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The Learning and Development Journal

Pharmaceutical experts wants right prescription for ailing

FSSAT

The Evolution of **FSSAI**

Top 10 Interesting Biological Research Paper Topics for

PhD

CO-DEPENDENCY EMOTIONAL PUPPETRY

Post Covid-19

Critical Quality Measures for Pharmaceutical Production

E-PHARMACY V/S BRICK AND MORTAR PHARMACIST Online war for Battle of survival

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Editor–in–chief Ms Anshu Yadav

Senior Copy Editor Ms Ragini Arya

Editor Dr. Sanjay Agrawal

Consulting Editor

M.D Parashar

Image Designer Amaresh K A-Cube Graphics

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Design & Publications QualPharma -International

Write to us @ qualpharmainternational@gmail.com

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FROM THE DESK OF EDITOR - IN – CHIEF

Dear Readers,

Pharmaceutical experts is fighting for more than a year to release the gazette approving methylcobalamin. So far the regulators had approved only hydroxycobalamin and cyanocobalamin which is an inferior B12 as compared to methylcobalamin. The former CEO Pawan Agrawal had promised in December 2019 that methycobalamin has been approved by scientific committee and will take the due course of its time to be included in the gazette. Nevertheless the Pharma experts has waited for almost a year without any progress for inclusion of the product in the gazette. QualPharma support the pharma experts opinion.

Coming back to our edition we have Bodh Raj Sikri Key Promoter of ABS Group on our cover page. 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 <u>http://www.qualpharma.in/</u>. **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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CORONA UPDATES

Vaccine progress in India

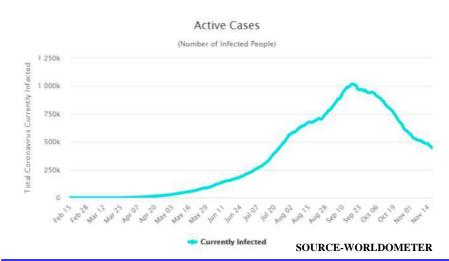
The centre is betting on five vaccine candidates currently undergoing clinical trials in India.

- 1. Oxford -AstraZeneca candidate for which Serum Institute is conducting Phase 3 trials.
- 2. Bharat biotech's COVAXIN conducting Phase 3.
- Russia's Sputnik V which is expected to start Phase 2/3 trials.
- 4. Cadila's shot which has almost completed Phase 2 trials
- 5. Biological E is in Phase1/2

SPUTNIK V UPDATES

Russian Sputnik V vaccine that claims 92% efficacy have not been peer reviewed or published. The Russian Direct Investment Fund has reached agreements with its Brazilian and Indian partners on conducting clinical trials. It has also reached an agreement with pharmaceutical firms in China and India to launch production of the vaccine in these countries not just to cover their needs, but for the third countries as well.

Active Cases in India



CORONAVIRUS SPECIAL

GLOBAL FRONTLINERS

Pfizer study found that the vaccine was 90% effective in preventing Covid.

Moderna's Vaccine found to be 94.5% effective

STORAGE AND DISTRIBUTION REQUIREMENT			
Pfizer-BioNTech	Moderna		
STORAGE AND TRANS	PORT TEMPERATURE		
-70 DEGREE CELCIUS	-20 DEGREE CELCIUS		
SHELF LIFE			
5 Days at refrigerator temperatures	30 days at refrigerated temperature		
DOSAGE			
Two doses, 3 weeks apart	Two doses, 4 weeks apart		

Though a positive result, both the companies result will not help to improve the conditions in India. Given an option Moderna vaccine would be better as it can be stored at -20 degree C in commercial deep freezers. Most other vaccine in the pipeline only require refrigeration , not freezing temperature . Moderna's longer shelf life will also make distribution easier.

However, as both Pfizer and Moderna's are two dose vaccines, India would need nearly 3 billion doses for its entire population. Neither of them will be able to produce such large quantities in the near future.

Pharmaceutical experts wants right prescription for ailing **FSSAI**

Our Fight Continues

Methylcobalamin is an essential nutrient and is required to treat vitamin B12 deficiency, in people with pernicious anemia, diabetes and other conditions as well. It is important for the brain, nerves and for the production of red blood cells (RBCs).

Pharmaceutical experts is fighting for more than a year to release the gazette approving methylcobalamin. So far the regulators had approved only hydroxycobalamin and cyanocobalamin which is an inferior B12 as compared to methylcobalamin. The former CEO Pawan Agrawal had promised in December 2019 that methycobalamin has been approved by scientific committee and will take the due course of its time to be included in the gazette. Nevertheless the Pharma experts has waited for almost a year without any progress for inclusion of the product in the gazette.

Alarmed and infuriated at the ongoing raids on methylcobalamin, manufacturers and industry has raked up methylcobalamin ban issue terming it as an extortion bid by state drug controllers (SDCs) in name of regulation.

FSSAI has been drawing flak from the Pharma experts as ban on methylcobalamin has become a contentious issue today. There is no clarity on tolerable upper limit (TUL) and RDA value.

According to an Pharma expert, "The dual standards of FSSAI can 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.



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.

According to Gujarat FDCA Commissioner Dr H G Koshia, **"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 earlier urged the FSSAI to take action against Gujaratbased 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.

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 me-

METHYLCOBALAMIN – 1MCG Vitamin C– 40 mcg Is it enough for prophylactic use?

thylcobalamin being manufactured and sold under FSSAI license.

Pharma experts have voiced concern that methylcobalamin's RDA value has been approved by Central Drugs Standard Control Organisation (CDSCO) to 2000 mcg but FSSAI is approving only 1 mcg which is of no use. Drugs Controller General of India (DCGI) had approved 2,000 mcg of methylcobalamin even in injectable form and such brands are also available as patients take methylcobalamin based on the medical condition.

Unfortunately due to slow process, though approval nod for Methylcobalamin, yet it is not included in the gazette. 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 have received many emails from the regulators who had referred RDA of methylcobalamin. So it is not clear how regulators are talking about RDA without inclusion of the product in the gazette. Surprisingly in the mails which we have received from FSSAI, methylcobalamin and cyanocobalamin both have the same RDA value to manufacture. Probably FSSAI is confused about the RDA required and per serving usage to be manufactured. We are repeatedly talking about per serving usage value which the manufacturer can refer to and not the RDA value for a healthy person.



However, 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.

The hurdles for the nutraceutical manufacturers will not be solved by only inclusion of methylcobalamin in the gazette but also by revising the irrational enforcement of RDA of methylcobalmin.

ICMR and National Institute of Nutrition has issued another report on RDA and estimated average nutrient requirements for Indians 2020 which says a completely different story. According to the report there is limited evidence to suggest a level at which adverse events can be observed. In the Norwegian Vitamin (NORVIT) intervention trial, patients with acute myocardial infarction received 400 µg of B12 daily for 3 years and reported no serious adverse events. In another study (HOPE 2), patients with vascular disease or diabetes aged >55 y received 1 mg B12 daily for 5 years and reported no serious adverse event with this treatment. Additionally, the IOM (1998) also states that there is no adverse effect associated with excess B12 intake from foods or supplements in healthy individuals.

The ICMR report also says that "there is limited absorption of Vit B12 from gastrointestinal tract with high doses, and therefore, IOM did not establish an upper limit for B12.

The evidence from the limited data is not sufficient for deriving Tolerable Upper Limit (TUL). Further, the Indian population mostly consume vegetarian diets which do not provide B12, except milk and its product. Therefore, high intakes of B12 from foods are unlikely.

Therefore the manufacture must be allowed to produce atleast to the therapeutic dose.

An another document University of Rochester Medical Centre have claimed that **"Your body can't absorb all the vitamin B-12 from dietary supplements. Absorption is limited by** how much intrinsic factor your stomach makes. Intrinsic factor is needed for your body to absorb B-12. For example, only about 10 mcg of a 500 mcg oral supplement is actually absorbed in healthy people."

Additionally "Vitamin B-12 deficiencies tend to be caused by not getting enough B -12 in your diet. They can also be due to a reduced secretion or lack of intrinsic factor. This is a stomach secretion that helps the body absorb vitamin B-12." In such case supplementation is recommended. I am leaving the readers with an open Question **"Is this ban on methylcobalamin by FSSAI really worth?"**

~By Dr Sanjay Agrawal

For any clarification or suggestions, readers may contact with QualPharma technical team.



The immune system against COVID 19 is long lasting

Researchers who monitored 185 men and women, aged 19 to 81, who had recovered from Covid-19 found that most still had enough immune cells to prevent illness eight months after the infection.

The new study, which has not been peerreviewed, involves analyzing multiple compartments of immune memory over time: antibodies, B cells and T cells, among other features of immune memory. This has been contradictory to the earlier claims which says antibodies for COVID-19 wane fairly soon which is causing re-infection.

The T-cell immunity is a better and more durable marker for this novel virus. If India's vaccination policy, when made, recommends that vaccines may be conserved for priority use for non-immune subjects, then, a rapid T-cell immunity test, such as the one developed in Cardiff, will be better than antibody tests.

Therefore, developing simple and rapid assays for T-cell immunity should be a priority for Indian scientists to work on, quickly. Those with T-cell immunity may need no vaccine, or only a single dose of a two-dose vaccine regimen.



CORONAVIRUS ADVISORY TO RESIDENTS

The Ministry of Health advised residents on Wam to take precautions while travelling to countries affected by the Coronavirus and described its symptoms and precautionary measures.

TRAVEL ADVISORY ON CORONAVIRUS BY MINISTRY OF HEALTH ADVISORY TO RESIDENTS TRAVELLING TO COUNTRIES AFFECTED BY THE CORONAVIRUS

- Avoid contacting with animals (live or dead).
- Not using animal products.
- Avoid attendance in livestock trading markets.

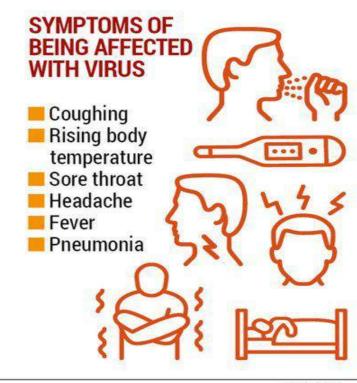


- Stay at home and avoid mixing with others.
- Immediate medical assistance providing travel information and symptoms.
- Ávoid travelling in case of any disease symptoms' seen.
- Cover mouth, nose with tissues/handkerchief when coughing or sneezing.
- Wash hands at least 20 seconds with water and soap or sterilisers.

HOW TO PROTECT FROM COMMON VIRUSES

- Wash hands with water andsoap.
- Avoid direct contacting with those affected by any disease.
- Avoid touching eyes, nose, mouth without washing hands.
- Cleaning surfaces, which gets contaminated quickly.
- Avoid direct contact with animals.





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PERSONALITIES

BODH RAJ SIKRI

KEY PROMOTOR ABS GROUP



B R Sikri

Bodh Raj Sikri is a Bachelor of Arts from **Punjab University Chandigarh** with 48 years of Experience in his pocket which includes Six Years in Haryana State Government (1970-76), three years in Government of India (1976-79), 10 Years in Public Sector Undertaking (1979-1989) and seven Years in Pharma Sector (1989-1997). Since 1997 onwards Mr Sikri is involved in his own business of Pharmaceuticals, Imports, Exports, Manufacturing, Trading, Indenting, Marketing, Printing & Packaging.

He has been serving the nation through various Pharmaceutical Associations in the following capacities: -

1) Chairman - Federation of Pharma Entrepreneurs (FOPE)

2) Vice President (north Zone) , Indian Drug Manufacturers Association (IDMA) 3) Secretary, Indian Drug Manufacturers' Association (I.D.M.A) (HP & UK)
4) Vice President (north zone) , Bulk Drug Manufacturers Association (BDMA)
5) Vice-Chairman, Confederation of Indian Pharmaceutical Industry (CIPI), which represents SME.

6) President, Pharma Indenting Agents Association (P.I.A.A.)

7) Chief Advisor, Himachal Drug Manufacturers' Association (H.D.M.A)
8) Advisor – Pharmexcil (Pharmaceuticals

Export Promotion Council of India)

9) Chairman, Local Organizing Committee

– Indian Pharmaceutical Congress 2018

Mr Sikri is a leader and takes part various SOCIAL ACTIVITIES. Few of them are

- Running charitable dispensary in the Name of "ABS Charitable Dispensary" in Gurugram and giving free consultation, and medicine to all patients. This dispensary has doctors in the fields of Allopathy, Homoeopathy, and Physiotherapy.
- President Trustee Shyam Ji Mandir, new Colony, Gurugram
- **Trustee** Panchnad Samarak Trust, Haryana, ABS Welfare Trust, Gurugram Jampur Nishkam Trust (Regd.), Hardwar – 25 bedded Bhawan, which is providing accommodation to yatries. and Rishi Chaitnya Trust being run by Her Holiness Anandmurti Guru Maa, Gannaur, Sonepat.

- Running a School in Gurugram;
- Vice-President, Punjabi Biradari Mahasabha, Gurugram.
- Patron All Punjabi Welfare Association (R), Gurugram.
- President Jampur Welfare Association (Regd.) – Running Jampur wellness center, E-library, Library.

The Pharma Express (A Publication of Indian Express) has included Mr. B.R. Sikri in the top 10 Pharma Leaders, in the recently published coffee book titled "Stalwarts of North India (visionaries transforming Indian Pharma). Mr. Sikri is awarded "President's Award" From IDMA for his "Fine initiative in representing important matters of the Indian Pharmaceutical Industry at Delhi. Indian Pharmacy Graduates Association has given him award of "Resource Person". Intellectual Property Rights (IPRs) and Regulatory Perspective for Pharma & Biotech Sectors presented an Award to him at Panjab University, Chandigarh in his capacity as Co-Chairman, Federation of Pharma Entrepreneurs (FOPE), New Delhi as Keynote Speaker. Pharmaceuticals Export Promotion Council of India (Pharmexcil) presented an Award to him on 13th Annual Meet of Pharmexcil He has recieved Samaj Ratna Samman and Pransha Patra by All Punjabi Welfare Association, Gurugram.

The evolution of

The FSSAI (Food Safety and Standards Authority of India) may have begun its operations by regulating the overregulated Pharmaceutical Industry, but is now evolving into a globally recognized food regulatory authority. The Economic Times on 10th August 2020, quoted former FSSAI CEO, Mr. Pawan Agarwal as saying that **"citizens have huge stakes in ensuring that the country gets its food system right and work towards that end".**

The gradual shift towards **'foods of mass daily consumption'**, the core food industry, is a welcome move for the public and this shift is getting global recognition. FSSAI has been named among the top ten finalists for the Food System Vision Prize by US-based Rockefeller Foundation. The entity was selected as a top ten finalist for its **'Eat Right India'** program from over 1,300 applicants across 110 countries. Mr. Pawan Agarwal opines that it is

"a global endorsement of the work

done under Eat Right India".

The vision statement of **'Eat Right India'** calls for 'a robust regulatory system that includes setting science-based, globallybench-marked standards, credible food testing, surveillance, and enforcement. It also called for hygiene and sanitation standards across the value chain through a graded approach, conscious consumption, mass mobilization and behavioural shifts to urge people to eat right'.

In recent times FSSAI has made moves to display 'date of manufacture' and 'best before' for sweets. It has now banned the blending of mustard oil with other cooking oils. Adulteration of milk, ghee, honey, icecreams, sweetmeats and many spices is a great public health concern. The use of unauthorised colouring and sweetening agents must be regulated in many 'foods of mass daily consumption'. In Pharma, even the miniscule amounts of colouring agents are tightly regulated, but mass exposure through foods can happen.



Mr Prabhakar Shetty

Mr Prabhakar Shetty is the founder of Body Satva Essentials and author of 'HOP in the Mind'. Prabhakar is a Microbiology graduate from St. Xavier's College, Mumbai. From MR in 1973, he rose to the position of Associate Director PMT, Parke Davis in 1997, which included a 1 year assignment based at New Jersey, USA.. He was part of the 'Strategic Planning Cell' and the world wide 'Core Marketing Team' of Parke Davis / Warner Lambert. He has handled many mega brands and launched over 50 brands in India, including Proleukin and Cardioxane of Chiron, US. He has conducted training programs at Puerto Rico, Philippines, Nepal and Sri Lanka. After his last assignment (ending July 2018) as VP Marketing at Apex Labs, he is a Marketing Consultant & owns Body Satva Essentials with an ecommerce portal

www.bodysatva.com

The Economic Times reported on 1st October 2020, that the Centre has moved to revamp FSSAI. It is proposed to giving it more powers, extending its jurisdiction over animal feed, enhancing penalties imposed for violations and simplifying processes. This will hopefully address the massive chemical contamination of the food chain. The meat and poultry industry, rampantly uses antibiotics, steroids and growth enhancers. This is in addition to pesticides and other environmental pollutants like toxic heavy metals.

A wide variety of chronic inflammatory diseases, infertility and even cancer are linked to these factors.

Adulteration of milk or diluting it with water is a compulsive obsession for milk vendors. Most of the vegetables and fruits sold in cities, like Mumbai, are chemically treated for various reasons. People who have spent some time in rural areas, can easily tell the difference between the natural and artificially ripened, coloured or preserved fruits.

In conformity with the Vision Statement of 'Eat Right India', FSSAI should **focus** on ensuring safe and 'balanced nutrition' to the general population. In India, we generally eat well cooked or fried foods. Awareness about trans fatty acids, may help to stop the reuse of cooking oil or it may reduce the consumption of fried foods. Balanced nutrition is a huge issue, because we generally consume low quantities of proteins. Consumption of fruits and salads is much lower than desirable levels, even amongst the well-fed people.

Hence, Vitamin and Mineral deficiencies are very common. Demographically, India is like many different countries, with major differences in dietary patterns. FSSAI is now undertaking another welcome step of fortifying certain foods with Vitamins, according to reports in the Press.

Vitamins, Supplements and Nutrients

This segment was worth Rs.11,744 Crores and 7.9% of the Indian Pharmaceutical Market in July 2020. Vitamins and Supplements would generally be the most sought after 'Physicians Samples' by Doctors across India. Yet the official position was always against Vitamins and Minerals as it could cause 'hypervitaminosis'. Have a look at the US statistics for Vitamins and Supplements. The projected Market Size is \$18.3 billion and growing at 15%. The annualized 'market size growth' from 2015-2020 is 17.4% (IBIS World). They are the ones who talk about the hazards of 'hypervitaminosis', and we get worried in a country where malnutrition is an issue. Currently, there is a lot of confusion about the classification of a formulation or molecule as a Drug or Nutraceutical or

Food Supplement. Between FSSAI and FDA, they should consider improving the 'ease of doing business', while protecting the interests of the public.

Water Soluble Vitamins

Often, the quantity of vitamins allowed for a Nutraceutical or Food Supplement is so low that it may be useless. This is true for most of the water-soluble vitamins. During the Covid19 pandemic, people were scrambling to find Vitamin C supplements. Most authorities were suggesting Vitamin C 1000 mg as a preventive, but there are hardly any brands available. A few brands with 500 mg could be located on the internet, but all others seem to



have 40mg, the ICMR RDA value. The RDA value of Vitamin C for adult males in the USA, is 90 mg per day. The top 10 OTC Vitamin C brands in the USA are having Vitamin C 500 mg or 1000 mg. Can we apply the same logic since the **'Tolerable Upper Limit'** or TUL is above 2000 mg for Vitamin C.

While nobody disputes the validity or the concept of RDA, supplements should be allowed to provide a useful quantity which is below the TUL, but above the RDA. A case in point is Vitamin B12 or it's active component Methylcobalamin. The RDA is set around 1.2 mcg (US 2.5 mcg) but the TUL is far above 1000 mcg. It takes 8 weeks of Vit B12 supplementation to normalize Vit B12 levels in 90% of 100 older patients (Marilyn H Hill et al, J Nutr. 2013 Feb.). In another 16 weeks RCT, they found that the lowest oral dose of Vitamin B12, to normalize mild Vitamin B12 deficiency 200 times greater than the RDA of approximately 3 mcg for older men (Eussen S J et al, Arch Intern Med. 2005 May 23;165(10):1167-72).

There are quite a few FSSAI approved brands with 1500 mcg Methylcobalamin, in spite of the low RDA. Diabetics using Metformin, develop Vitamin B12 deficiency and I was a bit concerned when there was some news that it will be banned as a supplement. Thankfully, it is not yet banned, and there are numerous clinical trials which have proven that it has a very high TUL.

There is a dire need to permit doses below the TUL but significantly higher than RDA, especially in India. This is because we thoroughly cook our food and destroy all the water-soluble vitamins.

Non-Prescription Drugs

The awareness level of Indian Patients is increasing by leaps and bounds. There is an increasing trend of just consulting the Pharmacist for minor ailments, because going to a Doctor is time consuming and expensive. The Government may be considering a demand from Pharmacists to dispense common medicines without a prescription. As in the USA, we must allow OTC sales of some common drugs, if they are at **50% of the therapeutic dose**.

A few illustrative examples are given below;

- Zantac 75, is the OTC version of Ranitidine whose therapeutic dose is 150 mg
- Prilosec OTC is a delayed release Omeprazole 20 mg tablet.
- Prevacid 24HR is a delayed release Lansoprazole 15 mg capsule.
- Advil and Motrin have OTC versions with Ibuprofen 200 mg
- Anaprox and Aleve have OTC ver-

sions of Naproxen Sodium 220 mg tablets

- Zyrtec and other Cetirizine brands are Non-Rx drugs
- Claritin and other Loratidine brands were shifted from Rx to OTC in 2002.
- Allegra and other Fexofenadine brands were shifted from Rx to OTC in 2011.
- Glucosamine HCL 1500 mg and its combinations with Chondroitin Sulphate and MSM are sold OTC. Medical evidence shows that Glucosamine has to be given as a single daily dose 1500 mg, to penetrate the knee joint (synovial fluid). This is a very apt case for allowing the therapeutic dose as the OTC or Non-Rx dose.

In a rapidly evolving market, with increasing digitalisation, on-line consultation and sales are bound to increase. Mobile phones with internet have penetrated every nook and corner of India. There is a massive increase in the number of people accessing information about medicines. OTC and Non-Rx drugs will be a boon for this new generation.

Nutrients

While infant foods may need tight regulation, a more liberal approach can be adopted for Probiotics, Protein Powders and Nutritional supplements, Vitamin analogues or derivatives and natural Antioxidants, including the flavonoids. Pyridoxamine is a vitamer of Pyridoxine (Vit B6) and therefore the RDA of Vit B6 (1.3mg for adult males) will apply to it's formulation. However, Pyridoxamine is proven to be effective for AGE inhibition, Neuropathy, Retinopathy and Kidney Stones at doses between 25-100mg. (US brand is Pyridorin).

Benfotiamine is an analogue of Thiamine (Vit B1), but at the RDA of Vit B1(1.2 mg for adult males) it is practically useless. At



doses between 50-200mg, it is useful for AGE inhibition, Neuropathy, Retinopathy and the treatment of Infertility.

Both Pyridoxamine and Benfotiamine cannot be classified as drugs. In such situations, currently there is no solution that is useful to the patients. In such situations, a joint consultative process with the FDA, must be adopted. It is a matter of pride that FSSAI has evolved into a globally recognized food regulatory authority. We in the Pharmaceutical and Nutraceutical Industry look forward to greater collaboration, for resolving the issues that may crop up, occasionally. Let's work together for the mutual benefit of all the stakeholders and most importantly, for our customers.

~ By Prabhakar Shetty

Conclusion

- . PATENT
- . INDUSTRIAL DESIGN
- . PLANT VARIETY PROTECTION
- . LITIGATION & ENFORCEMENT
- . TRADEMARK
- . COPYRIGHT
- . LICENSING ASSIGNMENT
- . FOREIGN INVESTMENT

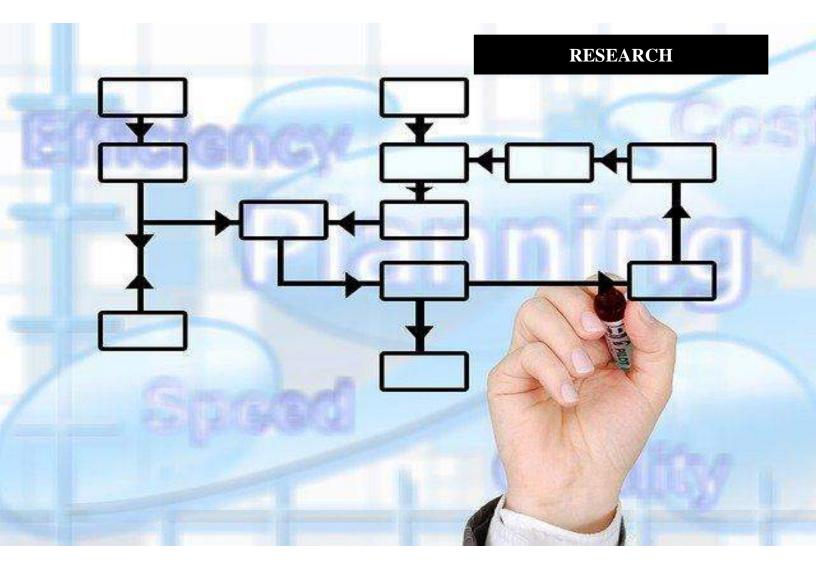
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Top 10 Interesting Biological Research Paper Topics for



RESEARCH

The field of biological sciences, studying the science of life, from the microscopic like-looking microorganisms to plants, animals, and humans, biology never fails to amuse us with fascinating knowledge about the way of life. Nowadays with more and more people opting for a career in this exciting field, the field of biosciences is witnessing a growing competition. Thus, it is vital to start proving your domain knowledge, abilities, and skills, as early as possible in your career. One of the ways to boost your knowledge in your area of interest and also to add value to your profile is by engaging in writing a research paper.

A research paper is a form of communication in which the researcher briefly, but in great detail, presents, and interprets data collected in the research. Writing a research paper requires you to engage with a variety of sources, demonstrate a strong knowledge of your topic, and make an original contribution to the area of research. But first, finding the right topic for your research paper a crucial part Given that the world of biological sciences is in itself greatly intriguing, trying to select the most interesting topic could seem like a daunting task. Of course, this is easier when you already have a favorite in mind, but if you are someone in search of interesting topics that are currently trending in the scientific research community, this article is for you. This Article is a special article dedicated to tell most important research topics for P.hd.

1.CRISPR and Genetic Engineering CRISPR, the Nobel Prize-winning technology that has capture the scientific community, is definitely one of the most interesting and exciting research areas., the CRISPR technology is the new faster and easier approach for modifying DNA. Scientists Emmanuelle Charpentier and Jennifer A. Doudna discovered this gamechanging genetic engineering technique, the CRISPR/Cas9 genetic scissors, for which they have been awarded the Nobel Prize in Chemistry 2020. This tool facilitates making specific changes in the DNA of humans, other animals, and plants, and has been adopted in research labs worldwide within only a few years.CRISPR has various applications and is made use in the industry, laboratory, and in the field of medicinal research. CRISPR has become a valuable tool in research. Imagine being able to make people permanently resistant to tricky viruses like HIV, or could cure genetic diseases, or change your eye colour. All these seem possible with this tool, while it could also cause great harm. Nowadays Scientists are working in this technique, thus making it a compelling topic for research.

2. Epidemiology and Coronavirus

Pandemic distrupted our lives on multiple levels, it had bad effect on ourself with anxiety peaking it is difficult to look at the positivity...Whenever there is any disease outbreak or other threats emerge, the causes of health outcomes and diseases in populations are determined with the help of epidemiology. Epidemiology involves studying how often diseases occur in different groups of people, why do they occur, and how does it spread in populations. The field of epidemiology is in particular, an interesting topic given that we are now in one of the largest pandemics the world can remember. Scientists called epidemiologists often called "Disease Detectives" working along with other scientists, are keen on finding out everything about a newly emerged infectious disease. Currently, epidemiologists all around the world are studying the disease and are working to identify the source of the COVID-19 outbreak, and are providing recommendations to control the spread of the disease. Epidemiology intrigued scientists even before the covid -19 outbreak and thus has always been an interesting area of research.

3. Cancer Biology

Cancer research has been a constant area of research in biology where scientists study about the various kinds of cancer and try to identify the causes, develop strategies for diagnosis, treatment, cure, and prevention of the disease. Research on the biology of cancer starts with the simplest of questions: What is normal and what isn't? Given that cancer is actually many diseases, each with its own cause,

RESEARCH

progression, outcome, and treatment, it is not as simple as finding the solution to one disease. Developing safe and effective methods for detecting, treating, preventing and, ultimately, curing cancer is the goal of studying cancer. Research on topics like molecular biology in cancer treatment, targeted therapy in cancer treatment, stopping cancer in its tracks, developing personalized cancer treatments, and so on are some of the interesting topics under this research area.

4. Prions

Prion' is a term first used to describe the mysterious infectious agent responsible for several neurodegenerative diseases found in mammals. These infectiousdisease-causing agents are the reason behind diseases such as chronic wasting disease, mad cow disease, and even Alzheimer's disease (possibly).

Prions enter brain through infection, or they can arises from mutation in the gene. Once present in the brain prions multiply by inducing benign protein to refold into normal shape.

5. Astrobiology

We are yet to discover life outside of Earth, however, astronomers have found overwhelming support for the idea that there's a good chance life exists somewhere out in the cosmos. Astrobiologists are the scientists who study life in the Universe, and are trying to find answers to the big questions: Does life exist elsewhere in the Universe? How does life begin and Astrobiology research has a significant impact on how agencies such as NASA plan for current and future space missions, and is already making major contributions to planetary science missions. Astrobiologists work on finding various things related to life on space such as what happens to circadian rhythms on **nifer A. Doudna** have been awarded for their discovery, **the CRISPR/Cas9 genetic scissors.** This tool can be used for changing the plant, animal, and microorganism DNA with extremely high precision. This revolutionary technology has had an exceptional contribution to the life sciences. The technology is contributing to the latest therapies and might make the dream of curing inherited diseases a real-



planets with a different day/night cycle, how plants grow in space, and how gravity affects astronauts' bones, and so on.

6.The Nobel Prize in Chemistry 2020 Goes To CRISPR Gene Editing Emmanuelle Charpentier and Jenity.

7. Anti Microbial Resistance

The ability of microorganisms to grow despite being exposed to antimicrobial substances developed to inhibit their growth is known as antimicrobial

RESEARCH

resistance (AMR). AMR poses a global challenge to human and animal health as well as to the environment, given that microorganisms are getting stronger at fighting against antibiotics, the medicines used to prevent and treat bacterial infections. This is a result of overusing and misusing antibiotics.

8. Microbiome

Microorganisms are present in various habitats (in and on plants, animals, water, soil, food, and humans), and they live together in communities called microbiome within each of the many habitats. The microbiome is a term that describes the genome of all the microorganisms, symbiotic and pathogenic, living in and on all vertebrates, categorized depending on where they exist, such as human microbiome, gut microbiome, and so on.

There are numerous facts and questions about the microbiome that are unanswered and understanding the human microbiome could help in yielding tremendous insight into the effects of the microbiome on humans. This exciting field has a lot of scope with researchers finding out more interesting facts about the microbiome and how it can help humans. Driven by advances in technology in recent years, microbiome research has increased dramatically.

9. Synthetic Biology

The field of science involving redesigning organisms for useful purposes by engiknown as synthetic biology. Synthetic biologists study and focus on ways to restructure organisms and enable them to perform useful tasks such as engineering microorganisms to help with bioremediation efforts in polluted areas or to produce medical-g In order to solve the problems faced in the medicinal field, agriculture, and other fields of biological sciences, synthetic biology researchers and companies around the world are harnessing the power of nature to develop a solution. This field has several interesting topics to unravel.

neering them to have new abilities is

10. Epigenetics

Epigenetics is one of the best part of biology,the study of how genes are inherited in either a switched-on or switched-off state. Even though this is also elebroate you inherit certain genes from your ancestors, some might not actually be "turned on" despite being present in your DNA. Genes that have been "turned off" are technically inactive, just like a light switch. Epigenetics is a relatively new field of biology that adds a whole new layer of complexity to the already exciting realm of genetic research.

So these are the special article dedicated to all P.hd students. ~By Monika Nagarkoti



Monika Nagarkoti

Monika Nagarkoti has completed her graduation in Bachelor in Science in Zoology and Post- Graduation in Microbiology subject from Department of Biotechnology, Bhimtal, U.K.

She has completed her schooling from L.W.S. School, Pithoragarh, Uttrakahand.

She has strong interest in Cancer Biology. In future, she would like to persue Cancer research.

She believe that one should follow our passion, and it will lead us to our purpose.

" I feel snug in the Qualpharma, as if it grew around me like a cosy blanket, comforting me while it nurtures my talents and hones my skills.

-MONIKA NAGARKOTI

CO-DEPENDENCY EMOTIONAL PUPPETRY

Addiction affects not only the individual afflicted by it but also affects loved ones closely associated with the person suffering from it. Addiction is thus a **"Family Disease"** and treating one without treating the other can have disastrous consequences.

Co-dependency has a range of behaviours that manifest in relationships. In addiction, the dependent lives his/her life around drugs/alcohol The family and close friends base their lives around them trying to control their usage, in the bargain losing their identity.

The co- dependent who has thus lost control over a chaotic life searches for a semblance of control by taking on responsibilities of the house, many times the business, the children and the affairs of the dependent.

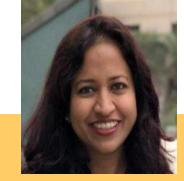
They give more love, care and respect to the dependent than they will ever receive back. They are ridden by insecurities and a low self esteem making them believe that they cannot live without the other person. What they think as "love" turns out to be clinginess, emotional dependency, possessiveness and the like, thereby stifling themselves and the loved ones.

There is a huge amount of resentment that accumulates. There are manipulative behaviours that consciously or unconsciously surface in order to get the love ,care and respect they crave from the other.

Co-dependents can be passive or active.

The passive co-dependents dread and fear conflict and will do anything to maintain the peace. This probably arises out of the fear of being alone, low self esteem and low self worth. They would be abject people pleasers who never can say no even if it hurts them or inconveniences them. They manipulate the dependent subtly and subversively into receiving love and care from them. This could be by:

- giving them money for their alcohol/ drug usage to avoid a fight
- Buying alcohol/drugs for them out of fear



Dr.Sujatha Nair

A Bachelor in Homoeopathic Medical Science from Mumbai with a Post Graduation from The Hahnemann College of Homoeopathy – London. In clinical Homoeopathic practice since the year 2000. She has been working in the field of Addiction since the year 2005. A Post Graduate in Counseling practices she uses her skills as a physician and counselor in treating her clients.

Also a Diploma Holder in the science of Yoga and Sanskrit from the Mumbai University. A meditator herself, she blends Yoga, Homoeopathy and meditation into the treatment of Addiction and its underlying ailments.

Dr.Sujatha Nair as is evident, is passionate about the Vision of Anatta Humanversity, of Paving a Path towards a Life beyond Substance Abuse.

One co-dependent who had visited us actually wanted her husband to continue to drink because only when he was drunk he would be nice to her and would not be violent towards her!

- Creating a wedge between other constructive relations and the dependent thus isolating him from others for oneself.
- Playing the victim consciously or unconsciously, blaming the person addicted for the miserable state of mind /life they are leading, thus emotionally manipulating the other through guilt.
- The children too are many a time emotionally manipulated and controlled as the dependency shifts to them.

Thus their methods adopted to manipulate are covert and subtle and the usually intelligent person addicted to the substance fails to see it.

The active co-dependents can appear to be domineering and are not afraid of confrontation. They would many times be confrontational when the person afflicted is intoxicated resulting in a fight which can take ugly turns. They can pick up arguments and demand the love, time, respect and care that they feel is their right, that the person afflicted should be fulfilling, but is not, due to the all consuming addiction to alcohol/drugs. Here too the codependent is unable to walk away or emotionally detach from the dependent and live their lives. Under the hope that some day this person shall look at them and see them and their Love and care and will change towards them.

The feeling that they need this relationship to feel complete or to fulfil them. The belief is that, the responsibility to care for their emotions, love and self respect is on the other person. Their lives have been made a living hell because of the person who is using.

This garners sympathy from family and friends and puts them in the "right " only as a matter of relativity of the other using the substance, thus, being in the wrong. Many times ,the addiction of the dependent is kept in wraps, excuses made for and violence hidden because of the feeling that it is my duty to protect him/ her from the world and I can take



care of him/her, I can make him stop his addiction. If I hide it I am listening to him and he will love me more and will value me. Or, If I talk about it I will have to face shame, blame and ridicule from society.

Thus the co-dependents emotional manipulation that is unconscious or conscious, most times results in enabling the afflicted person's addictions. Sadly, if the co-dependency is not treated, the codependent does not realise that they are responsible for whatever is happening in their lives and are the result of choices they have made.

When the person addicted goes into a rehabilitation treatment process and change happens in him, he takes control of his life and starts participating in the family dynamics which he/she had been isolated from due to the addiction, taking responsibilities of the children, of work etc. Here, the co-dependent if untreated, feels threatened and insecure again and the happiness at the sobriety of the afflicted is short-lived. The resentment and the bitterness boils over and they try to again control the situation which leaves them also baffled. Now, being in the "right" as a matter of relativity is also absent.

The Co-dependent can become a right kind of enabler to get the dependent into accepting help by following the guidelines below:

- The right time to speak is in the morning when you know the person is sober and clean and is in remorse.
- The right thing to share is what one feels and experiences as a consequence of the other's drinking/using without blaming and shaming the individual for it
- Say that if he thinks he needs help then get him to meet the experiential addiction counsellor who can motivate him to come into residential rehabilitation treatment.
- Once the person comes into treatment of his own free will, into a non-medical residential facility, then it is primarily through sharing, self disclosure, writing, meditation and other alternate therapies that would be the apt therapeutic modalities that would get him to understand himself, increase his awareness of self and reach to a stage of not finding the need to use.

When the individual who is addicted comes into treatment it is very essential for the family to come into counselling and receive parallel treatment themselves with the family therapist. It is very important for them to realise through therapy that they are solely responsible for their emotions and the way they feel, it is a choice. This realization and sense of responsibility makes them self- reliant and not emotionally dependent on the person who suffers from addiction.

The communication after the loved one comes back home after the right treatment:

It is very natural at this time for the codependent to feel that this individual who was an absentee father/mother, an absentee son/daughter, an absentee husband /wife suddenly wants to take on and participate in all these roles . It takes time for the co-dependent family to accept and acknowledge this apparent sudden shift in paradigm. It is not easy for them to then leave their control over the house, the children, the business, the finances. This is due to their past experiences with the individual when they were drinking and using. If they have not received help and worse, if they have not accepted help for themselves, the spouse , parent or children of the dependent continue to look at the addict who is now in recovery with " old eyes". The past is brought up frequently and thrown at them in arguments and conversations.

Expectations also increase with the person back home as though going to the rehab has been a miracle turning point and everything will now be fine. Far from reality, the actual life issues surface and are and have to be faced head on with emotional stability.

The right communication post treatment:

- Do not throw the past at each other's face
- Face a fresh issue as a fresh one.
- As Dr Jerajani says "Stop Comparing, Criticising, Complaining and Questioning each other" what remains is only the doorway to communication.
- Let the language change to that of sharing, being transparent and honest.

However, the above is truly possible only when the spouse/family are willing to and work on themselves too as much as the person addicted to the substance does, with the writing, the counselling and the meditations.

When the Individual in residential treatment and the co-dependent become selfreliant individuals, then they can meet on a common platform of friendliness and compassion. Dysfunctionalities dwindle away and a life that is truly fulfilling beyond drinking and using surfaces. This is a process and requires patience, effort and compassion between all parties involved.

Treatment involves Counselling with an experiential co-dependent counsellor and possible residential treatment in a loving, compassionate, understanding, non judgmental environment where in the codependent gets the time and space to look at oneself and learns to detach emotionally from the other and recognises that responsibility of one's happiness lies within oneself. The process involves, meditation, Counselling, introspective writing and other therapies in order to reconnect with one self.

Anatta Humanversity provides an in house facility for Co-dependents, a loving conducive environment through Meditation and Counselling to realise their true self, love themselves and live life with joy!

~Dr.Sujatha Nair

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Post Covid-19: Critical Quality Measures for Pharmaceutical Production

As, you all are aware about current pandemic transmission of Covid-19, a novel corona virus. To control the transmission and to get rid of this problem government has taken lot of steps. One of the step is lock down and restrictions on the people gathering, local transportation etc.

In today's discussion I will not discuss about how to safeguard from the Covid 19 transmission but yes I would like to make you aware about some potential risks due to this problem related to compliance level in our pharmaceutical industry. Hence today I am here with you for discussion about Consistent Compliance plan.

You may be aware that, about 25% of revenue is generated through the Pharmaceutical domain. Now considering the current situation Pharma manufacturing is considered as essential services and still working during this period. But one point we should not forget that considering the current situation the Pharma companies are running with some practical problems which may be directly or indirectly impact on the compliance level of the products manufactured during this period and overall cGMP compliance.

If we follow the GMP principles correctly, there will not be any non-conformance or product failure.

As, we all aware about basic GMP principles, we will not much focus on GMP principles, but will discuss the points which are normally not focussed.

Due to this pandemic situation, pharmaceutical companies are facing lot of problems. Hence, it is not good practice to raise deviation for each problem. So, you can prepare consistent compliance plan (CCP). On the basis of this plan, holistically you can evaluate the areas impacted and move on further on basis of evaluation of calculated risk. The actions can be taken by raising quality notifications.

Due to so many restrictions and lock down Pharma companies might have suffered from one or more problems;

The problems may be-

• Lack of Sufficient manpower,



Hitendrakumar Shah

CEO - NADH⁺ GXP Compliance Services

Web: www.nadhgmp.com

- The weak moment of the people working in the area led to more deviations, investigations, OOS or OOT etc.
- Unavailability of the transportation – Impact on receipt of input materials, dispatch of the finished goods.
- More focus on current product analysis and less focus on stability sample testing.
- SFDA 厚生労働省 来在品质品监计管理网 Bphrm : Germany Japan China in Medicines Agency European Medicine Agency Patient's Safety Canada TGA ustralia U.S. Food and Drug Administration Agência Nacional Sweden de Vigilância Sanitária US Brazil NADH+ GXP Compliance Services

Who regulates the Pharmaceutical Industry

- Less support Brazil
 from third parties for example pest control, calibration agencies, laundries etc.
- Lack of sufficient quality oversight etc. and many more.

There were so many such problems. Hence, I would like to suggest you to prepare the consistent compliance plan. The plan should be based on the risk assessment considering your organization practices. You may not perform fresh risk assessment. You can refer earlier risk assessment, review it, evaluate whether all the control measures or mitigation plan suggested are being followed or not.

Also, you need to develop a review mechanism of the activities performed.

We need to have problem solving approach to prepare consistent compliance plan.

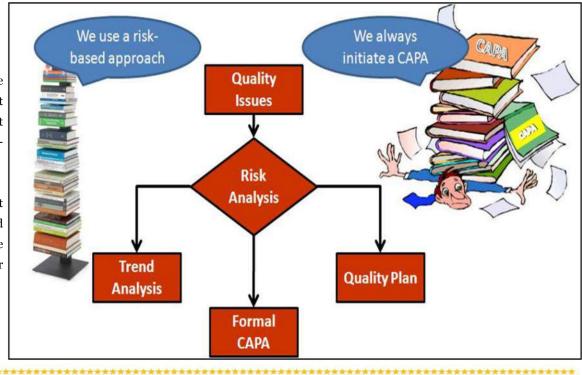
The problem solving approach includes;

Define Problem

- Analyze
- Develop Alternatives
- Select Action Plan
- Implement Action Plan
- Follow Up.

Avoid the finger pointing:

The personnel will be under pressure while working in such situation and weak moments. Hence avoid the finger pointing.



Deciding the priority: As, many activities are required to perform but due to lack of sufficient resources, you can perform priority matrix.

On the basis of consistent compliance plan, would like to suggest you to take additional precautions or actions to avoid



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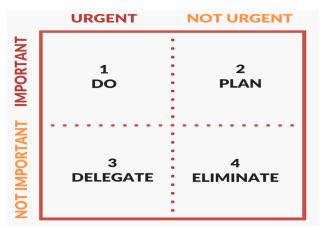
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errors, nonconformance or product failure.

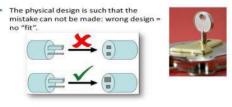
The additional precautions includes, increase in in process checks, increase frequency of quality oversight procedures, increase in Gemba etc.

If you want to have action plan to avoid noncompliance or failures, you can follow Poka-Yoke principle. For example, if you want to maintain social distancing in park or in your apartments, you can design the sitting benches such that, automatically the social distancing can be formed.

~By Hitendrakumar Shah



Poka Yoke- Example







POKA-YOKE

Poka-yoke is a Japanese term that means "mistake-proofing" or "inadvertent error prevention". A poka-yoke is any mechanism in any process that helps an equipment operator avoid (*yokeru*) mistakes (*poka*). Its purpose is to eliminate product defects by preventing, correcting, or drawing attention to human errors as they occur.

The concept was formalised, and the term adopted, by Shigeo Shingo as part of the Toyota Production System.

E-PHARMACY V/S BRICK AND MORTAR PHARMACIST

As the internet evolved and pervaded into the Country, the retail market had adopted a new technology adding one more medium to reach the consumers. When offering products including food items and other consumables are accepted, the trading of on-line medicine alone is challenged now. With lower price and easy accessibility, the members of the brick and mortar retail chemist/ pharmacist feel hurt and threatened.

The rapid growth of e-commerce continues to present challenges to the State and Central Governments in the trade of online pharmacy. The protests made, when Amazon, Flipkart and Snapdeal, entered in general / retail, are being continued in retail medicine. It has further intensified after Indian Giant Reliance has ventured in the same vertical.

The Central Government continues to lag in passing a specific legislation aimed at the On-line pharmacy industry as of now & thus an online war for the battle of survival continues

It is uniformly contended that purchasing the medicines through on-line is physically easier than going to the pharmacies especially for the senior citizens, i.e., the age group that spends most on drugs, the consideration is an important one. The on-line medium offers modern medical care tools and as such, their reminder information about the medicines and also render round the clock assistance. Online pharmacies allowed the patients to purchase the drugs discreetly without face to face interactions. The rise in online pharmacies also creates more supply options for the purchasers to find the best service and price. The above benefits undoubtedly have contributed to the growth of the on-line trading, of-course, without licence. While considering the benefits and advantages in the online trading, there are also several risks which are unique to the online trading.

<u>Disadvantages to a purchaser of on-</u> <u>line.</u>

- Misuse of a prescription, especially in narcotic and psychotropic drugs, schedule X drugs, etc.
- Yet another risk is that the patient may receive the counterfeit drugs, which are sub-standard
- A patient receives a prescription drug based on on-line questionnaire instead of a valid prescription, which may result in serious side effects and this may be the most common risk without any regulation.
- Lack of physical evaluation.



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- The on-line selling of medicines does not require valid prescription, even when selling the prescription drugs.
- The chance of the prescription drugs are delivered without any information to the patients.
- The sale of medicines through Internet intermediaries and the State and Central Governments cannot control the illegal sales.
- Some are related to online buying like missing items, price difference or incorrect pricing, receipt of substitutes or different brand's medicine, delay or refusal or cancellation of order and/or payment, unresponsive customer care, etc.
- Lack of understanding of the medical

history if buying from different online pharmacies

- Lack of cold chain logistic services and moreover, it is exorbitantly expensive for rural areas
- Lack of data security
- Illegal e-pharmacy websites selling contaminated, adulterated or expired medicines
- Unregulated sale of medicines
- Lack of specific governing regulations related to e-pharmacy

In on-line trading of medicine, the requirement imposed on a customer is the prescription of a drug, but it is alleged that on -line pharmacists do not comply with the laws and are selling prescription drugs and controlled substances without valid prescription and they are also offering discounts for bulk purchases of prescription drugs.

Pharmacies and Retailers have long sought to shield their market from on-line traders of medicines protecting consumers in the process. There are no distinction between legitimate and illegitimate on-line medical store. Intermediaries, who profit from dealing with online pharmacies, have no regulations. It is their broad reach and function, they are able to balance their interests. Another crucial lifeline in Internet commerce is the financial intermediary. They impose their own condition of use. Again, here only a handful of companies dominate the majority of the market.

The growth of on-line purchase of medicines is encouraged also by the direct exposure to pharmaceutical advertisement. The increased exposure to pharmaceutical products through all modes of communication like Television, Radio, Internet, social media etc coupled with less face to face consultation has given patients a false sense of empowerment. The practice of "self-diagnose" by consumers also drive them to on-line pharmacies. On-line pharmacies provide consumers the ability to compare the price and availability also. While it is timeefficient, it affords more privacy than the brick and mortar pharmacy.

AIOCD PERSPECTIVE

Rajiv Singhal, General Secretary, AIOCD had earlier informed that all epharmacies are operating illegally and in violation of the provision of Drugs and Cosmetics Act, 1940 and Rules, 1945 framed thereunder. AIOCD has already filed a case against the NITI AAYOG in the Delhi High Court & have been fighting against e-pharmacy entities since long and are in continuous discussion with Central Government, which were kept on hold due to sudden outbreak of pandemic COVID-19. Various High courts have passed an order against Central Government and E-pharmacy operating without a law in place and without a license.

Earlier as quoted by Mr Singhal (General Secretary, AIOCD) "Online pharmacies

will facilitate easy entry of drug mafias / spurious drugs severely impacting the health and wealth of common man and in particular youth of India. AIOCD also submitted memorandums to Government seeking action against E-Pharmacies. It continues to fight for its 8.5 lacs plus members who will be definitely be impacted with the blossoming of epharmacies. January 2019 witnessed a your raise voice programme by AIOCD who on behalf of 8.5 lacs chemists & druggists in India who held a nationwide "HALLA BOL" campaign against e-pharmacy on 8th Jan 2019. Under the campaign --district level associations brought out rallies to hand over memorandum to FDA & Collectors of 719 districts in the country. Same was also carried by state associations who submitted MEMORANDUM to state health ministers and state FDA Authorities.

The All India Organisation of Chemists and Druggist (AIOCD) has opposed the commercial promotion of online pharmacies on the AarogyaSetu App. It has also written a letter to PM objecting Niti Aayog's move to allow epharmacies to be promoted through the government's application. The AarogyaSetu App platform listed four epharmacies – 1MG, PharmEasy, NetMeds and MedLife.

AIOCD's main contention has been internet pharmacies and the illusion that epharmacies are reaching out to customers at their homes. AIOCD also complained against a link on the AAROGYA SETU application

WWW.AAROGYASETUMITR.IN, a website affiliated to the Central Government and AAROGYA SETU application. The AIOCD has appealed to Prime Minister and other concerned Ministries / top bureaucrats to delink the e-pharmacy marketing app, and resume a meeting with AIOCD to discuss the agenda of sale of medicines on the Internet after the COVID-19 pandemic lockdown.



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AIOCD had stated, "AarogyaSetu Mitr has been developed by private players in collaboration with the Government. AIOCD believes that private players and organisations who have developed the website have vested commercial interests and have misled the Government and the public trust reposed in the AAROGYASETU APP by permitting illegally operating e-pharmacies to register on the website. But the Government must keep in mind, during natural calamities like floods or pandemics like COVID-19, when normal operations were paralysed, it was only and only the local chemists who rushed to help of public across the country day and night.

The Swadeshi Jagaran Manch (SJM), an RSS affiliate, had also strongly objected to the promotion of some e-pharmacies via the Aarogya Setu app developed by the government.

The government later in June 2020 suspended the AarogyaSetu Mitr portal, which is linked to the Aarogya Setu app to promote online sale of medicines, following objections by nearly 8.5 lakh brickand-mortar retail chemists across India. The petitioner had termed the move to link the portal with the Aarogya Setu app as illegal, arbitrary and discriminatory because it served as a marketing tool for e-pharmacies only and excluded marketing, distribution and sales by the offline chemists.E-pharmacies are illegal under the law and continue to operate despite an injunction order passed by this court.

As on date, there are no proper rules or regulations for on-line trading of medicines. The State Government has conveniently shirked the responsibility stating that as the Drugs & Cosmetic Act is a central legislation, any addition/deletion/ amendment under the provisions of the D & C Act, can be done only by the Central Government.

Public notice way back in March 2011 was issued inviting comments from various stakeholders. The Union of India also seems to have received numerous comments and suggestions from various stakeholders, including the All India Chemists and Druggists Association, wherein, the petitioner association is a member, and the Indian Internet Pharmacies Association. After deliberations on the concerns raised by the stakeholders, the Central Government decided to bring a regulatory framework for the sale of online medicines

Notification in August 2018 was issued by the Ministry of Health and Family Welfare, Government of India, publishing the draft rules to amend the D & C Rules, once again calling for objections and suggestions from all the stakeholders to be considered by the Central Government. The comments and suggestions were received and after due deliberations, the draft rules have to be published for finalisation in the official Gazette.

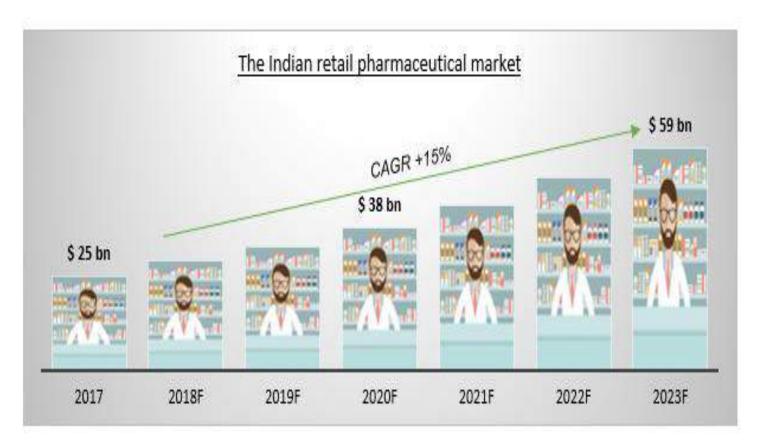
Unless the legislation keeps pace with the technology, the commerce based on technology has to lag behind. While the draft rules are published in the Gazette, they are yet to be notified. Once it is notified, there is bound to be disagreement between law makers, drug companies, online traders and finally the consumers. In the absence of any Central or State Government legislation or rules, on-line sale of prescription drugs could hardly be curbed. Countries like U.S.A. which has the new laws in place also finds the enforcement of the same as a difficult challenge. While the pros and cons of the online pharmacy is debated, the stakeholders and the Central and State Governments are aware of the need for a cohesive system of regulation to be notified regulating on-line drugs trade.

Online pharmacies are facilitating easy entry of drug mafias / spurious drugs severely impacting the health and wealth of common man and in particular youth of India. Online portals cannot sell narcotic drugs, tranquillisers and Schedule X drugs, and cannot advertise their services, as under the Drugs and Cosmetics Act. Under the new rules, complete information on the medicines will have to be provided by the e-pharmacy holders, and a 24/7 helpline should be made available. The attraction of the online pharmacy, for many, is the fancy discounts that are available, up to 60%, besides free home delivery and sometimes, other valueadded services.

AIOCD has been vehemently opposing entry of giants Reliance, Amazon and Flipcart and have written to respective companies and to PMO. Their contention are that traditional formats will always have the advantage of knowing customer personally and will always be emotionally well connected. This piece will and can never be served by online pharmacy. Traditional pharmacy are closer to the proximity of customers and hence they will remain customer's first choice when it comes to acute medicines

FUTURE OUTLOOK

With robust CAGR of 63%, buoyed by an increased access of medicines to a majority of under-served population, long term drug compliance for chronic conditions, and rising internet penetration some estimates put the total number of online pharmacies at 250, with at least 50-60 of them termed as large players. Online sale of medicines could account for 15-20% of total pharma sales over the next 10 years — due to multiple factors including 'Digital India', e-healthcare initiatives, increasing health insurance, and schemes like Ayushman Bharat — says a report by Frost & Sullivan. According to another report by IBEF, the Indian retail pharmaceutical sector is estimated to reach \$59 Bn (2023) from \$25 Bn (2017), growing at a CAGR of 15% (2018-23). For all domestic consumptions, Indian retail pharmacies are the dominant distribution channel with more than 85% share of the overall pharmaceutical sales in India. Retail pharmacy refers to retail channels which sell prescription and over the counter drugs along with FMCG products as well as certain generic testing services such as blood testing, sugar testing, etc.



Source: IBEF and EY

Like manufacturers, retail pharmacy market is also highly fragmented in India which currently has over 850,000 offline pharmacy retail stores with no dominant retail chain in terms of the market share. According to the Research and Markets, these traditional brick and mortar retail pharmacies are currently responsible for ~99% of the pharmaceutical sales, while online pharmacy or epharmacy contributes ~1% of the total therapeutic sales but according to Net-Meds, the e-pharmacy presently accounts for ~1.5-2% of the total pharma sale and by looking at the rapid growth that the industry is seeing today the penetration level can go to over 10% by 2023.

In recent years around 250 online pharmacies have sprung up in the country. According to Frost & Sullivan, the epharmacy market in India is estimated to grow at an exponential CAGR of 63% and reach \$3.6 bn by 2022 from the current \$512 million market (2018).

Research and Markets estimates that the e-pharmacy market potential is very high with giants like Reliance, Amazon, Flipkart, and more than 30 start-ups trying to grab a slice of the pie. The e-platform is led by Medlife, Netmeds, 1MG, PharmEasy, Myra, CareOnGo and Pharmasafe.

Co-founder of one digital platform had said that the priority would be to make

clarifications to the court. Hoping against hope they expect the draft is released soon so that there is continuous supply of medicines to millions of families which are now dependent on online platforms for purchasing monthly medicines & are spread across the country - right from tier one cities to a small taluka in a remote area.

So, there will be push for early publication of rules to help regulate emedicines market & online pharmacies considering legal recourse against ban.

So what is likely to happen is an appeal against the verdict.

The legal process will take its course and the affected companies will come together to make sure that on line model is understood well and the court clarifies the order.

E-pharmacy is not only competing with traditional pharmacies but also with the government-operated Jan Aushadi Kendra, which is a new initiative by the government, this offers discounted drugs and medicines. The market has a huge potential due to its model of access to medicines much faster, core convenience and real savings for consumers. The sector is lucrative for investors, who have fueled \$900 Mn during 2018 and 2019 in online pharmacies (Source: venture intelligence). Though brick and mortar stores will retain its dominant position, synergy should emerge with the right ecosystem, suitable and propitious policies with the desired scale of investments. It is believed that once the specific regulation will be finalized, there will be more and more online players in this untapped market with immense potential in the future. Amidst this, consumers will always be more important than online or offline pharma retailers when it comes to drugs.

Currently, there are no specific regulations governing e-pharmacies in India and this is a major growth inhibitor for the online pharmacy market in India. All online pharmacies are operating as per the Drugs and Cosmetics Act, 1940 (D&C Act); Drugs and Cosmetics Rule, 1945 (D&C Rule); Pharmacy Act, 1948; and Information Technology Act, 2000 (IT Act). The Union Health Ministry in August 2018 came out with draft rules on the sale of drugs by e-pharmacies to regulate the online sale of drugs and patients' accessibility to genuine drugs from authentic online websites. However, this draft is still awaiting formalisation and finalisation.

Indian Healthcare sector – A promising \$353 Bn opportunity by FY 25 The Indian healthcare industry is at an exciting tipping point, with Indian Govt. prioritizing healthcare as one of the key focus areas for the next few years. The Govt. plans to increase its healthcare

Legal Issues	Existing Regulations	Proposed Rules
License	It is mandatory for retailers to obtain a license for the sale of medicines as per D&C Act and D& C Rules.	Create a National Portal for transacting and monitoring the online sale of drugs
Storage and transportation	License is granted only after ensuring that pharmacist's premises is adequately equipped for storage of medicines and medicines sold are to be given by hand to a patient as per D&C rules.	Since e-pharmacy is an intermediary, its registration, functions, responsibilities need to be fixed under D&A Act
Prescription	A valid prescription is mandatory for the sale of drugs as per D&C Act.	Sale of online medicines is to be carried through the proposed Electronic Prescrip- tion Exchange
Dispensing medicine by regis- tered pharmacist	Medicines shall be dispensed under the personal supervision of a pharmacist ac- cording to D&C Act and Rules and Phar- macy Practice Regulation.	Prescription is required by a registered medical practitioner and sold through li- censed pharmacies only.
Geographical restriction	Geographical restrictions at the licensed premises by D&C rule	Sale of medicines within the respective state from where the order has been placed and this should not be interstate
Patient confidentiality	Indian Medical Council(Professional Con- duct, Etiquette and Ethics) Regulations, 2002: and Pharmacy Practice Regulations, 2015 makes strong provisions for patient confidentiality	Patient confidentiality in accordance with the IT act.
Supervision by drug inspector or drug controller	The premises where drugs are sold, stocked, exhibited can be inspected by drug inspector.	Provision relating to supervision shall be followed as per the existing laws.
spending from the current 1.6% to 2.5%		
of the GDP until FY 25.	-	\$255 healthcare expenditure per capita inFY 25, significantly up from the current\$99.
There is significant opportunity for im-	FY 25. This will lead to an overall (Govt.	+//
proving the healthcare services across the	and Private) increase from 4.6% to 7.1%	Source: Secondary Research & Articles /
country, where penetration of quality and	spending on healthcare (as % of GDP) in a	blogs and AIOCD bulletins/news
affordable outpatient & inpatient care ser-	span of 6 years. The private spending will	
vices is limited.Moreover, increased	witness a ~2.6x increase during this period	~Debasish M Banerjee
awareness levels amongst consumers is further going to drive higher healthcare	to reach \$228 Billion. This along with \$125	
interest going to unive inglier incaltificate	Billion government spending, will lead to	



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PREDICTIONS FOR December 2020 By Astrologer Sudha Agrawal

PREIDCTIONS FOR December 2020

ARIES (MESHA)-----{NAMES BY AA, LA, <u>EE, I}:-</u>



Aries Horoscope is not beneficial for career progression. You fail to enlist the support of seniors and associates. This will prevent you

from sticking to your targets. Even hard work will not be remunerative. Travel for professional purposes will not be gainful. You can only work hard and wait for the arrival of good tidings

TAURUS (VRUSHABHA)-----{NAMES BY BA, VA, OO, U}:-



Taurus Horoscope forecasts an encouraging month for career progress. You will have the support of colleagues and the man-

agement in your efforts. People engaged in fine arts and creative fields will make good progress in their fields. Travel for professional purposes will help career growth. Relationships in the workplace will be quite harmonious. This will help in achieving targets easily.

GEMINI (MITHUNA)-----{NAMES BY KA, CHHA, GHA}:-



Gemini Horoscope indicates that the month is encouraging for career growth. Professionals will have the backing of seniors and

colleagues for discharging their duties. You will be able to reach your targets easily. Your efforts will be rewarded generously. The environment at the workplace will be extremely pleasant.

CANCER (KARKA)-----{NAMES BY DA, HA}:-



Cancer Horoscope foretells that there will be major alterations in your career profile. If you are not

happy with the job, you will go in for a new job. There may be a change in career responsibilities in the same organization. It is also possible that there will be changes that may last for quite some time.



TA}:-



Leo Horoscope for professionals presents a pleasant scenario. You will be able to accomplish your projects easily. Relation-

ships with colleagues and the management will be extremely cordial. Social contacts will help your career prospects. The only precaution you should take is that you should not abuse your authority.

VIRGO (KANYA)-----{NAMES BY PA, THA}:-



Virgo Horoscope is not optimistic about career prospects this month. You fail to get the support of family and friends. The envi-

ronment at the office will not be cordial. Because of the non-cooperation of colleagues and juniors, targets cannot be achieved easily. Hard work does not result in any rewards and there will be no promotions or salary rises.

LIBRA (TULA)-----{NAMES BY RA, TA}:-

Libra Horoscope is not very much promising for career pros-LIBRA pects. Professional development

will be delayed by a focus on family issues and psychological stability. At the workplace, the atmosphere tends to be highly conflicting due to the negative attitude of associates. You fail to achieve your targets. Even professional travel will not be successful.

(VRUSHCHIKA)-----{NAMES BY NA, YA}:



Scorpio Horoscope predicts that there will be very good opportunities for career growth through change of job. The change of job

may be in the same organization or you may look for opportunities outside. Things happen for the better in strange ways.

SAGITTARIUS (DHANU)-----{NAMES BY BHA, DHA, FA}:-

Sagittarius Horoscope is not encouraging for your professagittarius sional development. Financial rewards are not in proportion to

the hard work you put in. The environment at the workplace is hardly congenial. Hence you will have a problem sticking to your targets. Even professional tours will

DECEMBER 2020

ZODIAC PREDICTION

not help your career growth.

CAPRICORN (MAKAR)-----{NAMES BY KHA, JA}:

Capricorn Horoscope is not favorable for career growth. You will be putting in more work, but CAPRICORN the rewards are negligible. Social

contacts and family members will not be able to help your prospects. Professional travel will not give the desired benefits. Under these circumstances, you should try your best and wait for good days!

AQUARIUS (KUMHA)-----{NAMES BY GA, SHA, SA}:-

Aquarius Horoscope is quite beneficial for professionals and their growth. You will ACQUARIUS have the support of social contacts. Your diligence will be rewarded with good financial remunerations. The atmosphere at the workplace will be delightful and you will have no problem in sticking to your schedules.

PISCES (MEEN)-----{NAMES BY DA, CHA, JHA, ZA, THA}:-



Pisces Horoscope for career indicates that the professional life will see enduring changes for the better. Both the eclipses

will cause some anxious moments before the modifications occur. There may be important changes in the corporate structure of your present organization or other associate companies. All these will help you to improve your hierarchy in the company.

~<u>Sudha Agrawal</u>

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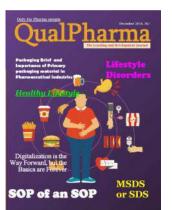
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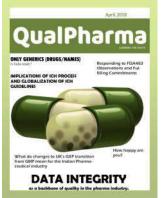






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