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Shardul Nautival, Mumbai

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The pharmaceutical industry in the country has sought the intervention of the Central government on the issue of implementation of the arbitrary pan-India ban on methylcobalamin, by the state drug controllers (SDCs), which has not been notified as yet. Industry experts have also questioned how the ban on methylcobalamin is justified when it is still awaiting notification from the Centre.

The SDCs, however, argue that the states need to follow it as per Centre's directive as per the law of the land.

An industry delegation also met Union minister of chemicals and fertilizers D V Sadananda Gowda 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.

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, diabetes and among others. It is important for the brain, nerves and production of red blood cells (RBCs).

According to Ahmedabad based pharmaceutical consultant Dr Sanjay Agrawal, "Methylcobalamin as a supplement is very essential specifically for Indians where the majority of the population is vegetarian as naturally it is present in nonvegetarian products. When a supplement is taken for prophylactic use it must at least be of the therapeutic dose."

The 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.

In a recent representation made to the union ministry of chemicals and fertilizers, industry had also recommended the Drugs Controller General of India (DCGI) to be given the sole authority for implementation of nutraceutical regulations citing FSSAI and Indian Council of Medical Research (ICMR) as toothless bodies.

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. Questions have been raised about the ambiguous RDA value and TUL of methylcobalamin which till today FSSAI is unclear about and has been taking refuge of ICMR due to lack of scientific evidence despite Centre's scientific panel approving new RDA values, industry sources have alleged.

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 micronutrients like methylcobalamin which are vital for boosting immunity, mental health and other comorbid chronic ailments in the crucial juncture of Covid-19 pandemic.

In a letter to the FSSAI, CDSCO had also brought to the notice that various brands of product containing methylcobalamin are manufactured and sold having therapeutic intervention under the FSSAI license. "We have been following with the union ministry of chemicals and fertilizers seeking clarity on methylcobalamin ban which is the most important B12 and about defining its RDA values by ICMR." Dr Agrawal added.

The industry has therefore alerted the Centre towards streamlining the drug regulatory regime related to regulating nutraceuticals as several brands containing ingredients above permissible limits have entered the drug retail supply chain evading ICMR prescribed RDA values. These brands have been evading the defined arbitrary RDA values of ICMR and despite being approved under the FSSAI license are being used as drugs for therapy purposes.

According to another pharma consultant Anshu Yadav "Different combination of products of methylcobalamin have flooded the Indian market due to ambiguous nature of regulations which as of today is neither regulated under drugs nor under nutraceuticals effectively despite the fact that the notification to revoke the ban on methylcobalamin is awaited following Centre's scientific panel nod."

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