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Where FSSAI is needed?

In what appears to be a clear case of red tapism and babudom, Food Safety and Standards Authority of India (FSSAI) has proved to be a worthless body on account of denying protocols and behaving irresponsibly by intimidating the industry with reference to mails shared by the industry with FSSAI on scientific/technical clarifications of recommended dietary allowances (RDAs) values, ban on methylcobalamin and notification on methylcobalmin awaited based on FSSAI scientific panel nod on June 19, 2019 presided by the then **FSSAI CEO Pawan Kumar Agarwal.**

Industry also has therefore been raising an alarm on the blatant violation of administrative protocols in the regulatory regime in the country citing FSSAI directive to state drug controllers (SDCs) to take action against manufacturers for production and sale of methylcobalamin meant for therapy in cases of diabetes and neurological disorders in contravention to norms.

Methylcobalamin is widely marketed in the country as a drug for chronic neurological disorders with a recommended dietary allowance (RDA) of 2000 mcg intramuscular but as per FSSAI it is detrimental for patients when used above 1 mcg for prevention and disease management.

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.

Industry experts have pinpointed that such a ban imposed on methylcobalamin warrants scrutiny in the wake of dual standards followed in such cases by the regulatory authorities of Central Drugs Standard Control Organisation (CDSCO) and FSSAI.

Repeated correspondences by industry experts on the issue have not yielded any response from FSSAI and CDSCO since June 2019 when the ban was invoked.

In a draft guideline issued in 2017 which is also considered as extension of regulation 2016, FSSAI added the word derivatives of Vitamins to the approved list. Manufacturers continued to manufacture methylcobalamin considering it as a derivative of methylcobalamin. However, in June 2019, the manufacturers of Gujarat were also taken aback when a letter was issued by Food and Drug Control Administration (FDCA) commissioner, Gujarat to ban methylcobalamin.

Dr Sanjay Agrawal

Dr Agrawal founded PHARMA CONSULTANTS and INVENTOR to fulfill his passion, capabilities and desire to assist pharmaceutical companies around the globe. He has actively worked in pharmaceutical and related industries for more than 28 years and started this firm in 2005. He is **Editor-in-Chief** of renowned IJM Today and honorable member of the editorial board of **The Antiseptic**.

It has been more amply evident with the correspondences made by the food regulator to the DCGI and the state drug controllers for taking action against the manufacturers when the matter warrants urgent scrutiny in the interest of patient safety with reference to RDA values.

Arguing on the matter, an FSSAI intimidating correspondence states,
"With regards to your persistent question of "why the industry is pressurized.....of no use?". The simple answer is that the Industry needs to provide the scientific evidence to either Indian Council of Medical Research (ICMR) or CDSCO to have the limits revised because the FSSAI's regulations are linked to the RDAs as specified by ICMR, especially for Indian population. Please note that the matter, as informed was examined by the Scientific Panel and the committee before making the decision. The regulations are bound to follow any other limitations placed by other acts/regulations/ rules set out in other ministries. For your information it is simply re-iterated that and it has been clarified that "Further, 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 one RDA. The Food Business Operator (FBO) who wants to manufacture, import, market or sell such products shall comply with the aforementioned regulations. Please note that RDA for different essential nutrients for Indians are specified by ICMR which also specified RDA for vitamin B12 (irrespective of its sources such as methylcobalamine or cyanocobalamine) as 1 mcg. Thus, the notification dated 7th January, 2020 mentions the same. Since revision of RDA does not fall under the scope of FSSAI and any such request may be taken up with ICMR rather than with FSSAI." (sic)

"Moreover, it is to mention that usage of single Vitamin B12 (Methylcobalamin) at higher doses for patients requires diagnosis by a physician and therefore falls under the scope of CDSCO and not FSSAI. Further, regulatory action against FBOs using methylcobalamin higher than 1 mcg in a food product is a matter of enforcement and will fall under the purview of Regulatory Compliance Division, FSSAI and the state food authorities." (sic)

I do not think there could be better clarification (rather the technical background) than what was provided by my colleague. And, the facts can not be overlooked or twisted to provide a reply you feel is appropriate. As the Authority is bound by the act, rules and regulations, please understand that it can not be violated to accommodate a request that can not be accommodated.

Besides, your statement - "Thank you for your mail. But unfortunately the revert is unsatisfactory. Until and unless we will receive a satisfactory reply on technical grounds we will pursue the matter to Indian regulatory authority i.e FSSAI and will not considered it as closed. If Cynocobalamin and Methylcobalamin have same RDA value than why water and fat soluble Vitamins ave given different RDA value." (sic) - does not sound like a request rather appears to be highly pressurizing and threatening.

I am not sure which Industry consortium your magazine or you represent, I would suggest that you may advise the industries concerned to take up the issue with the appropriate authorities. Hopefully, this time you and the industries (which you keep indicating in your mails) would consider taking up the issue with the concerned authorities rather than pressurizing and pestering FSSAI. I would reiterate my colleague's statement that the matter is treated as closed from FSSAI's perspective as there *is nothing much we can offer beyond what is already provided to you.*

The above (in italics) is mailed by N Bhaskar Advisor FSSAI

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 also been argued that there must also be some clarity on the technical aspect of methylcobalamin being approved for drugs with recommended dietary allowance (RDA) value of 2000 mcg and for nutraceuticals with RDA of 1 mcg. Cardiologists and gynecologists prescribe methylcobalamin along with regular treatment protocols.

The 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.

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.

According to the letter, it is pertinent to mention here that there are only two variants of vitamin B12 namely cyanocobalamin and hydroxocobalamin which are covered under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary use, Food for Special Medical Purpose, Functional Food And Novel Food Regulation 2016) (FSSAI-2016) but does not cover methylcobalamin.

In view of the above consideration, 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.

Many drugs including methylcobalamin, pantoprazole and other antacids inhibit the absorption of methylcobalamin. According to a research, Type 2 diabetes patients being treated with metformin had a greater risk of reduction in methylcobalamin by inhibiting absorption of methylcobalamin levels. Another research shows proton pump inhibitors have been associated with an increased risk of vitamin deficiencies impacting methylcobalamin.

~ By Dr Sanjay Agrawal