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## Policy & Regulations

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# No ban on methylcobalamin in health supplements & nutraceutical products: Health ministry

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The Union health ministry has clarified that the Food Safety and Standards Authority of India (FSSAI) has not imposed any ban on the usage of methylcobalamin in health supplements and nutraceutical products.

Consequently, there is no requirement to issue a gazette notification to lift any such ban. This announcement aims to address the confusion surrounding the regulatory status of this vital vitamin B12 derivative.

The ministry clarified this in a correspondence with Scientific Advisor at Alkomex GBN USA Dr Sanjay Agrawal.

Methylcobalamin is widely acknowledged for its neuroprotective properties, helping to reduce nerve damage and alleviate pain in diabetic neuropathy patients. In countries like the United States, it is readily available as a dietary supplement. However, in India, the ongoing debate over regulatory enforcement has sparked concerns among healthcare professionals and advocacy groups.

Dr Agrawal has welcomed this clarification but has also emphasized the need for clear regulatory guidelines to ensure methylcobalamin's accessibility and quality in the Indian market.

"Methylcobalamin is internationally recognized for its safety and efficacy, particularly in treating diabetic neuropathy. The molecule has been approved by the US FDA and is listed in the US Pharmacopoeia. Despite this, the regulatory framework in India remains ambiguous, which has caused uncertainty for manufacturers and consumers alike," Dr Agrawal stated.

While the Government of India's Scientific Committee had approved methylcobalamin's safety in 2019, and the ministry of health had initially announced the lifting of restrictions in 2021, stakeholders continued to demand clarity on its legal status. The latest statement from the Union health ministry now confirms that no ban exists, yet challenges remain regarding its market regulation and enforcement.

The Food Safety and Standards Authority of India (FSSAI) has reiterated that methylcobalamin can be used in health supplements and nutraceutical products under the FSS (Nutraceutical) Regulations, 2022. These regulations permit its use under specific conditions, including compliance with prescribed daily allowances. Food business operators (FBOs) must notify the Food Authority when using derivatives, salts, or chelates of vitamins and minerals, ensuring compliance with safety norms.

Dr Agrawal acknowledged that while the health ministry's clarification provides some relief, the lack of precise implementation guidelines continues to create ambiguity.

"The clarification from the Health Ministry is a step in the right direction, but there needs to be a stronger enforcement mechanism to ensure that only high-quality methylcobalamin products are available in the market," Dr. Agrawal emphasized.

Health experts and consumer advocacy groups continue to push for more comprehensive regulations, including stringent safety evaluations, standardized labelling, and robust market surveillance to protect consumers from misleading claims and substandard products.

With the Union health ministry confirming that no ban exists, industry stakeholders now look forward to clearer implementation guidelines that ensure the safe and effective availability of methylcobalamin in the Indian market.

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