TOP NEWS

Two years gone, FSSAI yet to issue gazette notification lifting ban

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It has been more than two years since the Food Safety and Standards Authority of India (FSSAI) lifted ban on methylcobalamin, also known as vitamin B12. However, the apex food regulator is yet to issue a gazette notification on the same, leaving nutraceutical manufacturers in a bind.

In 2021, FSSAI came out with a notification lifting the ban on methylcobalamin. Prior to that, the FSSAI banned methylcobalamin through a gazette issued in 2016. The product was later approved by the FSSAI's Scientific Committee in December 2019 based on scientific evidence of its safety.

"Methylcobalamin has been approved by the US FDA for use as a dietary supplement and is now listed on page 41 of the USP (US Pharmacopeia), but the FSSAI continues to ignore industry requests to release a gazette notification lifting the methylcobalamin ban," stated Dr Sanjay Agrawal, a leading pharmaceutical consultant.

Dr Agrawal appealed to former Union Health and Family Welfare Minister Dr Mansukh Mandaviya and Prime Minister Narendra Modi to direct the FSSAI to issue a gazette notification that would lift the ban on methylcobalamin, but to no avail.

Methylcobalamin is an essential nutrient to regulate certain vital bodily functions like cell multiplication, blood formation and protein synthesis.

Methylcobalamin has been used in clinical trials to treat some nutritional and other diseases, including Alzheimer's disease and rheumatoid arthritis. As an auxiliary agent, it protects neurons by promoting nerve regeneration and inhibiting glutamate-induced neurotoxicity. In recent experimental and clinical studies, several lines of evidence have suggested that methylcobalamin may have analgesic properties. For example, methylcobalamin reduced pain behaviours in diabetic neuropathy, low back pain, and neuralgia. Methylcobalamin improved nerve conduction, accelerated nerve regeneration, and reduced ectopic spontaneous discharges of injured primary sensory neurons.

In the absence of a gazette notification, there are no guidelines for the recommended dietary allowance (RDA) or tolerable upper limit (TUL) of methylcobalamin-containing products. The domestic market is flooded with various brands of methylcobalamin with RDAs of up to 1500 mcg intended for prophylactic use. This is in contravention of the FSSAI's recommended RDA of 1 mcg, stated Dr Agrawal.

Once notified, the approved RDA value can be defined scientifically based on available evidence, he added.

He had written to FSSAI time and again seeking clarification from it on easy availability of high doses of methylcobalamin in absence of the authority's gazette notification on removal of ban on the product.

In a communication to the pharmaceutical consultant on December 26, 2021, the FSSAI clarified that all vitamin B12 derivatives, including methylcobalamin, have been 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 through amendments notified on September 16, 2021. As a result, the food regulator has issued product licences for all vitamin B12 derivatives, including methylcobalamin.

Dr Agrawal demanded that the FSSAI issue a gazette notification lifting the ban on methylcobalamin, paving the way for guidelines on the tolerable upper limit of methylcobalamin-containing products. He also demanded that the FSSAI issue a notification approving the RDA of methylcobalamin up to 500 mcg for prophylactic use.

"The majority of vitamin B12 comes from non-vegetarian foods. The global recommended daily allowance is 2.4 mcg. In India, where the population is mostly vegetarian, the RDA is 1 mcg. Studies on methylcobalamin for therapy and prophylaxis in neurological disorders contradict the FSSAI's RDA for methylcobalamin. According to scientific studies, methylcobalamin should be taken at a dose of 500 mcg per day in order to live a normal life. In acute cases of neuropathy, a daily dose of 1,500 mcg is safe. A dose of 1 mg per day is required to treat age-related brain decay," he added.