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E. Srinivasan

Managing Director
Sai Primus Life Biotech (P) Ltd

The Ignorant FSSAI

Lack of regulatory surveillance to implement drug regulations forced industry to knock doors of Centre

PHARMACIST Giulia Guerrini warned that **"lack of vitamin B12 can affect the nervous system and lead to macrocytic anaemia, a condition where enlarged red blood cells have low haemoglobin levels."**

Off late below highlights of the leading digital newspaper has recalled the importance of Vitamin B12

- **"Pregnant women are often advised to be careful about their vitamin B12 levels as its deficiency can lead to obstructed growth in the baby."**
- **The Indian digital newspaper also claimed that average recommended amount of vitamin B12 in adults is 2.4 mcg (the number varies with age and gender).**

Besides informing the importance of B12, the above statements have also presented the ignorance and confusion, even in medical fraternity. The recommended average amount of vitamin B12 all over the world is 2.4 mcg but surprisingly the Indian regulators have finalized untechnically and unreasonably 1 mcg as the average recommended intake amount for Indians, who are consuming more of vegetarian diet. Moreover the regulators have banned the very important type of vitamin B12 aka methylcobalamin which is found in its natural and active form in body. The industry is following up with FSSAI since June 2019 and now has written to the Centre as state drug controllers (SDCs) are still implementing the arbitrary ban on methylcobalamin pan-India. Pharmaceutical industry has been questioning how the ban on methylcobalamin pan-India is justified when it is still awaiting notification from FSSAI. The SDCs argue that the states need to follow it as per Centre's directive as per the law of the land.

The Central Drugs Standard Control Organisation (CDSCO) has also been following up with FSSAI to take action against methylcobalamin manufacturers for production and sale of methylcobalamin meant for therapeutic intervention in contravention to norms. In a recent representation made to union ministry of chemicals and fertilizers, industry had recommended Drugs Controller General of India (DCGI) to be given the sole authority for implementation of nutraceutical regulations citing Food Safety and Standards Authority of India (FSSAI) and Indian Council of Medical Research (ICMR) as toothless bodies. Gujarat based manufacturers have alleged that the dual standards of FSSAI is very much evident with the presence of already FSSAI approved brands available of 1500 microgram (mcg) /per serving. Some of the widely sold brands are " **Health Aid's vitamin B12 (methylcobalamin)** 1500 micro gram (mcg), **Nature Made's** vitamin B12-1000 mcg, B-12 dots by **Twinlab**-500 mcg, **Jarrow Formula's** methyl B-12-1000 mcg, **Nature Bounty's** vitamin B-12 1000 mcg, **Source Natural's** methylcobalamin vitamin B12-5000 mcg, **Solgar sublingual's** methylcobalamin supplement-1000 mcg, **Cobaforte** CD3 plus tablet-1500 mcg, **Nocob** methylcobalamin 1500 mcg among others. There are more than half a dozen other brands with the same formula.

Dr Sanjay Agrawal
Dr Sanjay Agrawal founded PHARMA CONSULTANTS and INVENTOR in 2005 to assist pharmaceutical companies around the globe. He has actively worked in pharmaceutical and related industries for more than 28 years. He is Editor-in-Chief of renowned IJM Today and honorable member of the editorial board of QualPharma and The Antiseptic. Dr Sanjay Agrawal is also the illustrious member of the National Geographic Society and ex- member of scientific committee of IDMA. His prestigious articles are published in various magazines and websites for example—The Antiseptic, NuFFooDS Spectrum, Pharmabiz

Dr. Agrawal had received various awards for his valuable support and contributions in healthcare and pharmaceutical sector .Dr. Agrawal obtained his postgraduation in Biochemistry from prestigious institution, completed MBBS and MBA from IMT. He has worked with many international and national Pharmaceutical company. Dr. Sanjay Agrawal is the patent holder of many research formulations which are successfully commercialized.

Currently besides his core jobs, Dr Agrawal devotes his time for the benefit of pharma fraternity. He has raised his voice against the ban imposed on methylcobalamin manufacturing. He has been asking to the regulators from more than a year about

- Why Methylcobalamin is not added in the gazette yet when promised by the former CEO Mr Pawan Agrawal Ji?
- Why cyanocobalamin is promoted even though there is a cyanide group attached to it?
- Why 1 mcg RDA limit is imposed on methylcobalamin for nutraceutical manufacturer?
- Technical aspect of damage caused when 500 mcg of methylcobalamin is taken as prophylactic use?
- Why should we have faith in FSSAI when every time we have to go to ICMR for clarification?

Metformin and Vitamin B12 Deficiency

A number of studies have found an association between long-term use of metformin and depleted vitamin B12 levels. Among the most significant of these, for example, was a secondary analysis from the Diabetes Prevention Program (DPP)/DDP Outcomes Study (DDPOS), one of the largest and longest studies of metformin use ever conducted.

Published in the April of 2016 issue of the *Journal of Clinical Endocrinology and Metabolism,* it found that more than a thousand subjects who took metformin for approximately 12 years had a 13% increased risk of vitamin B12 deficiency for each year of total metformin use.

Another study found that people with type 2 diabetes who took metformin at doses of more than 1,000 milligrams (mg) for four or more years were especially at risk of vitamin B12 deficiency.

The main reason for the present situation is that the Centre is yet to come out with guidelines on the recommended dietary allowance (RDA) and tolerable upper limit (TUL) of the products containing methylcobalamin. Questions have been raised about the ambiguous RDA value and TUL of methylcobalamin which till today FSSAI is unclear about and has been taking refuge of ICMR due to lack of scientific evidence despite Centre's scientific panel approval of new RDA values, industry sources have alleged.

Nutraceutical and drug industry have alleged that FSSAI and CDSCO have 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.

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

Industry has been following with the union ministry of chemicals and fertilizers seeking clarity on methylcobalamin ban which is the most important B12 and about defining its RDA values by ICMR. The industry has therefore 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 ICMR prescribed RDA values. These brands have been evading the defined arbitrary RDA values of ICMR and despite being approved under the FSSAI license are being used as drugs for therapy purposes.

Our ancestors: who were once apes ate dirt, grits and drank unsanitised water which prevented them from Vitamin B12 deficiency. We are living in the modern world and vitamin B12 with stress, availability of fast foods, sanitised water and polluted air, we cannot mess with this wonder vitamin. It goes long back to a century ago when the first patient in the 1853's was found bed ridden with bed sores, pressure ulcers, pernicious anemia and when he was fed with animal food, he recovered remarkably. This recovery was due to vitamin B12. Vitamin b12 is not made by plants or animals or naturally by us- humans but it is made by the microbes which blankets the earth. But in today's world as a result of sanitization we chlorinate to kill off these bacteria.

Different combination of products of methylcobalamin have flooded the Indian market due to ambiguous nature of regulations which as of today is neither regulated under drugs nor under nutraceuticals effectively despite the fact that the notification to revoke the ban on methylcobalamin is awaited following Centre's scientific panel nod.

The Central government has also recommended 1000 mg of vitamin C as prophylactic use against COVID-19 whereas its RDA is 40 mg due to poor regulatory and policy intervent.

~ Dr Sanjay Agrawal