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QualPharma

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The Learning and Development Journal

**Patent
Opposition
in India**

**OXFORD
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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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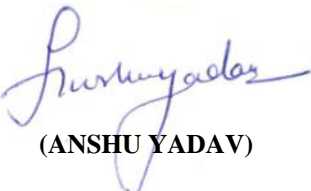
Dear Readers,

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 JAGAN-NATH SAKHARAM Chairman of MSCDA LTD , AIOCD LTD & President of 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)

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

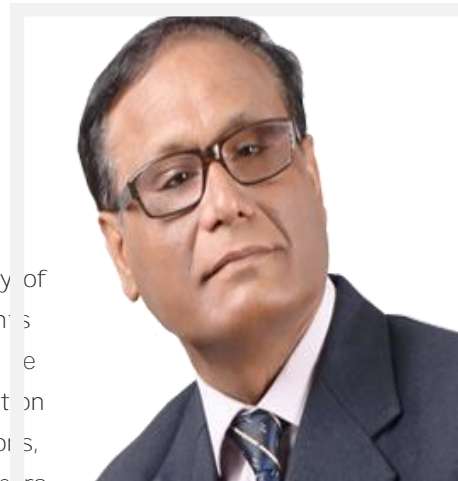
Our Fight Continues

Omission of key micronutrients like methylation has been made to Union Ministry of thylcobalamin in Food Safety and Stan-Chemicals and Fertilizer. The consultant's standards Authority of India (FSSAI) health have once again recommended DCGI to supplement regulations 2016 as well as the given the sole authority for implementation ongoing methylcobalamin ban have not of nutraceutical policies and regulations, only led to a chaotic scene in the industrying FSSAI as a toothless body. Ten years ago, nutraceutical was under DCGI itself.

tions like the Food Safety and Standards Authority of India (FSSAI) and the Indian Nutraceutical and drug consultants have Council of Medical Research (ICMR), so alleged that FSSAI has been turning a blind eye to the contentious issues raised with much so that the pharma experts have rightly defied the ban and asked for clarity reference to RDA values of Vitamin C and from the Union Health Ministry, Union other micronutrients like methylcobalamin, Ministry of Chemicals and Fertilizers & which are vital for boosting immunity, men- Drugs Controller General of India (DCGI). tal health and other morbid chronic ailments in the crucial juncture of COVID

Both FSSAI and ICMR have been adamant pandemic. in their approach wherein FSSAI has not responded responsibly as yet on the key prime Minister Narendra Modi has recom- issue of revoking the ban on methylcobalamended 1000 mg of Vitamin C for prophylactic use against COVID-19 whereas its RDA is suggested as only 40 mg due to poor

However, under the current premise and interventions by apex and responsible authorities having bore the brunt of the insensible authorities like ICMR, FSSAI and DCGI. behavior of the authorities, a recent represen-



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 at least 40 research formulations.

Methylcobalamin is an essential nutrient and food safety officers to launch survey improved, there is no value of prescribing and is required to treat vitamin B12 deficiency drives against various brands of RDA value for the same. Surprisingly the deficiency in people with pernicious anaemia, products containing methylcobalamin mails which we have received from FSSAI diabetes and other conditions as well. It is being manufactured and sold under mention the same RDA for both methylcobalamin and cyanocobalamin. It is important for the brain, nerves and for FSSAI license. It is noteworthy that here the discussion is the production of red blood cells (RBCs). Since, source of methylcobalamin is from On the other hand Former CEO of FSSAI about 'per serving' usage value which the non-vegetarian products hence supplement-Pawan Agrawal had promised in December- manufacturer can refer to and not the mentation with methylcobalamin before 2019 that methylcobalamin has been RDA value for a healthy person. comes very essential, specially for Indian approved by their scientific committee At present there is also no clarity on tolerance. Therefore, when a supplement is 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 on RDA value of methylcobalamin. taken prophylactically, it must at least be in the gazette. But it's been almost a year without any progress regarding the inclusion on RDA value of methylcobalamin. of the therapeutic dose. This is all the more contradictory considering that ICMR and National Institute of

There has been lot of confusion like whether Methylcobalamin is banned or On January 7, 2020, FSSAI issued a notification regarding RDA of vitamin B12 other report which has different stipulation value of the product etc. Methylcobalamin is widely marketed in the country about mentioning which type of vitamin B12 estimated average nutrient requirements a drug for chronic neurological disorders like methylcobalamin, adenosylcobalamin, hydroxycobalamin or cyanocobalamin (RDA) of 2000 mcg intramuscular but as per FSSAI it is detrimental for patients when used above 1 mcg for prevention and disease management. The dual standards of FSSAI can also be seen by the presence of already FSSAI approved brands available with 1500 mcg RDA for methylcobalamin is 2.4 mcg whereas, in India, most of the population there is a ban on methylcobalamin. Some of the widely sold brands are Copopen cap per FSSAI directive. The Central Drugs Standard Control Organisation (CDSCO) 500 mcg injection, Nuroz Forte, had urged the FSSAI to take action against Gujarat based manufacturers for 2500 injection, etc. There are more manufacture and sale of methylcobalamin than half a dozen other brands with 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

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 MU X U j ' ' = h ' '] g ' ' b c k ' ' U a d ' ' m issue about taking action on methylcobalamin manufacturers is totally uncalled for. Reason being that the letter issued by FSSAI deputy director to Gujarat state methylcobalamin manufacturers without

QA & REGULATORY

any intimation to the then FSSAI CEO medical condition. It is pertinent that try that methylcobalamin is approved, Pawan Kumar Agarwal indicating lobby- other countries have kept RDA and 'perthere is no value of prescribing RDA value ing and malafide intent to discourageserving' usage value as separate entitiesfor the same."

] b X i g h f m ' U b X ' h c ' g U h] This concept is currently being worked up by FSSAI in India. We as stakeholders of pharma fraternity

Pharma experts have also voiced concerns have appealed to the Centre to delegate

that when methylcobalamin has been "There is an urgent need for inclusion ofthe responsibility of nutraceutical divi- approved by CDSCO up to 2000 mcg themethylcobalamin in the gazette and re-sion to the DCGI in our recent represen-

why is FSSAI recommending only 1 mcg, viewing the RDA for nutraceutical prod-tation made to Union Ministry of Chemi- which is of no use. DCGI has approveducts, by not forgetting that products are als and Fertilizers. Ten years back 2,000 mcg of methylcobalamin even inalready available at higher concentra-nutraceutical was under DCGI only.

injectable form and respective brands aretions", informs pharma expert Anshu available as physicians recommend me- Yadav. She further adds, "that until and-By Dr Sanjay Agrawal methylcobalamin based on the patient'sunless FSSAI does not inform the indus-

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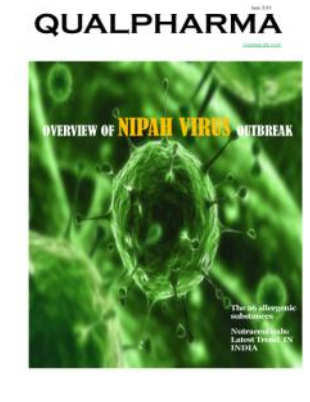
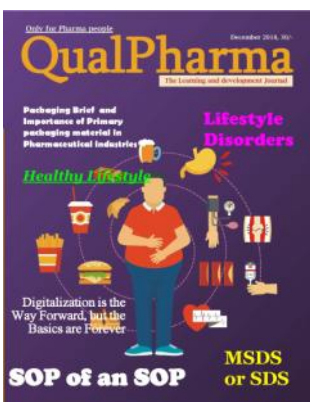
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