Policy & Regulations

Industry approaches Centre to urgently notify methylcobalamin for neurological disorders

Shardul Nautiyal, Mumbai
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The pharmaceutical industry has recently led a delegation to 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.

The pending notification which is being sought for is also based on former Food Safety and Standards Authority of India (FSSAI) CEO Pawan Agrawal's confirmation that methylcobalamin has been approved by its scientific committee in December 2019. Mail correspondences shared on the issue have been reviewed by Pharmabiz.

Drug and nutraceutical industry players have 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. However, 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.

"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 but industry is yet to see the much awaited notification on the same," informed Anshu Yadav who led the delegation to the Government further adding that we are pursuing the issue of banning methylcobalamin by FSSAI for more than a year without a logical conclusion. On the contrary, FSSAI has allowed usage of cyanocobalamin which has cyanide content within but banned methylcobalamin which is a superior form of vitamin B12.

"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 methylcobalamin and cyanocobalamin both have the same RDA value to manufacture. 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," Pharma consultant Dr Sanjay Agrawal argued.

Methylcobalamin is an essential nutrient and is required to treat vitamin B12 deficiency, in people with pernicious anemia, diabetes and other conditions as well. It is important for the brain, nerves and for the production of red blood cells (RBCs). 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 cause it must at least be of the therapeutic dose.

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