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Industry seeks Centre's intervention on issue of enforcement of arbitrary pan-India ban on methylcobalamin



By: **Shardul Nautiyal** | Updated: August 04, 2021 6:15 PM

Once notified, approved RDA value can be defined in a scientific way based on evidence. The issue, however, has been festering due to missing exact information on tolerable upper limit (TUL) of vitamin B12 or methylcobalamin for neurological disorders and immunity booster from the public domain.



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

The nutraceutical and pharmaceutical industry in the country have collectively sought the intervention of the Union Ministry of Chemicals and Fertilizers on the issue of implementation of the arbitrary pan-India ban on methylcobalamin despite it not being notified as yet.

An industry delegation met Union minister of chemicals and fertilizers Mansukh Mandaviya to urgently notify methylcobalamin for neurological disorders as regulatory action cannot be taken against those who are manufacturing methylcobalamin based formulations without scientifically defined efficacious recommended dietary allowance (RDA) value due to delay in notification.

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

Central Drugs Standard Control Organisation (CDSCO) has also been following the Food Safety and Standards Authority of India (FSSAI) to take action against methylcobalamin manufacturers for production and sale of methylcobalamin meant for therapeutic intervention in contravention to norms.

According to Ahmedabad based pharmaceutical consultant Dr Sanjay Agrawal, "The clarity on pending notification on methylcobalamin which is being sought for is also based on former FSSAI CEO Pawan Agrawal's official confirmation that methylcobalamin has been approved by its scientific committee during December 2019."

FSSAI in an official statement has also clarified, "Currently, methylcobalamin is not listed under the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016 and hence it can be used with prior approval by the FSSAI."

This response from FSSAI comes close on the heels of nutraceutical and drug industry earlier having sought clarity from the FSSAI regarding RDA values of vitamin C and other micronutrients like methylcobalamin which are vital for boosting immunity, mental health and other comorbid chronic ailments in the crucial juncture of Covid-19 pandemic.

"As per section 22 of FSS Act 2006, nutraceuticals/health supplements shall not claim to cure or mitigate any specific disease, disorder or condition. Products with such intended use therefore fall under the scope of CDSCO/DCGI and not FSSAI. We had already made this clear in our earlier communications as well," the FSSAI stated.

"We have received this information from your office that methylcobalamin should not be used by manufacturers. But please note thousands of FSSAI approved brands with methylcobalamin [far beyond the RDA limits] are already available in the markets. Some of the widely sold brands approved by FSSAI and available in the drug retail supply chain are Health Aid Vitamin B12 (methylcobalamin) 1500 mcg, Nature Made Vitamin B12-1000 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 B12-5000 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 and Garden of Life Vitamin Code vitamin B12-1000 mcg etc," an industry letter to the union ministry of chemicals and fertilizers stated.

According to industry sources, "The main reason for the present situation is that the Centre is yet to come out with guidelines on the recommended dietary allowance (RDA) and tolerable upper limit (TUL) of the products containing methylcobalamin."

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