

## FSSAI action sought for methylcobalamin sale

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THE Central Drugs Standard Control Organisation (CDSCO) has urged the Food Safety and Standards Authority of India (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 hydroxycobalamin 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 drive against various brands of products containing methylcobalamin being manufactured and sold

under FSSAI license.

Therefore, this warrants an apt action as per the provisions of FSSAI act 2006 Rules and Regulations made thereunder against the defaulting food business operators (FBOs) under intimation to FSSAI and CDSCO, the letter states.

Methylcobalamin also known as mecobal-

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amin or methyl B12 plays a key role in maintaining good health. It is the only form of vitamin B12 that can cross the blood brain barrier without bio-transformation. Its methyl group stimulates serotonin secretion, a neuro-transmitter which is responsible for mood enhancement and protects brain from damage against excitatory neurotransmitters.

Industry experts have pinpointed that ban on methylcobalamin warrants scrutiny in the wake of dual standards followed in such case by the regulatory authorities-CDSCO and FSSAI.

Repeated correspondences by industry experts on the issue have yielded no responses from FSSAI, CDSCO and Gujarat state drug control department since June 2019 when the ban was invoked.

Rues pharma consultant Dr Sanjay Agrawal, Industry is also discouraged with the ambiguous nature of ban and concerns have been raised by the industry on the ban on methylcobalamin only in Gujarat. There is no such ban on methylcobalamin in other states.

Cyanocobalamin which when enters the body leaves the cyanide group and takes methyl group from the human body to form methylcobalamin as methylcobalamin is the active form of vitamin B12 in the human body.

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 taken aback when a letter was issued by Food and Drug Control Administration (FDCA) commissioner, Gujarat to ban methylcobalamin. ○

# Export of medicinal herbs to China registers jump

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CHINA is one of the largest importers of medicinal herbs from India in 2018-19, according to export data presented in the Lok Sabha by Minister of Commerce and Industry, Piyush Goyal.

According to the data, the export of medicinal herbs to China has increased from US\$5.4 million in 2016-17 to US\$13.4 million in 2018-19, while export of medicinal herbs to US was also up from US\$90.43 million in 2016-17 to US\$102.89 million in 2018-19. The export of medicinal herbs to Germany has also increased from US\$30.95 million to US\$34.07 million in 2018-19, while export of medicinal herbs to Belgium was marginally up from US\$4.85 million to US\$4.92 million in 2018-19.

Export of medicinal herbs to Spain went up to US\$2.60 million in 2018-19 from US\$1.67

million in 2016-17, while that of Taiwan increased from US\$2.17 million in 2016-17 to US\$2.78 million in 2018-19.

The government has taken several measures to promote India's exports and to create export avenues for farmers opting for the cultivation of herbs and medicinal plants.

The Department of Commerce has set up Export Promotion Councils for promoting exports of various product groups / sectors. The export promotion of several herbal products has been assigned to Pharmaceuticals Export Promotion Council (Pharmexcil), besides others. These EPCs facilitate the exporting community and undertake various measures for promotion of export of their products, Goyal said.

Goyal added, "Under market access initiative (MAI) scheme of the Department of Commerce, the EPCs are provided financial assistance for participation and organising

trade fairs, buyer seller Meets (BSMs), reverse buyer seller meets (RBSMs), research and product development, market studies, etc.

Merchandise Exports from India Scheme (MEIS) provides incentives to the exporting community for specified goods, so as to offset infrastructural inefficiencies and the associated costs of exporting products produced in India, giving special emphasis to those which are of India's export interest and have the capability to generate employment and enhance India's competitiveness in the world market, he added.

Ministry of Ayush through its quality certification programme like Ayush mark and Premium mark is also assisting industry in setting up of quality standards. Ministry of Ayush has also entered into MoUs with a few countries for promotion of traditional medicines which will help exports in the long run. ○