Policy & Regulations

Industry seeks clarity on methylcobalamin ban and about defining its arbitrary RDA values

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Perplexed at the scenario of Food Safety and Standards Authority of India (FSSAI) approving brands having methylcobalamin for therapeutic use despite a ban, pharma industry has written to the union ministry of chemicals and fertilisers seeking clarity on methylcobalamin ban which is the most important B12 and about defining its recommended dietary allowance (RDA) values by Indian Council of Medical Research (ICMR).

Industry contention is that FSSAI has not yet notified that methylcobalamin is approved. Still lot of methylcobalamin brands are available in the market. According to the gazette notification of Food Safety and Standards Act 2006 regarding operationalisation of standards of health supplements, nutraceuticals, food for special dietary use, food for special medical purpose, functional food and novel food, methylcobalamin is banned and still FSSAI talks about adhering to ICMR stipulated RDA values.

The industry has therefore alerted the Centre towards streamlining the drug regulatory regime related to regulating nutraceuticals as several brands containing ingredients above permissible limits have entered the drug retail supply chain evading ICMR prescribed RDA values. These brands have been evading the defined arbitrary RDA values of ICMR and despite being approved under the FSSAI license are being used as drugs for therapy purposes.

Making a case in point, Ahmedabad based Pharmaceutical Consultant Dr Sanjay Agrawal argues, "According to Drugs and Cosmetic (D&C) Act, the definition of drug implies 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 available in the market today used for prevention of the disease must be under the oversight of the Drugs Controller General of India (DCGI) officials as they are more technically sound as compared to FSSAI . Before 2006, the nutraceuticals was under DCGI only."

Methylcobalamin is also widely marketed in the country as a drug for chronic neurological disorders with a recommended dietary allowance of 2000 mcg intramuscular but as per FSSAI, it is detrimental for patients when used above 1 mcg for prevention and disease management.

According to the letter, "Even if we consider methylcobalamin is banned but we have been continuously communicated in mails by the officials of FSSAI that its RDA value of methylcobalamin is 1 microgram (mcg). It has to be noted that researchers have claimed that the source of vitamin B12 is mostly non -vegetarian food. Globally, the RDA is 2.4 mcg. In India where the population is mostly vegetarian, on the contrary, RDA is defined as 1 mcg. We have the full right to know from the regulators where this scientific value has come. Also if methylcobalamin has not been included in the gazette notification, why FSSAI officials are talking about RDA value.

However, FSSAI has asked us to question ICMR about this concern. It has been recommended that FSSAI must discuss with ICMR and explain to us the reason for keeping RDA value as 1 mcg."

Some of the widely sold brands approved by FSSAI and available in the drug retail supply chain are health aid vitamin B12 (methylcobalamin) 1500 micro gram (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 1500 mcg among others.

The letter to the union ministry of chemical and fertilisers also pointed out the ambiguities related to regulatory actions on manufacturers.

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