INDUSTRY IS AT CROSSROADS AS THE UNION HEALTH MINISTRY IS BEING MISGUIDED

Industry at crossroads as health ministry misguided on putting in place right regulatory regime to control nutraceuticals and drugs. FSSAI and CDSCO have been drawing flak from the industry as there is no clarity on TUL and RDA values of many micronutrients including vitamin C and methylcobalamin.

Industry is at crossroads as the Union Health Ministry is being misguided with reference to putting in place the right regulatory regime to control nutraceuticals and drugs. A silent and yet intense anger is also raging in the industry in the absence of a clear

regulatory regime today. Industry insiders and experts have upped their ante against the intense lobbying related to **delegating power to regulate nutraceuticals to a toothless body like** Food Safety and Standards Authority of India (FSSAI).

Besides this, the Union Health Ministry is also being misguided to approve an irrational move to bring about certain amendments in the provisions of the **Drugs and Cosmetics (D&C) Act t**owards regulating nutraceuticals on the premise of recommended dietary allowance (RDA) value without even informing and consulting industry. This probably according to industry insiders is happening as a part of lobbying at the Centre towards appeasing a section of people in the industry and Ministry.

This is also very much evident as the state licensing authorities (SLAs) are trying to enforce the ban invoked by the Centre in June 2019. Drugs and nutraceutical manufacturers have since then been defying the one-year old arbitrary and draconian ban on methylcobalamin due to dubious nature of **Indian Council of Medical Research (ICMR) and FSSAI recommended dietary allowance (RDA) values and tolerable upper limit (TUL) even in major micronutrients like vitamin C.**

The Central Drugs Standard Control Organisation (CDSCO) has also been following with FSSAI to take action against Gujarat based manufacturers for production and sale of **methylcobalamin** meant for therapeutic intervention in contravention to norms. In a recent representation made to Union Ministry of Chemicals And Fertilizers, industry has also once again recommended **Drugs Controller General of India (DCGI)** to be given the sole authority for implementation of nutraceutical policies and regulations, citing FSSAI and ICMR as toothless bodies, giving reference that ten years back nutraceuticals were under DCGI only and was properly regulated.

Gujarat based manufacturers have alleged that the dual standards of FSSAI is very much evident with the presence of already FSSAI approved brands available with 1500 microgram (mcg) quantity/per

serving. 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. Rejunex CD3 of Intas is a FSSAI approved product containing 1500 mcg methylcobalamin. **In a letter to the FSSAI, CDSCO had brought to the notice that various brands of products containing methylcobalamin are manufactured and sold having therapeutic intervention under the FSSAI license.**

Nutraceutical and drug industry have alleged that FSSAI and CDSCO have been turning a blind eye to the contentious issues raised with reference to RDA values of vitamin C and other micro-nutrients like methylcobalamin which are vital for boosting immunity, mental health and other co-morbid chronic ailments in the crucial juncture of COVID-19 pandemic. The central government has also recommended 1000 mcg of vitamin C as prophylactic use against COVID-19 whereas its RDA is 40 mcg due to poor regulatory and policy interventions from apex and responsible authorities like ICMR, FSSAI and DCGI.

Unmindful of the concerns regarding RDA for mental health conditions and neurological disorders, industry has dubbed FSSAI as white elephant and urged the centre that there is no need of FSSAI as the authority is not competent enough to talk on technical and scientific aspects and only relies on the dictates of ICMR. It is a sheer wastage of public money which has been pooled in to maintain an authority which is doing more harm than good.

Industry players have also voiced concern that methylcobalamin's RDA value has been approved by CDSCO up till 2000 mcg but FSSAI is approving only 1 mcg which is of no use. DCGI has approved 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.

FSSAI and CDSCO have been drawing flak from the industry as there is no clarity on TUL and RDA values of many micronutrients including vitamin C and methylcobalamin. The issue has been festering due to missing exact information on TUL of vitamin B12 [methylcobalamin to be specific] from the public domain. No adverse effect has been associated with excess methylcobalamin intake from food or supplements in healthy individuals.

Methylcobalamin has a history of safe long term use as a therapeutic agent given in high dosage or via intramuscular injection for the treatment of disorders associated with impaired vitamin B12 absorption. Additionally, we had received a letter in December 2019 from FSSAI about methylcobalamin's approved RDA value for neurological disorders by the technical committee but industry is yet to see the notification on the same.

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). 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 1 year without any progress for inclusion of methylcobalamin in the gazette.

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