The Learning and Development Journal

QualPharma

Volume 4, Issue 2 February 2021, 40/-

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Health ministry recommendations to amend D&C Rules for effective regulatory regime flares up raging debate towards transparent regulations

Drugs Technical Advisory Board (DTAB)'s recommendations to amend Drugs and Cosmetics (D&C) Rules, 1945 for effective regulatory regime in the country has again flared up a raging debate towards effective and transparent regulations. Having said that, the union health ministry is clearly being misled to approve an irrational move to bring about certain amendments in the provisions of the D&C Rules towards regulating nutraceuticals on the premise of recommended dietary allowance (RDA) value without even informing and consulting the pharmaceutical and nutraceutical industry. The blurred line between drug and food supplements has been a subject of intense debate since 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.

Therefore, 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) simultaneously. A silent and yet intense anger is also raging in the industry in the absence of a clear regulatory regime today. Industry insiders and experts have upped their ante against the intense lobbying related to delegating power to regulate nutraceuticals to a toothless body like Food Safety and Standards Authority of India (FSSAI). This probably according to industry insiders is happening as a part of lobbying at the Centre towards appeasing a section of people in the industry and ministry. The state licensing authorities (SLAs) are also trying to enforce the ban invoked by the Centre in June 2019.

There has been a growing confusion about effectively regulating dietary supplements, multi-vitamins and drugs. Specifically, Drugs and nutraceutical manufacturers have been defying the one-year old arbitrary and draconian ban on methylcobalamin due to dubious nature of Indian Council of Medical Research (ICMR) and FSSAI recommended dietary allowance (RDA) values and tolerable upper limit (TUL) even in major micronutrients like vitamin C. The Central Drugs Standard Control Organisation (CDSCO) has also been following with FSSAI to take action against Gujarat based manufacturers for production and sale of methylcobalamin meant for therapeutic intervention in contravention to norms.

The DTAB having recently examined the Indian Council of Medical Research (ICMR)'s recommendation and suggested that vitamins with

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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.

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.

It has been 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."

Nutraceutical and drug industry have alleged that FSSAI and CDSCO have been turning a blind eye to the contentious issues raised with reference to RDA values of vitamin C and other micro-nutrients like methylcobalamin which are vital for boosting immunity, mental health and other comorbid chronic ailments in the crucial juncture of COVID-19 pandemic.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. 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. In a recent representation made to union ministry of chemicals and fertilizers, industry has also once again recommended Drugs Controller General of India (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 was under DCGI only and was properly regulated. Gujarat based manufacturers have alleged that the dual standards of FSSAI is very much evident with the presence of already FSSAI approved brands available with 1500 microgram (mcg) quantity/per serving. In a letter to the FSSAI, CDSCO had brought to the notice that various brands of products containing methylcobalamin are manufactured and sold having therapeutic intervention under the FSSAI license.

The central government has also recommended 1000 mcg of vitamin C as prophylactic use against COVID-19 whereas its RDA is 40 mcg due to poor regulatory and policy interventions from apex and responsible authorities like ICMR, FSSAI and DCGI.

Methylcobalamin is an essential nutrient and is required to treat vitamin B12 deficiency, in people with pernicious anaemia, diabetes and other conditions as well. It is important for the brain, nerves and for the production of red blood cells (RBCs). FSSAI and CDSCO have been drawing flak from the industry as there is no clarity on TUL and RDA values of many micronutrients including vitamin C and methylcobalamin.Unmindful of the concerns regarding RDA for mental health conditions and neurological disorders, industry has dubbed FSSAI as white elephant and urged the Centre that there is no need of FSSAI as the authority is not competent enough to talk on technical and scientific aspects and only relies on the dictates of ICMR. It is a sheer wastage of public money which has been pooled in to maintain an authority which is doing more harm than good.

Industry players have also voiced concern that methylcobalamin RDA value has been approved by Central Drugs Standard Control Organisation (CDSCO) uptill 2000 mcg but FSSAI is approving only 1 mcg which is of no use. Drugs Controller General of India (DCGI) recommended 2,000 mcg of methylcobalamin even in injectable form and brands are available as patients take methylcobalamin based on the medical condition.

Until and unless, FSSAI does not inform the industry that methylcobalamin is approved, there is no value of prescribing RDA value for the same. Surprisingly the mails which we have received from FSSAI on methylcobalamin and cyanocobalamin, both have the same RDA value for manufacturing. Please be advised we are talking about per serving usage value which the manufacturer can refer to and not the RDA value for a healthy person.

On January 7, 2020, FSSAI issued a notification regarding RDA of vitamin B12 which is specified as 1 mcg without mentioning type of vitamin B12 like methylcobalamin, adenosylcobalamin, hydroxycobalamin and cyanocobalamin. Former CEO of FSSAI Pawan Agrawal had promised in December 2019 that methycobalamin has been approved by the scientific committee and will take due course of its time to be included in the gazette. Nevertheless, the industry has waited for almost 10 months without any progress for inclusion of the methylcobalamin in the gazette.

The issue has been festering due to missing exact information on tolerable upper limit (TUL) of vitamin B12 [methylcobalamin to be specific] from the public domain. No adverse effect has been associated with excess methylcobalamin intake from food or supplements in healthy individuals. Methylcobalamin has a history of safe long term use as a therapeutic agent given in high dosage or via intramuscular injection for the treatment of disorders associated with impaired vitamin B12 absorption. Additionally, we had received a letter in December 2019 from FSSAI about methylcobalamin approved RDA value for neurological disorders by the technical committee but industry is yet to see the notification on the same.

Questions have been raised about the ambiguous RDA value and upper tolerance limit of Methylcobalamin which till today FSSAI is unclear about and takes refuge of ICMR due to lack of scientific evidence despite scientific panel approved new RDA values.

Many brands are available with Methylcobalamin under nutraceutical with 1500 mcg and available even online 100 brands are there in Gujarat only even Gujarat FDA Commissioner Dr Khosia is saying to reporters Methylcobalamin is ban even today.

Industry has contested that there is no need of FSSAI for nutraceutical when for technical aspects they take shelter of ICMR and for implementation of policies they approach DCGI which is a criminal waste of our money to maintain a toothless body like FSSAI when the fact is that ten years back nutraceutical was under DCGI only.

Methylcobalamin is an essential nutrient and is required to treat vitamin B12 deficiency, in people with pernicious anaemia, diabetes and other conditions as well. It is important for the brain, nerves and for the production of red blood cells (RBCs).

~ Dr. Sanjay Agrawal

Global brand-

- GNC Vitamin B12 capsules(USA) - **1000 mcg,**
- Methylcobalamin B12 (Canada)- **1000 mcg**,
- Life Extension (USA), Methylcobalamin, **1000 mcg**,
- Natural Factors(Methylcobalamin)- **5000 mcg**
- **and many more**

Indian Brand [All below are approved by FSSAI and are available to public]

- Health Aid Vitamin B12 (Methylcobalamin) **1500 mcg**
- Nature Made Vitamin B-12-**1000 mcg**
- B-12 Dots by Twinlab-**500 mcg**
- Jarrow Formulas, Methyl B-12-**1000 mcg**
- Nature's Bounty Vitamin B-12 **1000 mcg**
- Source Naturals Methylcobalamin Vitamin B-12-**5000 mcg**
- Solgar Sublingual Methylcobalamin Supplement-**1000 mcg**
- Cobaforte CD3 Plus Tablet-**1500 mcg**
- Nocob Methylcobalamin **1500mcg**
- Unived Methylcobalamin **1500mcg**
- Bhumija Lifesciences Vitamin B12 **1500 mcg**
- Bluebonnet Liquid Methylcobalamin Vitamin B12 **1000 mcg**
- EZ Melts B12 As Methylcobalamin, **2,500 Mcg**
- Garden of Life Vitamin Code Vitamin B12-**1000 mcg**