FSSAI RED FACED AS INDUSTRY LAMBASTS AUTHORITY FOR DENIGRATING SCIENCE BY SUBSCRIBING TO ICMR ARBITRARY RDA VALUES

FSSAI red faced as Industry lambasts authority for denigrating science by subscribing to ICMR arbitrary RDA values. There is an urgent need for inclusion of methylcobalamin in the gazette and reviewing the RDA for nutraceutical manufacturers.

Methylcobalamin has been in clinical use since the 1990s. **Methylcobalamin is an essential nutrient and is required to treat** vitamin B12 deficiency, in people with pernicious anaemia, diabetes

and other conditions as well. It is important for the brain, nerves and for the production of red blood cells (RBCs).

Methylcobalamin as a supplement is very essential specifically for Indians where the majority of the population is vegetarian as naturally it is present in nonvegetarian products. When a supplement is taken for prophylactic cause it must at least be of the therapeutic dose. Methylcobalamin is approved by CDSCO till 2000 mcg but FSSAI is approving only 1 mcg which is of no use to manufacture.

In a recent representation made to union ministry of chemicals and fertilizers, industry has once again recommended **Drugs Controller General of India (DCGI)** to be given the sole authority for implementation of nutraceutical policies and regulations citing **Food Safety and Standards Authority of India (FSSAI)** as a toothless body. Ten years back nutraceutical was under DCGI only.

A therapeutic dose for conditions requiring methylcobalamin would be a minimum of 1500 µg and a maximum of 6000 µg per day. No significant therapeutic advantage appears to occur from dosages exceeding this maximum dose; however, it is likely that beneficial physiological effects occur at dosages as low as 100 µg per day, especially if this dose is given for long time.

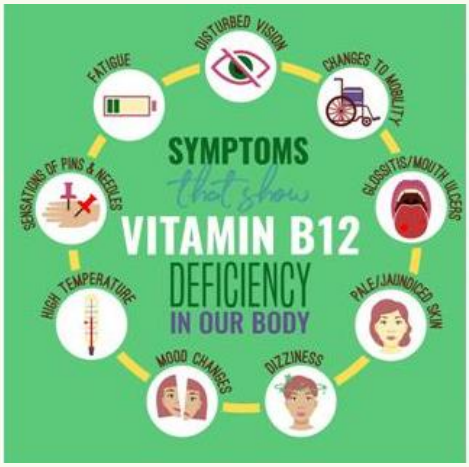
Nutraceutical and drug industry have alleged that FSSAI has been turning a blind eye to the contentious issues raised with reference to RDA values of Vitamin C and other micro-nutrients like methylcobalamin which are vital for boosting immunity, mental health and other co-morbid chronic ailments in the crucial juncture of COVID-19 pandemic.

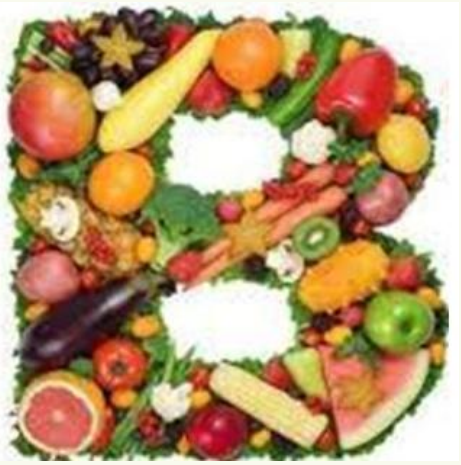
Prime Minister Narendra Modi has also recommended 1000 mcg of Vitamin C as prophylactic use against COVID-19 whereas its RDA is 40 mcg due to poor interventions from apex and responsible authorities like ICMR, FSSAI and DCGI. Manufacturers of methylcobalamin have also been defying the arbitrary and draconian ban on methylcobalamin in Gujarat due to dubious nature of Indian Council of Medical Research and FSSAI

recommended RDA value and upper tolerance limits in major micronutrients.

Unmindful of the concerns regarding RDA for mental health conditions and neurological disorders, industry has dubbed FSSAI as white elephant and urged the Centre that there is no need of FSSAI as the authority is not competent enough to talk on technical and scientific aspects and rely on the dictates of **Indian Council of Medical Research (ICMR)**. It is a sheer wastage of public money which have been pooled in to maintain an authority which is doing more harm than good.

FSSAI has been drawing flak from the industry as there is no clarity on tolerable upper limit (TUL) and RDA value. There is a nationwide ban on the methylcobalamin with state drug regulators citing that FSSAI has imposed the ban based on ICMR recommendation.





This is all the more contradictory considering that ICMR and National Institute of Nutrition (NIN) has recently issued another report which have different stipulated RDA values of methylcobalamin and estimated average nutrient requirements for Indians.

According to an industry expert, **"The dual standards of FSSAI** can also be seen by the presence of already FSSAI approved brands available with 1500 mcg qty/per serving. Rejunex CD3 of Intas is a FSSAI approved product containing 1500 mcg methylcobalamin. Some of the widely sold brands are Locopen capsule, Neugaba M 75 capsule, Nervup 500 mcg injection, Nuroz Forte, Nurofine-2500

injection, Actavis 2500 injection, etc. There are more than half a dozen other brands with the same formula."

According to Gujarat FDCA Commissioner Dr H G Koshia, "There is a ban on methylcobalamin pan-India and the states need to follow it as per FSSAI directive." The Central Drugs Standard Control Organisation (CDSCO) had earlier urged the FSSAI to take action against Gujarat-based manufacturers for manufacture and sale of methylcobalamin meant for therapeutic intervention in contravention of norms.

Industry can't comprehend that under which policies CDSCO and FSSAI are directing each other. Both are two autonomous regulatory body with their independent domain expertise. Specifically a letter was addressed to Dr H. G Koshia by Deputy Director RCD Shri Sanjeev Kumar to investigate the issue having higher Methylcocbalamin concentration without intimating FSSAI Delhi office and the Ministry of Chemical and Fertilizer. In another letter Gujarat FDA office has informed FSSAI regarding manufacturing of methylcobalamin in Gujarat.

In a letter to the FSSAI, CDSCO has brought to the notice that various brands of product containing methylcobalamin are manufactured and sold having therapeutic intervention under the FSSAI license.

In view of the same, it has been recommended on priority basis to instruct drug inspectors and food safety officers to launch surveillance drives against various brands of products containing methylcobalamin being manufactured and sold under FSSAI license, the letter further stated.

Industry players have also voiced concern that methylcobalamin RDA value has been approved by Central Drugs Standard Control Organisation (CDSCO) uptill 2000 mcg but FSSAI is approving only 1 mcg which is of no use. Drugs Controller General of India (DCGI) recommended 2,000 mcg of methylcobalamin even in injectable form and brands are available as patients take methylcobalamin based on the medical condition.

“Until and unless, FSSAI does not inform the industry that methylcobalamin is approved, there is no value of prescribing RDA value for the same. Surprisingly the mails which we have received from FSSAI on methylcobalamin and cyanocobalamin, both have the same RDA value for manufacturing. Please be advised we are talking about per serving usage value which the manufacturer can refer to and not the RDA value for a healthy person,” Ahmedabad based pharma consultant Dr Sanjay Agrawal argued.

On January 7, 2020, FSSAI issued a notification regarding RDA of vitamin B12 which is specified as 1 mcg without mentioning type of vitamin B12 like methylcobalamin, adenosylcobalamin, hydroxocobalamin and cyanocobalamin.

Former CEO of FSSAI Pawan Agrawal had promised in December 2019 that methylcobalamin has been approved by the scientific committee and will take due course of its time to be included in the gazette. Nevertheless, the industry has waited for almost 10 months without any progress for inclusion of the methylcobalamin in the gazette, an industry expert remarked.

RDA for methylcobalamin in the US is 2.4 mcg where most of the population is vegetarian whereas India with a vegetarian population mcg is set as 1mcg. I would like to apprise you that Vitamin B12 is present in non vegetarian sources only. Also other countries have kept RDA and per serving usage value as a separate entity that is being goofed up by FSSAI in India.

There is an urgent need for inclusion of methylcobalamin in the gazette and reviewing the RDA for nutraceutical manufacturers by not forgetting that products are already available at higher concentrations, informed pharma expert Anshu Yadav adding that until and unless FSSAI does not inform the industry that methylcobalamin is approved, there is no value of prescribing RDA value for the same. Surprisingly the mails which we have received from FSSAI regarding methylcobalamin and cyanocobalamin both have the same RDA value to manufacture. We are talking about per

serving usage value which the manufacturer can refer to and not the RDA value for a healthy person.

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