Policy & Regulations

Industry rues nationwide ban on methylcobalamin proved to be extortion bid by SDCs

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Even as notification regarding approving right recommended dietary allowance (RDA) value for methylcobalamin remains pending for almost a year despite Food Safety and Standards Authority of India (FSSAI) scientific panel's nod of notifying it in December 2019, the drug and nutraceutical industry rues that the nationwide ban on methylcobalamin has proved to be an extortion bid by state drug controllers (SDCs) in the guise of regulations.

FSSAI has been drawing flak from the industry as a ban on methylcobalamin has become a contentious issue today. 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 Indian Council of Medical Research (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. In the Norwegian Vitamin (NORVIT) intervention trial also, patients with acute myocardial infarction received 400 mcg of B12 daily for 3 years and reported no serious adverse events.

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).

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.

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," 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, hydroxycobalamin and cyanocobalamin.
Former CEO of FSSAI Pawan Agrawal had promised in December 2019 that methycobalamin 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.

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