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Industry seeks health ministry's intervention in notifying removal of ban on methylcobalamin

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The pharmaceutical industry has sought intervention of Union minister of health and family welfare Mansukh Mandaviya in notifying removal of ban on methylcobalamin, commonly known as vitamin B12.

Food Safety and Standards Authority of India (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.

Even though the FSSAI has yet to come out with notification on lifting ban on methylcobalamin, a number of brands containing methylcobalamin have received FSSAI approval.

When asked about this, FSSAI clarified that currently, methylcobalamin 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 and hence it can be used with prior approval by the FSSAI.

Some of the widely sold brands approved by FSSAI and available in the drug retail supply chain 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, nocab methylcobalamin 1500mcg, uncived 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.

Methylcobalamin based formulations are being manufactured by several drug units without scientifically defined efficacious recommended dietary allowance (RDA) value due to delay in notification, said Dr Sanjay Agrawal, pharmaceutical consultant.

Once notified, approved RDA value can be scientifically defined based on evidence, he said.

He added, "Former FSSAI CEO Pawan Agrawal informed us that methylcobalamin has been approved by its scientific committee during December 2019. Since then, we are waiting for the amended gazette but the amended gazette has not been made available in public domain."

The central government is yet to come out with guidelines on the RDA and tolerable upper limit (TUL) of the products containing methylcobalamin, he added.

In whole world the RDA for a healthy person and per usage value are different. There are thousands of brands of methylcobalamin available which are between 1000 to 5000 mcg which is 41000 per cent above RDA value.

Researchers claims that source of vitamin B12 is mostly non-vegetarian food. In whole world the RDA is 2.4 mcg. In India where the population is mostly vegetarian, RDA is defined as 1 mcg, stated 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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