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VACCINE UPDATE

A Macro Insight to a Micronutrient METHYLCOBALAMIN

Management of co-infection of COVID-19 with other seasonal epidemic prone diseases

Dilly dallying in notifying METHYLCOBALAMIN lays bare red tapism in key apex Institutions like FSSAI and ICMR

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ADDRESS
INDIAN OFFICE
Jaipur-167, Pratap Nagar, Khatipura Road, Jaipur, Rajasthan-302021
+91 9821104101, 9958855039
Ahemdabad 7, Om Complex, Near Swastik Cross Roads,CG Road,Ahmedabad, Gujarat-380009 # +91 9821104101, 9958855039
INTERNATIONAL OFFICE
Denmark Dr. Janne Harild, Skovduevej 23 3120 Droningmoelle. Denmark

Write to us @
qualpharmainternational@gmail.com

FROM THE DESK OF EDITOR - IN – CHIEF

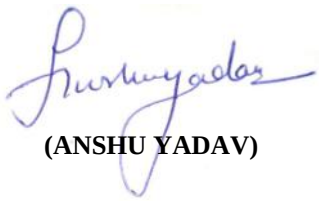
Dear Readers,

There has been lot of confusion like whether Methylcobalamin is banned or approved, what is the per usage serving value of the product etc. Methylcobalamin is 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.

At present there is no clarity on tolerable upper limit (TUL) along with confusion on RDA value of methylcobalamin. This is all the more contradictory considering that ICMR and National Institute of Nutrition (NIN) have recently issued another report which have different stipulated RDA values of methylcobalamin and estimated average nutrient requirements for Indians. QualPharma fully endorse that the RDA and per usage entity must be separated entity for nutraceuticals and FSSAI should review it technically.

Coming back to our edition we have **SHINDE JAGANNATH SAKHARAM Chairman – MSCDA LTD , AIOCD LTD & President** – The Maharashtra State Chem & Drug Association **(p16)**on our cover page and profile of Mr **RAJIV SINGHAL General Secretary of AIOCD (p18)**. You may keep yourself updated on Corona stories, medical and marketing articles and zodiac prediction from our expert.

You may know more about us through http://www.qualpharma.in/. **STAY UPDATED STAY BLESSED** and do not forget to follow up our blog https://qual-pharma.blogspot.in/ to receive regular interesting updates.



(ANSHU YADAV)

December Contents

Dilly dallying in notifying METHYLCOBALAMIN lays bare red tapism in key apex institutions like FSSAI and ICMR

Our Fight Continues

Omission of key micro-nutrients like methylcobalamin in Food Safety and Standards Authority of India (FSSAI) health supplement regulations 2016 as well as the ongoing methylcobalamin ban have not only led to a chaotic scene in the industry but also laid bare red-tapism of key institutions like the Food Safety and Standards Authority of India (FSSAI) and the Indian Council of Medical Research (ICMR), so much so that the pharma experts have outrightly defied the ban and asked for clarity from the Union Health Ministry, Union Ministry of Chemicals and Fertilizers & Drugs Controller General of India (DCGI).

Both FSSAI and ICMR have been adamant in their approach wherein FSSAI has not responded responsibly as yet on the key issue of revoking the ban on methylcobalamin.

However, under the current premise and having bore the brunt of the insensible behavior of the authorities, a recent representation has been made to Union Ministry of Chemicals and Fertilizer. The consultants have once again recommended DCGI to be given the sole authority for implementation of nutraceutical policies and regulations, citing FSSAI as a toothless body. Ten years ago, nutraceutical was under DCGI itself.

Nutraceutical and drug consultants have alleged that FSSAI has been turning a blind eye to the contentious issues raised with reference to RDA values of Vitamin C and other micronutrients like methylcobalamin, which are vital for boosting immunity, mental health and other co-morbid chronic ailments in the crucial juncture of COVID-19 pandemic.

Prime Minister Narendra Modi has recommended 1000 mg of Vitamin C for prophylactic use against COVID-19 whereas its RDA is suggested as only 40 mg due to poor interventions by apex and responsible authorities like ICMR, FSSAI and DCGI.

Dr Sanjay Agrawal

Dr Agrawal has actively worked in pharmaceutical and related industries for more than 35 years and started this firm Pharmaceutical Consultants and Inventor in 2005. He is **Editor-in-Chief** of renowned IJM Today . Dr Sanjay Agrawal is the illustrious member of the National Geographic Society and ex-member of scientific committee of IDMA. He had received various awards for his valuable support and contributions in Healthcare and pharmaceutical sector Dr. Agrawal obtained his postgraduation in Biochemistry from prestigious institution. He has worked with many International and national Pharmaceuticals companies. Dr. Sanjay Agrawal is the patent holder of atleast 40 research formulations.

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). Since, source of methylcobalamin is from non-vegetarian products hence supplementation with methylcobalamin becomes very essential, specially for Indians. Therefore, when a supplement is taken prophylactically, it must at least be of the therapeutic dose.

There has been lot of confusion like whether Methylcobalamin is banned or approved, what is the per usage serving value of the product etc. 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.

Gujarat FDCA Commissioner, Dr H G Koshia, has been quoted as saying that 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 urged the FSSAI to take action against Gujarat-based manufacturers for manufacture and sale of methylcobalamin meant for therapeutic intervention which is in contravention of the norms. 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.

On the other hand Former CEO of FSSAI Pawan Agrawal had promised in December 2019 that methylcobalamin has been approved by their scientific committee and in due course of time will be included in the gazette. But it's been almost a year without any progress regarding the inclusion of methylcobalamin in the gazette.

On January 7, 2020, FSSAI issued a notification regarding RDA of vitamin B12 wherein it was mentioned as 1 mcg without mentioning which type of vitamin B12 like methylcobalamin, adenosylcobalamin, hydroxycobalamin or cyanocobalamin.

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.**

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 mention the same RDA for both methylcobalamin and cyanocobalamin. It is noteworthy that here the discussion is about 'per serving' usage value which the manufacturer can refer to and not the RDA value for a healthy person.

At present there is also no clarity on tolerable upper limit (TUL) along with confusion on RDA value of methylcobalamin. This is all the more contradictory considering that ICMR and National Institute of Nutrition (NIN) has recently issued another report which has different stipulated RDA values of methylcobalamin and estimated average nutrient requirements for Indians.

It is well-known that Vitamin B12 is present majorly in non-vegetarian sources. Here it is noteworthy that in a country such as US wherein major population consume non-vegetarian products, the RDA for methylcobalamin is 2.4 mcg whereas, in India, most of the population consumes vegetarian diet, but the RDA set is a mere 1 mcg.

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 indicating lobbying and malafide intent to discourage industry and to satisfy vested interests."

Pharma experts have also voiced concerns that when methylcobalamin has been approved by CDSCO up to 2000 mcg then why is FSSAI recommending only 1 mcg, which is of no use. DCGI has approved 2,000 mcg of methylcobalamin even in injectable form and respective brands are available as physicians recommend methylcobalamin based on the patient's medical condition. It is pertinent that other countries have kept RDA and 'per serving' usage value as separate entities. This concept is currently being goofed up by FSSAI in India.

"There is an urgent need for inclusion of methylcobalamin in the gazette and reviewing the RDA for nutraceutical products, by not forgetting that products are already available at higher concentrations", informs pharma expert Anshu Yadav. She further adds, "that until and unless FSSAI does not inform the industry that methylcobalamin is approved, there is no value of prescribing RDA value for the same."

We as stakeholders of pharma fraternity have appealed to the Centre to delegate the responsibility of nutraceutical division to the DCGI in our recent representation made to Union Ministry of Chemicals and Fertilizers. Ten years back nutraceutical was under DCGI only.

~By Dr Sanjay Agrawal

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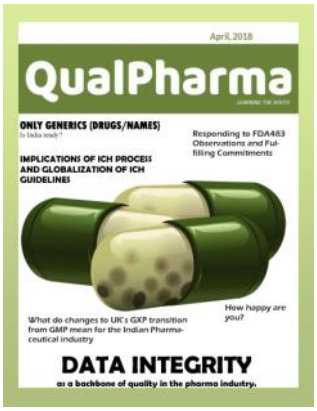

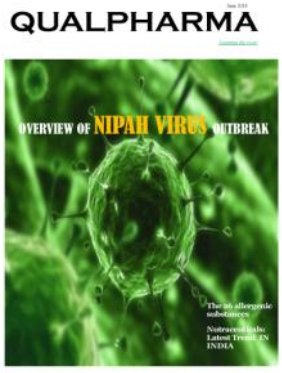

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ADDRESS INDIAN OFFICE

Jaipur

167, Pratap Nagar,
Khatipura Road,
Jaipur, Rajasthan-302021
+91 9821104101, 9958855039

Ahemdabad

7, Om Complex, Near Swastik Cross Roads,
CG Road,
Ahmedabad, Gujarat-380009
+91 9821104101, 9958855039

INTERNATIONAL OFFICE

Denmark

Dr. Janne Harild
Skovduevej 23
3120 Droningmoelle
Denmark

http://www.qualpharma.com