Policy & Regulations

Experts lambast FSSAI for approving high doses of methylcobalamin as against its RDA value

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Healthcare experts have lambasted the Food Safety and Standards Authority of India (FSSAI) for granting approval to methylcobalamin 1500 mcg tablet under nutraceutical segment surpassing its recommended dietary allowance (RDA) value of 1 mcg.

Methylcobalamin is a form of vitamin B12 taken to regulate certain vital bodily functions like cell multiplication, blood formation and protein synthesis. It is also prescribed to treat vitamin B12 deficiency in people with pernicious anaemia. Vitamin B12 is found in many foods, such as meat, poultry, seafood, eggs, dairy products and fortified cereals.

There is evidence suggesting that high doses of B12 may lead to negative health outcomes in those with diabetes or kidney disease. People with diabetic nephropathy (loss of kidney function due to diabetes) experienced a more rapid decline in kidney function when supplemented with high-dose B vitamins, including 1 mg per day of B12, said Dr Sanjay Agrawal, a leading health expert.

According to a study, pregnant women who consume high doses of B12 are facing the risk of autism spectrum disorder in their offspring, he said.

On January 7, 2020, FSSAI had 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.

As per Section 22 of the Food Safety and Standards Act, 2006 and nutraceutical regulations, health supplements or nutraceuticals shall contain minerals or vitamins only in amounts not exceeding the RDA for Indians. Hence, as per the said Act and Regulations, these products can contain vitamins or minerals only up to its RDA. Manufacturers who want to produce, import, market or sell such products shall comply with the aforementioned regulations, pointed out Dr Agrawal.

"Surprisingly, a product on the market named Nezexa tablet includes methylcobalamin 1500 mcg which is duly approved by FSSAI. The product is being manufactured by Asta Organics and marketed by Indolixa Pharmaceuticals. The manufacturing date on the product is May 2021. This showed a double standard of FSSAI on methylcobalamin approval. On the one hand, the food authority has specified the RDA value of methylcobalamin as 1 mcg and on the other hand, it is approving high doses of the product," he stated.

Besides this, Dr Agrawal also pointed out lacuna in the regulatory mechanism dealing with nutraceutical approval in the country.

He said FSSAI had banned methylcobalamin through the gazette passed in 2016. The product was later approved by the scientific committee of FSSAI in December 2019 based on scientific evidence of its safe use but the amended gazette has not been issued in this regard so far.

Due to a delay in notification, numerous drug units produce methylcobalamin-based formulations without a scientifically defined RDA value, he added.

"Since 2019, we have been waiting for the updated gazette, but it hasn't been made available in the public domain. The central government has yet to issue guidelines on the RDA and tolerated the upper limit (TUL) of products containing methylcobalamin. The RDA for a healthy person and the per-use value vary around the world. Many brands of methylcobalamin range from 1000 to 5000 mcg, which is 41000 per cent more than the RDA dose. According to researchers, the majority of vitamin B12 comes from non-vegetarian foods and milk products. The RDA for the entire world is 2.4 mcg," said Anshu Yadav, another healthcare expert.

Due to the poor technical information, FSSAI is not able to control nutraceuticals where DCGI is able to do better, as they were taking care of nutraceuticals 10 years back as well, Yadav, said.

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