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## Policy & Regulations



# FSSAI defined RDA values of methylcobalamin, vitamin C for drug and nutraceuticals for COVID-19 therapy baffles industry experts

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The Food Safety and Standards Authority of India (FSSAI) defined Recommended Dietary Allowance (RDA) value of methylcobalamin and vitamin C to boost immunity for COVID-19 has baffled industry experts as methylcobalamin and vitamin C are important nutrients for overall health and immune system of humans based on scientific evidences.

Evading the prescribed values, most of the nutraceutical manufacturers are producing methylcobalamin and vitamin C in higher concentrations than the stipulated RDA values both for drugs and nutraceuticals. Like methylcobalamin, FSSAI has decided RDA for vitamin C as 40 mcg despite the fact that 1,000 mcg of vitamin C has been prescribed for prophylactic use for many disorders. "The regulators must understand that there is a difference between RDA and the amount per serving in both the cases," according to experts.

Methylcobalamin is a form of vitamin B12 taken to regulate certain vital bodily functions like cell multiplication, blood formation and protein synthesis. It is also prescribed to treat vitamin B12 deficiency in people with pernicious anaemia. It has been argued that there must be some clarity on the technical aspect of methylcobalamin been approved for drug with RDA value of 2000 mcg and for nutraceuticals with RDA of 1 mcg.

RDAs are the levels of intake of essential nutrients that, on the basis of scientific knowledge, to be adequate to meet the known nutrient needs in healthy individuals. But the moot question still remains to be answered what must be the dose to be prepared by a nutraceutical manufacturer to give the desired efficacy or clinical outcomes.

On January 7, 2020, FSSAI had issued a notification regarding RDA of vitamin B12 which is specified as 1 mcg without mentioning type of vitamin B12 like methylcobalamin, adenosylcobalamin, hydroxycobalamin and cyanocobalamin. Vitamin B12 is found in many foods, such as meat, poultry, seafood, eggs, dairy products and fortified cereals. Most of them are classified as non-vegetarian food whereas majority of the Indian public is vegetarian. In addition to this various medications, namely metformin, proton-pump inhibitors, such as prilosec or H2 receptor antagonists such as pepcid interfere with B12 absorption. Therefore, such people need more of methylcobalamin.

As per Section 22 of FSS Act, 2006 and nutraceutical regulations health supplements or nutraceuticals shall contain minerals or vitamins only in amounts not exceeding the RDA for Indians. Hence, as per the said Act and Regulations, these products can contain vitamins or minerals only up to its RDA. Manufacturer who wants to produce, import, market or sell such products shall comply with the aforementioned regulations.

"The drug authorities have recommended 2,000 mcg of methylcobalamin even in injectable form and brands are available since long as patients take methylcobalamin based on the requirement," argues pharma consultant Dr Sanjay Agrawal who has been advocating the case of methylcobalamin RDA value with FSSAI for the benefit of mental health and boosting immunity since a long time.

"The issue has been festering due to missing exact information on tolerable upper limit (TUL) of vitamin B12 [methylcobalamin to be specific] from the public domain. 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 given in high dosage or via intramuscular injection for the treatment of disorders associated with impaired vitamin B12 absorption. Additionally, we had received a letter in December 2019 from FSSAI about methylcobalamin approved RDA value for neurological disorders by the technical committee but industry is yet to see the notification on the same," according to pharma consultant Anshu Yadav.

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