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FSSAI gives clarity on methylcobalamin usage

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‘Most of the Indian population is deficient of methylcobalamin due to a number of factors and most important among them is the higher vegetarian population’

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The Food Safety and Standards Authority of India has provided clarity on use of methylcobalamin, a form of Vitamin B12, in health supplements, medical purposes and nutraceutical products.

However, the Union Health Ministry's decision to lift the ban on methylcobalamin, the critical vitamin B12 derivative, is yet to be formalised, leaving its regulatory status in limbo despite scientific backing and growing demand for its use in treating conditions such as diabetic neuropathy.

While the Government of India's Scientific Committee approved the molecule's safety in 2019, the necessary gazette notification to officially lift the ban is still pending, raising concerns among health professionals and industry stakeholders.

Dr Sanjay Agrawal, Scientific Advisor of ALKOMEX GBN USA and leading pharmaceutical consultant said as per the Food Safety and Standards Regulations, 2022, the permitted forms of Vitamin B12 currently include cyanocobalamin and hydroxocobalamin. However, he said methylcobalamin may also be permitted under certain conditions, provided that food business operators notify the Food Authority and submit any additional safety data requested.

The regulations also stipulate that the level of Vitamin B12 in products must not exceed one Recommended Dietary Allowance except in specific categories such as Food for Special Medical Purposes and Food for Special Dietary Use. In such cases, prior approval from the Food Authority is required for levels exceeding the RDA.

Most of the Indian population is deficient of methylcobalamin due to a number of factors and most important among them is the higher vegetarian population.

Best source for methylcobalamin is milk and milk products, said Agrawal.

Vitamin B12, a crucial water-soluble vitamin, is integral to DNA synthesis, red blood cell production, and neurological function. Deficiency in this vitamin can lead to serious health consequences, often requiring supplementation.

Food Safety and Standards Authority of India clarification will guide manufacturers and stakeholders in aligning their products with regulatory standards while addressing the growing demand for diverse forms of Vitamin B12 in health supplements.