Policy & Regulations

Industry on panic mode as FSSAI directs SDCs to take action on production of methylcobalamin meant for diabetes, neuro disorders

Shardul Nautiyal, Mumbai
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Industry has raised alarm on the blatant violation of administrative protocols in the regulatory regime in the country citing Food Safety and Standards Authority of India (FSSAI)'s 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.

According to industry person Anshu Yadav, "It is now amply evident that the issue about taking action on methylcobalamin manufacturers is totally uncalled for. Reason being that the letter issued by FSSAI deputy director to Gujarat state drug control department to take action on methylcobalamin manufacturers without any intimation to the then FSSAI CEO Pawan Kumar Agarwal indicates lobbying and malafide intent to discourage industry to satisfy vested interests."

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 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.

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," clarified Ahmedabad based pharma consultant Dr Sanjay Agrawal who has been fighting the case for the past one year in the interest of patient safety.

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.

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.

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