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Stakeholders concerned over delay in officially lifting ban on methylcobalamin

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Tuesday, December 31, 2024, 08:00 Hrs [IST]

The Union health ministry's decision to lift the ban on methylcobalamin, a critical vitamin B12 derivative, is yet to be formalized, 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 at Alkomex GBN USA has criticized the delay in formalizing the decision, highlighting the growing gap between regulatory approval and practical availability.

"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 Ministry of Health's decision to lift the ban in 2021 has not been formalized through a gazette notification, leaving the regulatory framework unclear," Dr Agrawal stated.

The lifting of the ban was initially announced in 2021 following a thorough review by the Government of India's Scientific Committee, which confirmed methylcobalamin's safety profile. However, experts, including Dr Agrawal, warn that the lack of formal notification creates uncertainty in the marketplace, affecting both manufacturers and consumers who rely on this vital nutrient for various health conditions, including diabetic neuropathy and neurological disorders.

Methylcobalamin has been lauded for its role in managing conditions such as diabetic neuropathy, where its neuroprotective properties help reduce nerve damage and alleviate pain. Despite its approval in other countries, including the US, where it is widely used as a dietary supplement, its delayed entry into the Indian market raises concerns among patients and healthcare providers.

The FSSAI's regulatory framework surrounding vitamin B12 sources, including methylcobalamin, has also faced criticism for its lack of clear enforcement mechanisms. The FSSAI's response to the Union health ministry outlined the legal framework for methylcobalamin, allowing its use under certain conditions. However, public grievances persist, particularly about the absence of a robust enforcement system and the potential for products exceeding safe limits of vitamin B12 in the market.

Dr Agrawal expressed frustration over the FSSAI's response, noting that while the decision to allow methylcobalamin's use under the 2022 amendment to the Food Safety and Standards regulations was a step forward, the absence of clear and enforceable regulations only adds to the confusion. "The delay in formalizing the lifting of the ban, combined with the lack of clear enforcement guidelines, leaves consumers vulnerable to substandard products," Dr Agrawal emphasized.

Health experts and consumer advocacy groups have called for urgent action to formalize the lifting of the ban and introduce comprehensive regulatory mechanisms for methylcobalamin. They stress the need for market surveillance, rigorous safety evaluations, and clear labelling to protect consumers.

As the debate continues, it remains to be seen whether the Union health ministry and FSSAI will take decisive steps to resolve the regulatory uncertainty surrounding methylcobalamin, ensuring that this essential nutrient can reach the market safely and effectively.

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