The Learning and Development Journal

QualPharma

Volume 4, Issue 1 January 2021, 40/-

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Planning to amend Schedule V of D&C Rules1945 for regulation of vitamins –Centre

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. 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.. On the other hand many nutraceuticals which are approved by FSSAI with doses above the recommended dietary allowance will get themselves approved from DCGI.

"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.

It will bring in the required clarity to both the pharmaceutical and food industries and also to consumers. There is a need for clarity for vitamin and mineral preparations and the very old notification like Schedule V of the Drugs and Cosmetics Ruleswas required to be amended. It is a good step in the right direction. 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

Dr Sanjay Agrawal

Dr Sanjay Agrawal founded PHARMA CONSULTANTS and INVENTOR in 2005 to assist pharmaceutical companies around the globe. He has actively worked in pharmaceutical and related industries for more than 28 years. He is Editor-in-Chief of renowned IJM Today and honorable member of the editorial board of QualPharma and The Antiseptic. Dr Sanjay Agrawal is also the illustrious member of the National Geographic Society and ex- member of scientific committee of IDMA. His prestigious articles are published in various magazines and websites for example—The Antiseptic, NuFFooDS Spectrum, Pharma biz

Dr. Agrawal had received various awards for his valuable support and contributions in Healthcare and pharmaceutical sector .Dr. Agrawal obtained his postgraduation in Biochemistry from prestigious institution, completed MBBS and MBA from IMT. He has worked with many International and national Pharmaceuticals company. Dr. Sanjay Agrawal is the patent holder of many research formulations which are successfully commercialized

Currently besides his core jobs, Dr Agrawal devotes his time for the benefit of pharma fraternity. He has raised his voice against the ban imposed on methylcobalamin manufacturing. He has been asking to the regulators from more than a yeat that

- Why Methylcobalamin is not added in the gazette yet when promised by the former CEO Mr Pawan Agrawal Ji?
- Why cyanocobalamin is promoted even though there is a cyanide group attached to it?
- Why 1 mcg RDA is imposed on nutraceutical manufacturer
- Technical aspect of damage caused when 500 mcg is taken as prophylactic use.
- Why should we have faith in FSSAI when every time we have to go to ICMR for clarification.

be incorporated in Drugs & Cosmetics Rules, 1945 especially in Schedule V 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 and the higher to be recommended by DCGI, from the provisions of Drugs & Cosmetics Rules, 1945. The Drugs Technical Advisory Board further deliberated the matter in its78thmeeting held on February 12, 2018; the DTAB discussed and opined that the matter may be referred to Director General 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 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 banned 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 as 1mcg. 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 and 1 mcg of dose is of no use to manufacture.

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 1000 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.

~By Dr Sanjay Agrawal

Methylcobalamin is important for maintaining the normal differentiation, proliferation, and metabolic status of all cells. It act as a coenzyme for two key enzymatic reaction: the conversion of homocysteine to methionine and the conversion of methylmalonyl coenzyme A (coA) to succinyl coA. Deficiency of MeCbl (Vit B12) leads to intracellular accumulation and eventual secretion into the plasma of the metabolites of these two reactions, homocysteine and methylmalonic acid. Elevated plasma levels of these two metabolites are a strong indication of an intracellular deficiency of MeCbl(Vit B12). Intracellular MeCbl deficiency can arise due to multiple causes that include both acquired and inherited disorders. Strict vegetarians and vegans develop Vit B12 deficiency due to a lack of intake, and patients with tapeworm infestation or bacterial overgrowth develop the deficiency due to competition for dietary Cbl. These patients can be treated successfully with adequate intake of MeCbl when the underlying cause is eliminated with antibiotics. However, patients with gastric surgery (partial or complete) or surgery of the ileum (chronic inflammation) will develop MeCbl deficiency as they will not be able to absorb MeCbl due to decreased levels or total loss of intrinsic factor or the ileal receptor, respectively. In these patients, along with children who have inherited disorders involving intrinsic factor, its ileal receptor, or the plasma transporter transcobalamin II or a number of defects that involve its intracellular utilization, deficiency of Cbl is permanent and must be treated on a regular basis with intramuscular injections of pharmacological doses of Cbl. Another factor that interferes with intestinal Cbl absorption in humans is excessive ethanol consumption.