**Policy & Regulations**



# Experts ask govt to bring nutraceuticals for prevention of diseases under DCGI's regulation

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Poor regulatory oversight and lack of clarity on upper tolerable limit (UTL) and recommended dietary allowance (RDA) standards have prompted manufacturers across the country to produce methylcobalamin above permissible limits.

Amidst the grave scenario, regulatory experts have raised alarm and written to the Centre that nutraceuticals available in the market for the prevention of diseases must be brought under the oversight of the Drugs Controller General of India (DCGI) as it is more technically sound as compared to the Food Safety and Standards Authority of India (FSSAI) which has been drawing flak from the industry and experts over poor enforcement of compliances.

The industry has alerted the Centre towards streamlining the drug regulatory regime related to regulating nutraceuticals as several brands containing ingredients above permissible limits have entered the drug retail supply chain evading Indian Council of Medical Research (ICMR) prescribed RDA values.

These brands have been evading the RDA values of ICMR and despite being approved under the FSSAI license are being used as drugs for therapy purposes.

Methylcobalamin is widely marketed in the country as a drug for chronic neurological disorders with a recommended dietary allowance of 2,000 microgram (mcg) intramuscular but as per the FSSAI, it is detrimental for patients when used above 1 mcg for prevention and disease management.

Industry has also raised the contention that FSSAI has not yet notified that methylcobalamin is approved despite a FSSAI scientific panel nod in 2019 on the same and also not issued a gazette notification as per the approvals of the scientific committee.

According to the Gazette Notification of Food Safety and Standards (FSS) Act 2006 regarding operationalisation of standards of health supplements, nutraceuticals, food for special dietary use, food for special medical purpose, functional food and novel food, methylcobalamin is banned.

But industry experts rue that still FSSAI talks about adhering to ICMR stipulated RDA values.

Pharmaceutical industry had earlier written to the union ministry of chemicals and fertilisers seeking clarity on methylcobalamin ban while giving reference about FSSAI approving brands having methylcobalamin for therapeutic use despite a ban.
According to the letter, "Even if we consider methylcobalamin is banned but we have been continuously communicated in mails by the officials of FSSAI that its RDA value of methylcobalamin is 1 mcg. It has to be noted that researchers have claimed that the source of vitamin B12 is mostly non - vegetarian food. Globally, the RDA value is 2.4 mcg. In India where the population is mostly vegetarian, on the contrary, RDA is defined as 1 mcg. We have the full right to know from the regulators where this scientific value has come from. Since, methylcobalamin has not been included in the gazette notification, why FSSAI is talking about RDA value. However, FSSAI has asked us to question the ICMR about this concern. We have been recommending that FSSAI must discuss with ICMR and explain to us the reason for keeping RDA value at 1 mcg."

Some of the widely sold brands approved by FSSAI and available in the drug retail supply chain are health aid vitamin B12 (methylcobalamin) 1,500 micro gram (mcg), nature made vitamin B12-1,000 mcg, B-12 dots by twinlab-500 mcg, jarrow formulas, methyl B-12-1,000 mcg, nature's bounty vitamin B-12 1,000 mcg, source naturals methylcobalamin vitamin B12-5,000 mcg, solgar sublingual methylcobalamin supplement-1,000 mcg, cobaforte CD3 plus tablet-1,500 mcg, nocob methylcobalamin 1,500 mcg among others.

In a recent letter addressed to the Union ministry of chemicals and fertilisers, the industry has drawn the attention to the industry's consistent efforts of also seeking clarity on the ban on methylcobalamin and about defining its arbitrary RDA values by ICMR and approved by FSSAI as mentioned in correspondences or emails shared with the concerned divisions of ICMR and FSSAI dated December 17, 2020, dated November 2, 2020, dated October 7, 2020, dated September 26, 2020, and dated September 16, 2020.

"Our continuous follow-ups with the FSSAI has yielded no positive and desired response makes it amply evident that nutraceuticals were well regulated when it was under DCGI ten years ago," the letter further stated.

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