Policy & Regulations

Drug makers in bind due to FSSAI's dubious stand on approval of methylcobalamin

Laxmi Yadav, Mumbai
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Drug makers are in a bind due to Food Safety and Standards Authority of India (FSSAI)'s dubious stand on approval of methylcobalamin, commonly known as vitamin B12.

On the one hand, Bhaskar Narayan, advisor (science & standards), FSSAI has reiterated that methylcobalamin should not be used by manufacturers as it is not listed under the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016.

On the other hand, thousands of FSSAI approved brands with methylcobalamin (far beyond the recommended dietary value limits) are already available in the markets.

Few of them are Health Aid Vitamin B12 (methylcobalamin) 1500 mcg, Nature Made Vitamin B12-1000 mcg, B-12 dots by Twinlab-500 mcg, Jarrow Formulas, Methyl B-12-1000 mcg, Nature's Bounty Vitamin B-12 1000 mcg, Source naturals methylcobalamin Vitamin B12-5000 mcg, solgar sublingual methylcobalamin supplement-1000 mcg, Cobaforte CD3 plus tablet-1500 mcg, nocob methylcobalamin 1500mcg, unived methylcobalamin 1500mcg, Bhumija Lifesciences vitamin B12 1500 mcg, bluebonnet liquid methylcobalamin - vitamin B12 1000 mcg, EZ Melts B12 as methylcobalamin, 2,500 mcg and Garden of Life Vitamin Code vitamin B12-1000 mcg etc.

FSSAI had banned methylcobalamin through the gazette passed in 2016. The product was later approved by the scientific committee of FSSAI in December 2019 based on scientific evidence of its safe use but the amended gazette has not been issued in this regard so far.

Methylcobalamin is an essential nutrient to regulate certain vital bodily functions like cell multiplication, blood formation, and protein synthesis. Most of the manufacturers are continuously manufacturing the said product which proves the inefficiency of FSSAI.

When asked about easy availability of methylcobalamin in absence of FSSAI's gazette notification on removal of ban on the product, Bhaskar Narayan clarified that methylcobalamin can be used with prior approval by the food authority.

The easy availability of methylcobalamin far beyond the recommended dietary value (RDA) has led the experts in a dilemma to conclude whether methylcobalamin is approved or not and if the RDA is applicable to methylcobalamin or not. Considering methylcobalamin is banned, how many brands of methylcobalamin are available in the market? And if considering methylcobalamin is not banned the question arises, why approval status is not mentioned in the gazette.

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 the 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 methylcobalamin, said Dr Sanjay Agrawal, pharmaceutical consultant.

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 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 individuals. 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," added Dr Agrawal.

He stressed the need to bring regulation of nutraceuticals under the jurisdiction of DCGI who are well equipped to regulate these products.

According to Drugs and Cosmetics Act, the definition of drug includes all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.

Therefore, nutraceuticals which are used for prevention of the disease must be handled by DCGI as they are more technical compared to FSSAI. Before 2006, the nutraceuticals were handled by DCGI only, said the pharmaceutical consultant.

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