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Policy & Regulations

FSSAI yet to notify methylcobalamin as nutraceutical ingredient for neurological disorders despite scientific panel's nod

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Despite assurance regarding notifying methylcobalamin as nutraceutical ingredient based on Food Safety and Standards Authority of India (FSSAI)'s scientific panel nod in December 2019, industry has raised concern that FSSAI has not yet notified it.

Besides this, FSSAI has also not defined recommended dietary allowance (RDA) of vitamin B12 as there are four types of vitamin B12 namely methylcobalamin, adenosylcobalamin, hydroxycobalamin and cyanocobalamin. The contention is that Indian Council of Medical Research (ICMR)'s scientific committee has recommended RDA value of 1 micro gram per day for vitamin B12 to FSSAI and FSSAI technical team has not been able to clearly define new RDA values based on scientific evidence.

"Correspondences by industry experts since June 2019 finally yielded the desired outcome from CDSCO, FSSAI and Gujarat state drug control department when FSSAI's Scientific Panel finally approved methylcobalamin (vitamin B12) as a nutraceutical ingredient after risk assessment based on secondary data," as per a letter shared from Pawan Agarwal, chief executive officer, FSSAI's office to pharma consultant Dr Sanjay Agrawal on December 18, 2019.

Methylcobalamin is widely marketed in the country as a drug for chronic neurological disorders with an RDA of 2000 mcg intramuscular but as per FSSAI it is detrimental for patients when used above 1 mcg for prevention and disease management. Name of some widely sold brands are Locopen capsule, Neugaba M 75 capsule, Nervup 500 mcg injection, Nuroz Forte, Nurofine-2500 injection, Actovis 2500 injection, etc.


The much awaited notification is based on the scientific premise that the recommended daily intake and dosage values are two different things. Peer reviewed studies on methylcobalamin for therapy and prophylactic use in neurological disorders have contradicted ICMR recommended dietary allowance values, industry experts have argued.

Scientific studies have concluded that methylcobalamin is recommended to be taken in the dose of 500 microgram (mcg) per day for an individual to lead normal life. In the acute cases of neuropathy, dose of 1,500 mcg per day can be safely taken. Dose of 1 mg per day is required to be taken for age related brain decay. RDA for methylcobalamin is currently set at 1microgram for neurological disease management by FSSAI based on data provided by Indian Council of Medical Research.

According to Dr Agrawal, "It is to be noted that no adverse effect has been associated with excess methylcobalamin intake from food or supplements in healthy individual. Methylcobalamin has a history of safe long term use as a therapeutic agent. If manufacturer is producing 1 mcg methylcobalamin, how will Indian population combat with vitamin B12 deficiency."

"The body's ability to absorb vitamin B12 from dietary supplements is largely limited by the capacity of intrinsic factor. Some people—particularly older adults, those with pernicious anemia, and those with reduced levels of stomach acidity (hypochlorhydria or achlorhydria) or intestinal disorders—have difficulty absorbing vitamin B12 from food and, in some cases, oral supplements. As a result, vitamin B12 deficiency is common. RDA and dosage value are two different things. Now here the RDA is 1 mcg. If manufacturer is producing 1 mcg tablets, it is far below than the therapeutic dose. Nutraceutical manufacturer must be allowed to produced at least 500 mcg," pharma consultant Anshu Yadav concluded.

The Food Safety and Standards [Health Supplement, Nutraceuticals, Food for Special Dietary Use, Food for Special Medicinal Purpose, Functional Food and Novel Foods] Regulation, 2016 allows the use of vitamins or minerals only upto the RDA in health supplements and nutraceuticals. RDAs are the levels of intake of essential nutrients that, on the basis of scientific knowledge, are judged to be adequate to meet the known nutrient needs of healthy person.

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