related Articles:



MAGAZINES

SUBSCRIBE MAGAZINE

CLICK HERE