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ANNUAL ISSUE YEAR 2020 100/-

The Learning and Development Journal

SPECIAL ISSUE

YEAR BOOK

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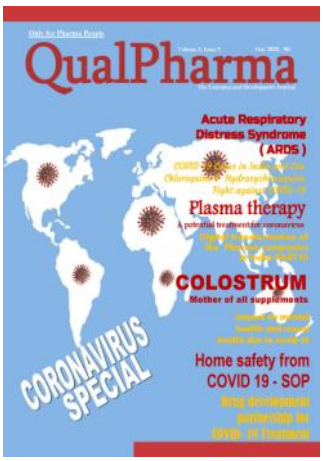

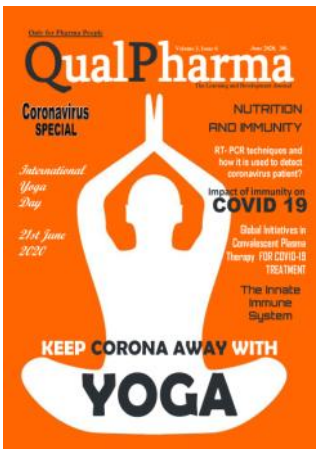

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ANNUAL ISSUE / YEAR 2020 [SPECIAL ISSUE]

QualPharma is a monthly magazine

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FROM THE DESK OF

EDITOR-IN-CHIEF

Dear Readers,

It gives me immense pleasure to extend my heartiest Greetings on behalf of QualPharma to all my fellow colleague and stakeholders as we mark the beginning of New Year 2021. This new year we have brought the special edition **Year book 2020**

Many think that 2020 has been a catastrophic year as the year appeared with a terrible bushfire in Australia that displaced 300 crore animals. Then came the Covid-19 pandemic that infected almost 80 million people and killed nearly 1.68 million worldwide till the filing of this story. Economies collapsed, job losses, study losses are at a peak and several sectors witnessed a doom. Still on a positive node skies are bluer, fewer cars are crashing, crime rate is falling, and some other infectious diseases are fading from hospital emergency departments. Researchers are claiming that end of Corona is near which will start from beginning of the new year . **I wish you all the good luck and may God bless your family with prosperity, good health, and happiness in the New Year.**

In 2020 QualPharma has continued its fight against the injustice of banning **METHYLCOBLAMIN** and also enforcing the RDA as 1 mcg. Methylcobalamin is a form of Vitamin B12 and prescribed to treat Vitamin B12 deficiency . It is taken to regulate certain vital bodily functions like cell multiplication, blood formation, and protein synthesis.

Methylcobalamin formulations are widely available as health supplements in the unregulated market. It is likely that a large number of people are prescribed or self-medicate these supplements either for deficiency states or for prophylaxis. There are already established brands of methylcobalamin in the market which are very well accepted as supplements. Few of them with 1000 mcg to 5000 mcg are given below.

Banning of this important nutrient has raised many questions to the regulators, but remains unanswered. The important one is that, the Americans and European has majority of non vegetarians with RDA of 2.4 mcg of methylcobalamin. Whereas Indians where the majority of people who are vegetarian, the RDA is decided as mere 1 mcg. Why?

This is what Mayo Clinic says about the safety of vitamin B12: "When taken at appropriate doses, vitamin B12 supplements are generally considered safe. While the recommended daily amount of vitamin B12 for adults is 2.4 micrograms, you can safely take higher doses. Your body absorbs only as much as it needs, and any excess passes through your urine.

Why take more Methylcobalamin than the DAILY VALUE? Fifteen percent of the general population is thought to be deficient in vitamin B12[MeCbl], which is needed to make red blood cells, nerve tissue, and DNA, plus vitamin B12 is required for healthy cardiovascular function and proper nerve function. Vegans, the elderly, elite athletes, and individuals who have certain genetic polymorphisms have a higher need for vitamin B12. During pregnancy and lactation, a higher amount is needed to support the needs of the mother and the added needs of the developing baby. Vitamin B12, along with folate, is considered one of the most important nutrients during pregnancy because it's essential for the development of the nervous system. Rather than supplying formulas with nutrient content to simply prevent a deficiency, supplements are generally prepared with the amounts of nutrients that support optimal health for a wide range of individuals, including those with less than ideal diets. We are regularly updating the regulators technically. Hope they understand soon. If not, we urge ministry to transfer nutraceuticals to DCGI who are more technically sounds to resolve our queries.

QualPharma in its **NEW AVATAR?**
This year new segments like Ayurveda, naturopathy and Homeopathy will get position in our magazine . We will discuss about one yoga asana in each edition. 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)

Manufacturer should be allowed to manufacture

METHYL-COBALAMIN

Or explain why it is banned.

FSSAI

to understand the technical aspects

If not the nutraceutical to be shifted
to DCGI as it was before existence of FSSAI

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Fighting since June 2019

Requirements

1. **Include Methylcobalam into the gazette "Food Safety and Standards Act 2006 regarding operationalisation of standards of Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel food.**
2. **Differentiate between RDA and per serving usage value .**

Or Justify

- **Why Methylcobalamin is not added in the gazette yet when promised by the former CEO Mr Pawan Agrawal Ji?**
- **Why cyanocobalamin is promoted even though there is a cyanide group attached to it?**
- **Rationality why 1 mcg RDA is imposed on nutraceutical manufacturer**
- **Technical aspect of damage caused when 500 mcg is taken as prophylactic use.**
- **Why should we have faith in FSSAI when every time we have to go to ICMR for clarification.**

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WORKING FOR THR BENEFIT OF PHARMA, NUTRACEUTICAL AND FOOD FRATERNITY

ANNUAL BOOK [SPECIAL ISSUE] 2020

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ORAL SPRAY

Methylcobalamin 750 mcg, Ginkgo Biloba 20 mg, Sodium Selenite 50 mcg, Tinosporacordifolia 10 mg, Vitamin B_6 1.5 mg, Folic Acid 0.5 mg & Inositol 100 mcg

In PCOS, there is deficiency of Inositol

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Methylcobalamin ICMR Dictates FSSAI: Regulatory Regime in India EXPOSED

Methylcobalamin, an essential nutrient, is required to treat vitamin B12 deficiency, in people with **pernicious anemia, diabetes, and other conditions**. Usually people take such supplement as protective measure. In a country like India where majority of the natives are herbivore, such supplements have become an indispensible element. Methylcobalamin is a step ahead of its sister cynocobalamin [also a Vitamin B12]. Cyanocobalamin when taken is converted into methylcobalamin leaving a cyanide group which is a toxic component.

The Methylcobalamin Issue

It is very unfortunate that FSSAI, the only regulating authority of India has approved cyanocobalamin but banned Methylcobalamin **The most important -Vitamin B12** . Surprisingly m**ethylcobalamin** has been in use for medical purpose in various doses approved by FSSAI. QualPharma is battling since June 2019 against this injustice and is in continuous talks with FSSAI officials and making them understand the importance of Methylcobalamin. **Nutraceutical** is a substance used to prevent disorders and generally referred as health products. Though nutraceutical is for prophylactic cause, still it should be a therapeutic dose. 1mcg of methylcobalamin is of no use as it is too less to prevent any type of disease. A favourable outcome was achieved when we received a letter from former CEO **"Shri Pawan Agrawal Ji"** stating

Quote

"Such decisions are taken by FSSAI's Scientific Panel after risk assessment based on secondary data and then goes through a process of approval through Scientific Committee, Food Authority and the Ministry of Health.

Good news is that Methylcobalamin (Vitamin B12) has been okayed by the Scientific Panel. However, for this to come into effect it has to go through a process, hence will take sometime. We will try and expedite it as much as possible."

Unquote

FSSAI made the condition worse by mentioning the RDA value of methylcobalamin as 1 mcg which is lower than 2.4 mcg specified by USFDA for the United States where the natives are non vegetarian. As per Section 22 of FSS Act, 2006 and Nutraceutical regulations health supplements or nutraceuticals shall contain minerals or vitamins only in amounts not exceeding the Recommended Daily Allowance (RDA) for Indians. Hence, as per the said Act and Regulations, these products can contain vitamins or minerals only up to its RDA. The Food Business Operator (FBO) who wants to manufacture, import, market or sell such products shall comply with the aforementioned regulations. **Ignoring that RDA and per serving usage are different FSSAI is adamant to enforce 1mcg** as per serving usage value by the manufacture.

Dr Sanjay Agrawal

Dr Sanjay Agrawal founded PHARMA CONSULTANTS and INVENTOR in 2005 to assist pharmaceutical companies around the globe. He has actively worked in pharmaceutical and related industries for more than 28 years. He is Editor-in-Chief of renowned IJM Today and honorable member of the editorial board of QualPharma and The Antiseptic. Dr Sanjay Agrawal is also the illustrious member of the National Geographic Society and ex- member of scientific committee of IDMA. His prestigious articles are published in various magazines and websites for example—The Antiseptic, NuFFooDS Spectrum, Pharma biz

Dr. Agrawal 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, completed MBBS and MBA from IMT. He has worked with many International and national Pharmaceuticals company. Dr. Sanjay Agrawal is the patent holder of many research formulations which are successfully commercialized

Currently besides his core jobs, Dr Agrawal devotes his time for the benefit of pharma fraternity. He has raised his voice against the ban imposed on methylcobalamin manufacturing. He has been asking to the regulators from more than a yeat that

- **Why Methylcobalamin is not added in the gazette yet when promised by the former CEO Mr Pawan Agrawal Ji?**
- **Why cyanocobalamin is promoted even though there is a cyanide group attached to it?**
- **Why 1 mcg RDA is imposed on nutraceutical manufacturer**
- **Technical aspect of damage caused when 500 mcg is taken as prophylactic use.**

These doses of 1 mcg methylcobalamin are far beyond the therapeutic value.

Methylcobalamin Vs Cyanocobalamin

When methylcobalamin is consumed it is directly absorbed whereas when cynocobalamin is consumed, only one tenth of its part is converted into methylcobalamin and absorbed by the body. So, if 1 mcg methylcobalamin is taken, the body will react differently as compared to 1mcg of cynocobalamin. When 1mcg of cynocobalamin is taken, one tenth of it is converted to methylcobalamin and absorbed by the body. **But in this case both Cyanocobalamin and Methylcobalamin are having RDA /per usage serving value as 1 mcg.**

Methylcobalamin safety profile

Evidence 1

A randomized, open labeled study comparing the serum levels of cobalamin after three doses of 500 mcg vs. a single dose methylcobalamin of 1500 mcg in patients with peripheral neuropathy [This study include healthy patients also on which prophylactic study is conducted.]. Conclusion of this study shows that The 500 µg methylcobalamin thrice weekly regime is more effective in increasing the serum cobalamin levels as compared to the 1500 µg methylcobalamin once weekly regime. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6037815/

Evidence 2

Study of Dr. Schweikart on Vitamin B 12 concluded that in dietary supplement for *prevention and maintenance doses*. The aim is to cover the daily requirement and to keep the B12 supply stable.

Recommended dose: depending on the individual between 10 – 1000 µg/ day. https://www.b12-vitamin.com/dosages/

Evidence 3

Dr. Schweikart again states There are different factors which increase the vitamin B12 requirement. Among the most important are:Pregnancy and lactation/ Exposure to toxins and radicals/Stress/ Athletic sport/Infections and malabsorbtion due to Old age /Inflammation of the stomach, intestines and/or pancreas/ Intestinal surgery/ Interactions with medicines or drugs/Nutrient deficiencies (e.g. calcium)/Fungal, parasite or bacterial infections in the intestine. With age, the absorption ability decreases. Therefore, B12 markers do not completely normalise in older people unless daily doses between 500-600 µg or more are administered . This is an average value and in individual cases significantly higher doses may be necessary, which is why a dose of 1000 µg has also proven to be effective here.https://www.b12-vitamin.com/high-dose/

Evidence 4

In a review article *Review Article* ***Austin J Pharmacol Ther. 2015; 3 (3).1076. It is mentioned that*** *For daily stress relief, methylcobalamin should should be taken in the dose of 500 mcg per day. In the acute cases of neuropathy, dose of 1500 mcg per day can be safely taken. Dose of 1 mg per day is required to be taken for age related brain decay. Methylcobalamin can be combined with similar dose of folic acid and pyridoxine [20]. Deficiency of vitamin B_{12} is strictly seen in pure vegetarian, dose of 100 mg day can rebalance its requirement in the intestine. All human being need at least 3 mg per day of this drug for the basic nerve support. The medicine is stored in the refrigerator below 41°F (5°C) to avoid moisture. Methylcobalamin is also injected deep in to the muscles.*

https://austinpublishinggroup.com/pharmacology-therapeutics/fulltext/ajpt-v3-id1076.php

Evidence 5

The dose of methylcobalain can vary depending on what you are specifically treating. For fatigue conditions it is common to take 1-2 mg daily either subcutaneously or via nasal spray, however lozenges are also available. https://custommedicine.com.au/health-articles/methylcobalamin-vitamin-b12/

Evidence 6

The absorption of vitamin B12 mediated by the glycoprotein, intrinsic factor, is limited to 1.5–2.0mg per meal because of the limited capacity of the receptors. In addition, between 1% and 3% of any particular oral administration of vitamin B12 is absorbed by passive diffusion. Thus, if 1000mg vitamin B12 (sometimes used to treat those with PA) is taken orally, the amount absorbed would be 2.0mg by active absorption plus up to about 30 mg by passive diffusion. Intake of 1000mg vitamin B12 has never been reported to have any side-effects (8). Similar large amounts have been used in some preparations of nutritional supplements without apparent ill effects.

https://apps.who.int/iris/bitstream/handle/10665/42716/9241546123.pdf;jsessionid=7EA2C12295BA7D9DA9FDF7E1B8965998?sequence= 1

Vitamin C Issue

Methylcobalamin is not an exception, if we talk about Vitamin C honorable prime Minister Narendra Modi encouraged usage of 1000 mg Vitamin C as prophylactic dose to protect oneself from Coronavirus. Whereas FSSAI has 40 mg as its RDA which is in opposition to Mr. Prime Minister's statement. When asking for clarification QualPharma was informed to contact ICMR. As the RDA for different essential nutrients for Indians are specified by Indian Council of Medical Research (ICMR) which also specified RDA for vitamin B12 (irrespective of its sources such as methylcobalamin or cyanocobalamine) as 1 mcg.

FSSAI Official Quotes

"The notification dated 7th January, 2020 mentions the same. Since revision of RDA does not fall under the scope of FSSAI and any such request may be taken up with ICMR rather than with FSSAI."

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

What is ICMR

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world.

The ICMR has always attempted to address itself to the growing demands of scientific advances in biomedical research on the one hand, and to the need of finding practical solutions to the health problems of the country, on the other. The ICMR has come a long way from the days when it was known as the IRFA, but the Council is conscious of the fact that it still has miles to go in pursuit of scientific achievements as well as health target.

What is FSSAI

Food Safety and Standards Authority of India is an autonomous body established under the Ministry of Health & Family Welfare, Government of India. The FSSAI has been established under the Food Safety and Standards Act, 2006, which is a consolidating statute related to food safety and regulation in India.

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

FSSAI is preparing regulations for the nutraceutical industry , therefore the QualPharma has approached FSSAI to share the rationals to decide RDA for which QualPharma is fighting for justice for which we recieved completely in appropriate response from FSSAI consultant N Bhaskar who blamed us to pressurize FSSAI.

Our last 1 year of contact with FSSAI was horribly flawed leading us to think that FSSAI has become political body not the scientific body misleading to the industry.

- Why Methylcobalamin is not added in the gazette yet when promised by the former CEO Mr Pawan Agrawal Ji?
- Why cyanocobalamin is promoted even though there is a cyanide group attached to it?
- QualPharma is asking for rationality why 1 mcg RDA is imposed on nutraceutical manufacturer
- Technical aspect of damage caused when 500 mcg is taken as prophylactic use.

And last but not the least

- Why should we have faith in FSSAI when every time we have to go to ICMR for clarification.

~By Dr Sanjay Agrawal

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

IMPORTANCE OF METHYLCOBALAMIN

Methylcobalamin is a naturally occurring form of vitamin B12 which can be obtained through supplements, as well as food sources like fish, meat, eggs and milk. Methylcobalamin is better utilized and is direct active form. It is a cofactor for the cytosolic methionine synthase. It is needed for the function of the folate-dependent enzyme and methionine synthase. This enzyme is required for the synthesis of methionine from homocysteine. Methionine in turn is needed for the synthesis of S-adenosylmethionine, a methyl group donor employed in several biological methylation reactions, including the methylation of a number of sites within DNA, RNA, and proteins. Inadequate function of methionine synthase can lead to an accumulation of homocysteine, which has been associated with increased risk of cardiovascular and neuropsychiatric disorders. Methylcobalamin due to its high plasma protein binding capacity is accumulated and retained in the body much better than cyanocobalamin therefore the retention time is more. In any form, methylcobalamin has higher bioavailability than cyanocobalamin. It is so efficient that even orally it was found effective in pernicious anemia – a disease with deficiency of red blood cells.

Methylcobalamin shows its greatest utility with people suffering form acute or chronic degenerative neurological symptoms, here it is considered as the only promising treatment available. It bypasses several potential issues in the absorption cycle and helps relieve or completely reverse symptoms

Majority that is 99% of people in the world are in need of extra vitamin B12, and Methylcobalamin would be considered as a better option compared to cyanocobalamin. It exhibits many neuro protective effects, improving brain cognition back to normal levels. Plus, Methylcobalamin is donating an extremely valuable methyl group that further enhances our health (and doesn't steal any, like cyanocobalamin does). This is especially important for pernicious anemia patients or anyone suffering from high homocysteine levels. This donation of methyl groups may be the reason why Methylcobalamin is helpful to multiple conditions.

Increase your Immunity with COLOSTRUM [MOTHER OF SUPPLEMENTS!]

Colostrum is **'Nature's first food**. It is the pre-milk fluid that all female mammals including human give their new born in the first few days following the birth. It is a highly complex cocktail of vital immune and growth factors required by the baby for protection against the diseases it will be exposed to. **Colostrum assists with the development of the new born into a strong and healthy adult.**

History

The use of colostrum for the treatment of illness and for the maintenance of well-being dates back thousands of years. The Ayurvedic physicians and the Rishis of India have been using colostrum for medicinal purposes since 5000 years in past. Ayurveda **Epic Bhav Prakash clearly indicates the strength of colostrum.**

Cow's colostrum be utilized as an infant food to protect the infant against diseases. Prior to the development of sulpha drugs and antibiotics, colostrum was majorly used worldwide by leading medical practitioners for its antibiotic properties. In fact **Albert Sabin**, the physician credited with developing the first polio vaccine advocated the use of colostrum and in fact originally isolated anti-polio antibodies from bovine colostrum.

The prophylactic and therapeutic use of Colostrum has been shown to be successful in preventing and treating entero pathogenic Escherichia coli infections, Rotavirus gastroenteritis in infants, Cryptococcidiosis and diarrhoea in AIDS and other immune deficient patients, dental caries formation, can prevent gastrointestinal disease in infants.

Colostrum is Natures perfect food! It contains all the natural nutrients need for optimal health and vitality. **It is the only 100% natural source of vital growth and healing factors and cannot be laboratory reproduced.**

There are many benefits of using Colostrum. It strengthens the immune system, fights against viruses, bacteria and parasites. It helps with better digestion and bowel function, rejuvenates body and mind. It assists athletes build lean muscle and helps with recovery and enhances .

energy and general wellbeing. It helps relieve chronic pain combats the effects of aging joint pains.

Colostrum enhances assimilation of nutrients through the intestines and thus increases the efficiency of carbohydrate and amino acid uptake. Growth factors in Colostrums help "seal" the lining of the small intestine and provide protection from invading organisms and from ulceration, so more of the nutrients from the food you eat can be utilized as fuel for exercise, whether of the cardiovascular or muscle-building variety.

Bovine Colostrum is the only form of Colostrum that is not species specific.
In other words, it contains all of the immune and growth factors found in all other sources and thus it can significantly benefit all other mammals, including humans of course.

Research conducted over the past two decades has proven that B**ovine colostrum** is one of the most effective nutritional supplements available for support of the immune system. It is also well renowned for aiding tissue repair. It contains numerous immune system and growth factors as well as essential nutrients, trypsin, and protease inhibitors that protect it from destruction in the gastro.
It is low in fat, and high in protein, carbohydrates, and antibodies Easy to digest. **There are over 90 known components in Bovine colostrum.** The primary components of Bovine Colostrum is divided into two classes,

- **Immune factors**
- **Growth factors.**

The immune and growth factors found in bovine colostrum are beneficial to humans of all ages. Beneficial for all Age groups from Infants to old age.

S.Murali

S Murali is a Chemistry graduate from Madras University, Started carrier in the year 1986 at Chennai as Trainee Chemist with well reputed PHARMA COMPANY namely TAMILNADU DADHA PHARMACEUTICALS LTD, later it was taken over by SUN PHARMACEUTICAL INDUSTRIES, worked till 1998. Then he joined with MICRO LABS as Production Manager and worked around 8 years and later as PLANT HEAD with Crescent Therapeutics, Baddi. Moved to MEDOPHARM, CHENNAI as PLANT HEAD a UK MHRA approved plant. Having good technical and Document knowledge and Administrative Capacity, he faced many national and International Audits and several International Customer Audits during those periods. With the rich technical experience and marketing support by well wishers started HILSON HEALTH PRODUCTS and started promoting brand FORELACT Colostrum. WORLD'S BEST IMMUNITY BOOSTER at Very affordable price! Few more products are under pipeline and scheduled for launch this Financial Year..

IMMUNE FACTORS:

Immune Factors in colostrum help the body fight harmful invaders such as bacteria, yeast, virus and fungus. It contains Immunoglobulins A, D, E, G, and M

IgG neutralizes toxins and microbes in the lymph and circulatory system.
IgM destroys bacteria.
IgE and IgD are highly antiviral. It contains **Lactoferrin** which is an antiviral, antibacterial, anti-inflammatory, iron-binding protein with therapeutic effects in cancer, HIV, Candida albicans and other infections.

Lactoferrin helps deprive bacteria of the iron they require to reproduce and it also releases iron into the red blood cells, enhancing oxygenation of tissues. **Lactoferrin** modulates cytokine release, and its receptors have been found on most immune cells, including lymphocytes, monocytcs, macrophages, and platelets. **Proline-rich polypeptide (PRP)** is a hormone that regulates the thymus gland, stimulating an underactive immune system. It also helps down-regulate an overactive immune system, as seen in autoimmune diseases such as multiple sclerosis (MS), rheumatoid arthritis, lupus, scleroderma, chronic fatigue syndrome, and allergies.

Growth Factors

GROWTH FACTORS include

- Epithelial growth factor **(EgF),**
- Insulin-like growth factor-I and II **(IGF-1 and IGF-II),**
- Fibroblast growth factor **(FgF),**
- Platelet-derived growth factor **(PDGF),**
- Transforming growth factors A & B **(TgA and B),** and
- Growth hormones **(GH).**

These all help stimulate cell and tissue growth by stimulating DNA formation.

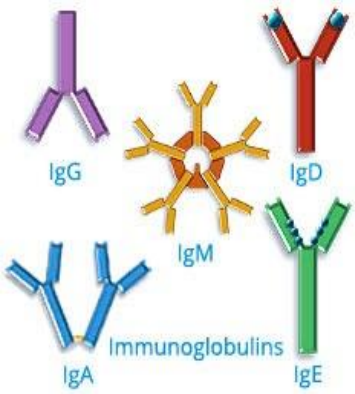
Researches have shown the COLOSTRUM as supplement can improve and potentially protect against illness hence it is called as MOTHER OF SUPPLEMENTS. Colostrum must be processed at low temperatures so the immune and growth factors remain biologically viable. **Research has shown that the molecular structure of bovine colostrum is identical to human colostrum**. It fights against **Viral Illnesses, Allergies and Autoimmune Diseases, Bovine colostrum is biologically transferable to all mammals, including man. It is much higher in immune factors than human mother's colostrum** with no reports of allergic or anaphylactic reactions to date.

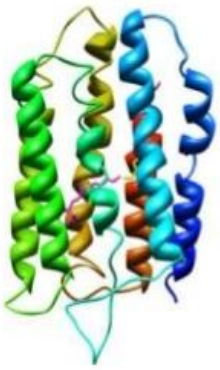
Colostrum boosts the immune system and aids with natural stamina so that athletes can achieve their best time after time. Colostrum also contains powerful anti-inflammatory agents which inhibit the activities of inflammation causing agents inside the body, thereby reducing the inflammation and its associated pain. Colostrum assists with the burning of fat, whilst increasing muscle mass thus giving a leaner, stronger body. IGF-1 which is just one of the growth factors present in colostrum can promote an increase of up to 15% in muscle mass and 14% in strength. The regenerative effects of the growth factors in Colostrum can also benefit active sportspeople by reducing injury recovery time.

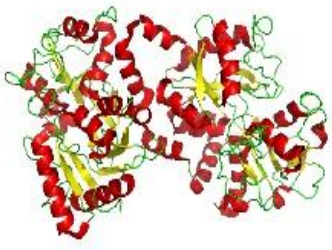
The GI component of the immune system produces about 75% of the antibodies in the human system, The

ability of AIDS/HIV patients to fight infectious disease is severely compromised, partially due to damage to the gut from chronic inflammation and diarrhea.

Several recent studies report colostrum's role in the reversal of this chronic problem, stemming from opportunistic infections like Candida albicans, cryptosporidia, rotavirus, herpes simplex, pathogenic strains of E.coli, and intestinal flu infections. Colostrum handles all gut pathogens well without side effects. Colostrum is composed of numerous factors with strong antiviral activity, especially the immuno-globulins, lactoferrin, and the cytokines.







PRP from colostrum can work as a regulatory substance of the thymus gland." It has been demonstrated to improve or eliminate symptomatology of both allergies and autoimmune diseases (MS, rheumatoid arthritis, lupus, myasthenia gravis). PRP inhibits the overproduction of lymphocytes and T-cells and reduces the major symptoms of allergies and autoimmune disease; pain, swelling and inflammation

Colostrum and aging

Extensive research has shown that colostrum is unique as it is the only substance that offers anti-aging hormones in perfect balance - just the way nature intended. This explains why there are no known negative side effects from taking colostrum, even in large doses.

When colostrum is **taken regularly as a supplement**, skin can appear more youthful, age and liver spots can be reduced and bone mass, density and lean muscle mass is increased.

Fat levels decrease, while energy and disease resistance levels increase. In some cases hair can begin to regain its thickness and colour.
Colostrum also contains other vital growth factors such as EGF (Epidermal Growth Factor), which demonstrates the highest ability to stimulate skin regeneration and wound healing.
IGF-I and IGF-II are insulin-like growth factors which are important in reducing fat deposits as they tell your body how to store and use food for energy. IGF-I also accelerates the healing process, balances blood glucose and reduces the need for insulin. It can also increase muscle mass and strength and assists in bone growth and repair.

Conclusion: Human body organs designed by the Nature. It is designed for Pollution free Air, Water and Nature's food. Now everything has got polluted and food habits have changed completely. Result Imbalance in Immunity system... which leads to diseases.

Nature protects us and science cures us Prevention is better than cure

Still Mother Nature is so kind enough and has provided many Immunity boosters and the Bovine Colostrum is the top in this table. Let us make it a habit of consuming Good Quality Bovine Colostrum every day and maintain our immunity level and protect from any INVADERS. It creates the foundation of life-long immunity. Bovine Colostrum has greater potency than Human colostrum.

Hippocrates - Father of Medicine , ca.460-370 B.C said
"Leave your drugs in the chemist's pot, if you can heal the patient with food" "Illness occurs when the body's systems are toxic and out-of-balance. One must treat the body as a whole, rather than a series of parts"

Colostrum can enhance Pet's health also. If your kittens or puppies are failing to thrive, if one of your animals has a wound, abscess, stomach bug or coats are not gleaming with good health, they could well benefit from the goodness of colostrum powder.

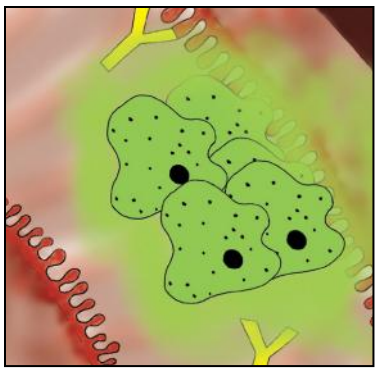
Diarrhoea can be a common problem in recently weaned puppies and studies have shown that the wellbeing of the animals supplementation with bovine colostrum can assist in the reduction of symptoms and improve faecal quality. It can be sprinkled on to their food or given in a more concentrated form mixed with water or honey to aid an upset stomach or to fight infection.

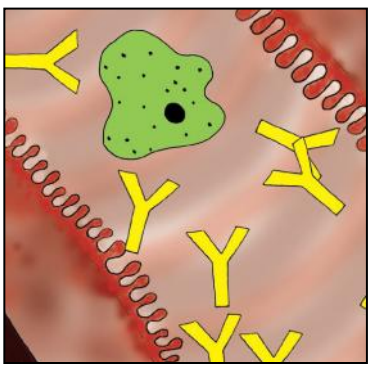
So whether your pet is a top show animal or simply a loved member of the family unit, be they young or old, just like their owners they can benefit from the addition of a daily dose of colostrum.

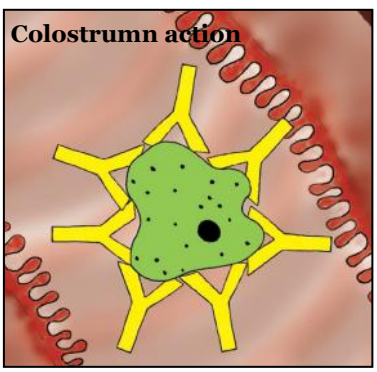
SO IT IS A TOTAL HEALTH SOLUTION

1. Germs enter the body and make their way to the gut wall.
2. Once attached to the gut wall, germs begin to multiply freely, causing illness and disease.
3. The antibodies in colostrum remain in the gut, increasing your natural antibody levels.When a germ invades they attach themselves to it.
4. Once the antibodies are attached, the germ cannot stick to the gut wall, and passes harmlessly through your system.

~By S Murali







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What I Don't know about antibiotics?

Antibiotics, also known as antibacterial, are types of medications that destroy or slow down the growth of bacteria. The Greek word **anti** means **"against",** and the Greek word **bios** means **"life" (bacteria are life forms).** I wonder today we are in a **Sea of Antibiotics,** India is one country which has many ambitions to fulfill the shortage of Antibiotics. The education on Antibiotics is the magic bullets which has gone deep into the minds of the public. But today there is no magic but only we are left with Bullets which can kill many in the hospitals and in community with its indiscriminate use.

I must tell from my knowledge on antibiotics before I go further. When I was working in a Government hospitals only available Antibiotics are **Penicillin, Strepto penicillin injections**, and **Sulfadiazine tablet** in tins of 1000 tablets. I still remember that we had no journals for information, we had no choices, patients were not aware of their health and hygiene, however people started refusing to take Sulphas and throw the sulphas tablets around the compound of the hospitals. Many infections were treated with **Procaine Penicillin injection**, and more complex respiratory infections with **Streptopencillin injection**. The end of the both the drugs came in early 1980's, they were no longer working. People were not willing to take but many General practitioners insisted, as they will get fees by giving injections.

In 1970 the doctors started using **Erythromycin** to give to little better people in the Society as it was expensive. It was available to patients with the permission of Medical Superintendents or RMO's in Government Hospitals. Once I had a bitter experience for prescribing to a poor person and the Medical superintendent fired at me as Senior house man cannot prescribe. it needs experience and importance of the patient. I continued to follow the order of the day as I had no better knowledge on Infection or Antibiotic use till I am qualified with MD in Microbiology. In MD examination there was a question on Ciprofloxacin in recent advances in 1990's Microbiology paper.

India has liberalized the trade of Antibiotics and pharmaceutical industry. We all are flooded with Antibiotic formulation and it was a trade war between the companies, so we learnt many good and bad knowledge from Medical representatives. To best of my knowledge, no senior person prevented us to prescribe the drugs.

In majority of the patients who visited the hospital, the matters went wrong. The upcoming pharmaceutical industries started promoting the drugs in the hand of the unqualified quacks and drug prescribers. It acted well in many infections in poor people, however suboptimal doses were sold and few continued for few days.

If you take antibiotics when you do not need them, they may not work when you do need them. Each time you take antibiotics, you are more likely to have some bacteria that the medicine does not kill.

Matter boomeranged overusing antibiotics lead to misuse of Antibiotics. There is concern worldwide that antibiotics are being overused. Antibiotic overuse is one of the factors that contributes towards the growing number of bacterial infections which are becoming resistant to antibacterial medications. Doctors too benefited like with quantum of Antibiotic prescriptions linked with freebies and many foreign tours. In developing society, many honest people live at mercy of the dishonest person, it became a fashion to prescribe antibiotics with knowledge gained from pamphlets supplied by representatives. The proliferation of Cephalosporins caused confusion in even highly qualified professionals when the spectrum of activity of these compounds on selective use in targeting the specific bacteria as the Microbiology laboratories were least developed in our country. It was call on competent doctors and few-Physicians are available for caring when the matters went wrong. Today we all wake up to the retribution on use and misuse of Antibiotic use. Today we live in world with many resistant microbes, and still there is no much change in the curriculum in MBBS course, however few are fighting to change curriculum.

Dr. T.V Rao

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The world is heading towards a post-antibiotic era, in which many common infections will no longer have a cure and once again, kill unabated.

Many die or live to spread the resistant microbes in the environment. The patients in the Hospital are beginning a new and important chapter in Medicine as the hospital acquired infection which is Darwin's theory as the Microbes are fighting back on the evils of the Hospitals. It is not just the hospitals, our livestock too are messengers and amplifiers of Antibiotic resistance. It is no wonder these animals depend on drugs to survive factory farms. But this 'regular fix' results in more bacteria that are resistant to drugs.

As you can imagine, this could have catastrophic implications. Soon, we could find ourselves in a world where there are no drugs left strong enough to fight infection – in farm animals and humans. The livestock-associated MRSA super bug can lead to life-threatening conditions like septicaemia, pneumonia and meningitis. Research indicates battery cage egg farms may be six* times-more likely to harbor dangerous Salmonella than higher welfare farms. Strong evidence suggests antibiotic overuse on farms has already contributed to a highly drug-resistant strain of E.Coli. Resistance is a major health concern because it increases healthcare costs, causes people to stay in hospital for longer, results in treatment failures, and sometimes death. An estimated 25,000 people die each year in the EU from antibiotic-resistant bacterial infections,

Professor Peter Hawkey, a clinical microbiologist and chair of the UK government's antibiotic-resistance working group, informs on the events and quote *"We have no data to formulate as we have no guidelines on antibiotic use and unhealthy competition in the trade. We live at the mercy of wisdom of the Doctors we visit."* Today every educated person is informed through the press and multimedia and public are realizing that Antibiotics are prescribed without scientific basis and antibiotics are losing their effectiveness at a pace that was unforeseen even five years ago. **This is because antibiotic use causes bacteria to become resistant to antibiotic treatments.** CDC estimates that more than 50% of antibiotics are unnecessarily prescribed in office settings for upper respiratory infections (URIs) like cough and cold illness, most of which are caused by viruses. **Up to 50% of antibiotic use in hospitals is either unnecessary or inappropriate.** The improvement of hygiene is the best solution to prevent many common infections, prevent infections by practicing good hand hygiene and getting recommended vaccines.

Patients, clinicians, healthcare facility administrators, and policy makers must work together to employ effective strategies for improving antibiotic use and ultimately improving medical care and saving lives.. Public be informed on facts on antibiotic misuse. **If you take antibiotics when you do not need them, they may not work when you do need them.** Each time you take antibiotics, you are more likely to have some bacteria that the medicine does not kill. These bacteria can change (mutate) so they are harder to kill. Then, the antibiotics that used to kill them no longer work. We all swim in a complex ignorant world, Protect yourself from illnesses. Keep your hands clean by washing them well with soap and clean running water. If the physicians prescribe the antibiotic our patients may find our decision are dangerous to them as the society is going for mass education on Antibiotic. If we wish to continue with Scientific approach on use of antibiotics learn the basics of the Antibiotics, as we are shy to accept our Ignorance on Antibiotic rationalism. Today we have many Antibiotics many choices, and never forget many reasons to think before prescribing ? Think before you prescribe or take an Antibiotics

~ Dr TV Rao

Role of antioxidant Lycopene in human

Current dietary guidelines recommend increased intake of plant foods, including fruits and vegetables, which are rich sources of antioxidants, to reduce the incidence of numerous chronic diseases in humans.

The role of dietary antioxidants together with vitamin C, vitamin E, carotenoids, and polyphenols, in disease prevention has received much attention in recent years. About 50% of all cancers have been attributed to diet. Oxidative stress induced by reactive oxygen species is one of the main reasons for diseases. Reactive oxygen species are highly reactive oxidant molecules that are generated endogenously through regular metabolic activity, lifestyle activity, and diet. ROS react with cellular components, causing oxidative damage to critical cellular biomolecules as lipids, proteins, and DNA. This oxidative damage could play a major role in the causation of several chronic diseases.

Antioxidants (a substance that protects against cell damage) prevent oxidative damage by inactivating reactive oxygen species and therefore act as protective agents. Antioxidants such as SOD (superoxide dismutase), catalase, and glutathione peroxidase are naturally present within human cells. In addition, antioxidants such as polyphenols, carotenoids, vitamin E, and vitamin C are available from food.

One important dietary antioxidant in the defense against oxidation is lycopene, of which tomatoes are an important dietary source. Since the human body is unable to synthesize carotenoids from endogenously produced biochemicals, the body is totally dependent on dietary sourced (exogenous) carotenoids. Humans depend on dietary sources for lycopene.

What is Lycopene?

Carotenoids are powerful antioxidant agents found in fruits and vegetables. They play an important role in the maintenance of overall human health and protect against cancer, heart diseases, oral malignancies and diseases.

Among the carotenoids, lycopene is the most potent antioxidant with no vitamin A activity and naturally occurs in many fruits and vegetables . Lycopene is a bioactive carotenoid, which are yellow, orange, or red pigments that give this color to its plants. Lycopene is the pigment principally responsible for the distinctive red color of ripe tomato and tomato products, watermelon and grapefruit.

Lycopene is a fat-soluble pigment that has antioxidant properties and found to be measured in the blood serum. In the human body, lycopene is naturally found in the liver, blood, adrenal glands, lungs, prostate, colon, and skin at higher levels than other similar pigments. But high concentration is seen in testes, adrenal gland and prostate.

Preventive Effect of Lycopene toward Diseases

One of the biggest benefits of lycopene is that it is an antioxidant and protects against oxidative damage to lipids, proteins, and DNA from free radical stress. ROS-induced oxidative stress is responsible for several human diseases and antioxidants having the ability to mitigate the damaging effects of ROS provide an effective means of preventing chronic diseases. The antioxidant property of Lycopene is thought to be primarily responsible for its beneficial effects.

Among the carotenoids, lycopene is a major component found in the serum and other tissues. A lycopene rich dietary intake have shown association with decreased risk of chronic diseases such as cancer and cardiovascular diseases in several recent studies. Serum and tissue lycopene levels have also been inversely related with the chronic disease risk.

Cancer

Epidemiological data from around the world have all recommended increasing dietary intake of citrus fruits, cruciferous vegetables, green and yellow vegetables, and fruits and vegetables high in vitamins A and C to lower risk of numerous cancers. Lycopene has the highest singlet oxygen quenching capacity and a high capacity of quenching other free radicals in vitro among dietary carotenoids. It is one of the most potent antioxidants with singlet-oxygen-quenching ability twice as high as that of β-carotene and 10 times higher than that of α-tocopherol.

Increasing clinical evidence supports the role of lycopene as a micronutrient with important health benefits and remarkable chemopreventive and antiproliferative activity. Its inhibitor effects include a considerable (ROS) reactive oxygen species scavenging activity, which allows lycopene to prevent lipid peroxidation and DNA damage. It simultaneously induces enzymes of the

Ms Uma Jothi

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cellular antioxidant defense systems by activating the antioxidant response element transcription system. It also increases gap junctional communication, which is suppressed during carcinogenesis.

Prostate cancer
Prostate cancer is the most common malignancy and cause of death in men. Studies indicate that regular consumption of lycopene rich food has been reported to be associated with 30 to 40% lower risk of prostate cancer. Oxidative damage to DNA is reduced and serum PSA declined significantly with lycopene treatment.

Pancreatic cancer
Data shows that those consuming lycopene had a 31% reduction in their risk of pancreatic cancer. Research has identified the unique mechanism through which lycopene protects against cancer, by activating cancer-preventive phase II detoxification enzymes NAD (P)H quinone oxidoreductase 1(NQ01) and glutamylcysteine synthetase (GCS)to eliminate carcinogens and toxins from the body.

Coronary heart diseases
Tobacco use, unhealthy diet, physical inactivity and high intake of alcohol increase the risk of CVD. Plasma low density lipoprotein (LDL) is the major risk factor of CVD (cardiovascular diseases). Increase in LDL oxidation is associated with increasing of atherosclerosis and coronary heart disease. Studies have shown that lycopene rich diet significantly reduces the levels of oxidized LDL and lipid peroxidation in patients with cardiovascular disease. Lycopene can prevent cardiovascular diseases by boosting the body's natural antioxidant defenses and protecting against DNA damage with its lipophilic compounds.

Those with higher amounts of lycopene in their tissues have lower risk of heart attack, blocked or clogged arteries, lower blood pressure, and other cardiovascular diseases.

Inflammation
Intake of lycopene rich foods helps in treating respiratory infections. Epidemiological studies have shown lycopene to suppress infiltration of inflammatory mediators and cells into the lung, decrease airway hyper responsiveness; and inhibit cell infiltration. Lycopene rich diet reduces sputum neutrophil elastase activity and improvement in airway inflammation.

Osteoporosis
Lycopene rich diet shows results of possible decrease in bone turnover and oxidative stress markers and an increase in antioxidant status. It has a stimulatory effect on cell proliferation and the differentiation marker alkaline phosphatase of osteoblasts as well as inhibitory effects on osteoclasts formation and resorption. Thus lycopene plays a role in bone health and provides dietary alternative to drug therapy for those at risk of osteoporosis.

Neurogenerative diseases
Oxidative damage of the neurons is now recognized as a causative factor in the etiology of these disorders. Antioxidants act as protective agents against oxidative damage. Studies show Parkinson's disease and vascular dementia patients have lower levels of blood lycopene and how high blood levels of lycopene help in the effective management of these diseases.

Hypertension
Antioxidant property of lycopene offers a protective role in hypertension. A recent study showed lycopene-rich diet in hypertensive patients cause reduction in their diastolic blood pressure. Recognizing the importance of antioxidants in the management of hypertension, a diet that contains substantially higher levels of lycopene along with other carotenoids, polyphenols, flavanols, and flavanones is recommended.

Male Infertility
One of the important contributory factors for male infertility is oxidative stress. A few studies have suggested the beneficial role of antioxidant therapy in the treatment of male-factor infertility. Lycopene treatment has shown increased sperm concentration, sperm motility and morphology, and the sperm functional concentration. Furthermore, it was found lycopene treatment resulted in 36% successful pregnancies.

Eyes
Lycopene protects your eyes from oxidative stress that causes common eye diseases. By virtue of its antioxidant properties lycopene protects against cataract development and may be useful for prophylaxis or therapy against cataracts. Lycopene also has a great effect on the chemical processes that lead to age-related macular degeneration which is the leading cause of blindness in old age.

Dental hygiene
Lycopene may be effective as a first-line therapy in treating oral submucous fibrosis and in combination with other therapies in treating gingivitis.

Dermatology
Studies show that lycopene rich foods provide photoprotective effects against ultraviolet light-induced erythema (superficial reddening of the skin). Higher levels of lycopene antioxidants in the skin effectively led to lower levels of skin roughness. This antioxidant helps heal sunburn and prevent UV damage in humans.

Diabetes
Lycopene may be useful in patients with type 2 diabetes by suppressing oxidative stress and enhancing innate immunity or serum levels of immunoglobulin M. .

Immune System
There is increasing evidence that dietary components that possess antioxidant properties can help protect the immune system from oxidative damage and thereby enhance cell-mediated immune responses.

A lycopene rich diet can be beneficial in the elderly helping restore immune function, increase resistance to infection and tumor formation.

Lycopene is generally considered safe and beneficial especially when it is obtained from your diet. Many studies suggest that eating Lycopene rich foods or having high Lycopene levels in the body could support in reducing the risk of diseases and contribute to overall wellbeing, naturally. Regular ingestion of red fruits and vegetables is the best way to ensure you are obtaining enough lycopene in your diet. The main food sources of lycopene in our diet are fruits and

vegetables. At least 85% of dietary lycopene come from tomato fruit and tomato -based food products. The remaining 15% are usually obtained from watermelon, pink grapefruit, guava, and papaya—all fruits that are dietary sources of lycopene.

Rich sources of Lycopene

- Tomato
- Red cabbage
- Watermelon
- Papaya
- Guava
- Pink Grape fruit
- Mango
- Asparagus
- Grape fruit
- Carrots
- Sweet red peppers
- Apricots
- Red oranges

Tomato soup - Start your meal with a cup of healthy tomato soup with some fresh basil.

Spaghetti Sauce- Make your own spaghetti sauce by adding tomato paste and a little olive oil. Spaghetti sauce (or any red sauce made from tomatoes) is rich in lycopene, vitamins and minerals. Enjoy a healthy meal by serving it on whole grain pasta with a garden salad on the side.

Tomato Juice- Refreshing glass of tomato juice is another delicious way to get lycopene. It is low in calories and with plenty of vitamin A & C..

Salsa- Using salsa as a dip or a topping is another great way to get plenty of lycopene. Serve salsa with baked tortilla chips. Try topping your eggs, chicken breasts, pork chops and baked potatoes with salsa.

Watermelon- Eat regular servings of cut watermelon to get a bit of lycopene in every bite. Low calorie watermelon is a delicious source of potassium, vitamin C, and A.

Grapefruit - You can enjoy pink grapefruit juice with no added sugar to get lycopene in your diet. Pink grapefruit is also low in calories and is a rich source of vitamins A and C.

Daily Intake Levels and Recommended levels of Lycopene

With an increasing awareness of a healthy lifestyle, people are seeking added health benefits from their dietary intake. This has paved way for functional foods with supplemented components to promote wellness. Lycopene has the greatest antioxidant potential among carotenoids. Patients with cancer, infertility, metabolic syndrome and liver damage have been benefited by the nutraceutical effects of lycopene. Therefore, lycopene supplementation can function as a proper causative treatment of disease. According to results published in the journal Atherosclerosis, on an experiment conducted on certain individuals, that a daily supplement of lycopene 15mg for eight weeks resulted in increased activity of a powerful antioxidant enzyme SOD (super oxide dismutase), as well as reductions in measures of DNA damage in white blood cells.

Although regular eating of lycopene rich foods is recommended for optimal health, it can be difficult to obtain the appropriate daily servings. To ensure optimal daily lycopene consumption, nutritional supplements can help. Nutritional medicine practitioners often recommend 10-30 mg of lycopene daily to support optimal health, as no ideal daily dosage has been established. However, those with more serious health concerns may require larger doses of lycopene.

Lycopene Supplements

Lycopene accounts for about 50% of carotenoids in human serum. To increase lycopene levels in tissues is one prerequisite for using it as a dietary supplement to improve health.

Benefits of Organic Lycopene Supplements

For those seeking dietary lycopene supplementation can now consider organic lycopene produced exclusively from organic certified raw sources. Organic Lycopene is obtained by extraction from whole tomatoes (instead of their skin and other waste products), through carbon dioxide (CO_2) in supercritical conditions. The tomato berries are devoid of pesticides, heavy metals, dioxides, and they only come from natural varieties of tomatoes and are not genetically modified. Toxins and noxious chemical solvents are not used at any stage of production. Organic Lycopene carries a higher antioxidant and antitumoral activity.

Several factors such as the user's age and health are taken into consideration to know the appropriate dose of lycopene. However, always be sure to consult with your doctor before adding a regular lycopene supplement to your diet.

~Ms Uma Jothi

ADDICTION – Various Facets

[Identifying the disease in your Loved one and Understanding its complexities]

Human beings are mainly hedonistic in nature. Addiction is part of human nature. Addiction is defined as **"A chronic progressive behavioural pattern of an individual to seek pleasure or to reduce pain , has a tendency to grow in intensity, frequency and / duration , there is inability to reduce or refrain from the behaviour , when tried, there is a distinct physical psychological pain, that is reduced by repeating the same act. This behaviour directly causes impairment of interpersonal, personal, social and spiritual aspects of the individual."**
Traits of an individual with an **Addictive personality** – Intellectually superior, emotionally fragile, sensitive , unable to deal with one's emotions and socially manipulative. A person is born with an addictive personality. In a constructive direction he/she will be a super achiever, but would always require more love and attention than the other children. In the self- destructive direction he/she turns to substance use addictively.

How would you identify that your loved one is addicted to a substance from an early phase ? The following are the signs:

Early Phase

1. There is an Increased Tolerance to alcohol/drugs to get the same high.

2. There are episodes where a person goes through activities like walking, talking, even driving a vehicle 'apparently normally', with NO recollection of them afterwards, this is called a Blackout.

3. There is a constant preoccupation with planning the next drink session/fix. Family plans are made around availability of drinks or avoided for the same.

Middle Phase

1. Loss of control through an increasing number of drunk episodes

2. Justifying usage through emotional reasons outside of oneself- the blame game

3. Grandiose behaviour through spending unnecessarily , taking wrong business decisions under influence

4. Trying to control using by not drinking for a few days to keep the job or keep the family members quiet.

5. Addictive logic takes over wherein illogical decisions are made to protect one's drinking or using- eg jobs are left as the job was being affected because of one's drinking.

Chronic Phase

You see a

1. Physical, mental and social deterioration.

2. Binge drinking -drinking for days on end, loss of physical health but unable to stop.

3. Ethical breakdown- stealing, lying and hiding takes over. Every relationship, beginning with oneself, is strained and damaged.

4. Thus the transformation from Dr.Jekyll to Mr.Hyde is complete

One of the major obstacles in getting treatment or accepting help are the **Denials** you see in your loved one regarding their addictive using :

Avoiding the topic Making someone else feel guilty is one of the most common diversion tactics in such situations.

Absolute Denial one refuses to see the truth even though that truth is plain to everyone else. This is not lying, because the individual actually believes s/he is correct and that everyone else is mixed up.

Minimizing Eg:"I drink, but I don't do drugs."; " I don't drink that much – I don't fall in the gutter!"

Rationalizing Rationalizing and Justifying **Eg:**" I worked hard all week and deserve to party on Friday."

Blaming ("It's Not My Fault!"). Blaming other people for individual problems is almost a societal epidemic, and the addict is an expert.

Intellectualisation They spend a lot of time analysing themselves, other people, and the world around them. They use this "thinking about the problem" as a way of "looking for solutions," while

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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 .

not actually taking any true personal responsibility or steps toward change.

Thus addiction is a baffling, cunning and manipulative illness. It is a relapse prone progressive disease which if left untreated will result in insanity or death of the individual.

Substance Abuse in Women The woman at present is independent and managing home and work with energy.

But she has a deep rooted conditioning of emotional dependency making her vulnerable to dependency and co-dependency. Despite financial and educational independence they cannot get beyond emotionally dependence. Amongst the elite, the woman feels emotionally neglected by an over occupied spouse. In all instances, the woman feels under appreciated. The addiction is detected after a longer period of time and still remains hidden many times due to fear of social stigma. Women are affected physically more, owing to their shorter stature, metabolism and hormones. The loss of inhibitions and rationality makes them also more vulnerable to sex and to sexual abuse. She is ridden by guilt, resentments and fears which isolate her from her own true self and her loved ones

Childhood Trauma and Substance Abuse

The story of substance abuse leading to addiction lies not in the substance but in the individual- especially how one perceived one's childhood experiences , translated them to one's reality and perpetrated self -harm to escape from that trauma.

Forms of Childhood trauma :

- Child sexual abuse
- Maltreatment -physical and emotional abuse
- If your child has been neglected or there has been childhood negligence perceived towards your loved one.
- Witnessing domestic violence or experiencing it.
- Loss of parent resulting in guilt and feeling of abandonment.
- Illness of a loved one , physical or mental where the child goes through feelings of responsibility of having to be an adult before time- care-giver , co-dependent.
- Many adults who get into substance abuse might unconsciously imitate parents of using seen in parents who have been substance abusers.

Sexuality and Intimacy in Addiction

Alcohol and drugs reduce inhibitions and increase sexual drive. As inhibitions drop with intoxication, promiscuity and unsafe sex is indulged in. The duration of the sexual act from initiation to orgasm lasts longer under intoxication, giving the illusion of it being better, but though the drive and desire is high, the performance is affected. As a consequence intimacy and sexual relationships with one's partners is affected.

Youth and Addiction Issues

The youth of any generation are the clay from which future adults emerge. Today they have the world literally in the palm of their hands. There is so much information bombardment. The minds that are already highly impressionable are spoilt for choice . There is also an excessive experimentation, use, abuse and addiction to drugs and alcohol seen amongst them.

The patterns of drug consumption have also changed. Alcohol intake is not to savor the taste but to get completely "wasted". Marijuana today is no longer just " a herb" but comes in very potent forms and adulterated with chemicals too. Too many young people with addiction to only marijuana have wasted their lives consequently by dropping off studies and being non- productive.

Marijuana gets one acquainted with dealers and users who deal in other drugs, thus becoming a "gateway" for further use. A naturally curious adolescent and young mind craving for new experiences does not even realize before it is engaged and engulfed in usage of drugs that are addictive even on single use.

Today heroin is laced with fentanyl, Nbome is sold as LSD, mefedrone as cocaine etc. and these are extremely addictive and potentially very fatal.

The youth of today are thus looking for answers in drugs/alcohol etc. , the world gets more virtual and real time communication with family diminishes. A grounding within themselves is lost. This intelligence, curiosity and drive if channelized through meditative practices, inwards, there can be tremendous progress in every sphere in life, physical, mental and spiritual and the world can progress. Else it is going to be a zombie world where a substance is taken for everything from waking up[coffee], to work, to stay alert [Adderal] , to stay calm[alprazolam] to sleep [alcohol, valium] and would be apocalyptic.

The most common questionnaire for alcohol and drug use is the CAGE questionnaire

CAGE Questions Adapted to Include Drug Use (CAGE-AID)

[CAGE is an acronym for Cut, Annoyed, Guilty, Eye-opener]

- Have you ever felt you ought to **c**ut down on your drinking or drug use
- Have people **a**nnoyed you by criticizing your drinking or drug use.
- Have you felt bad or **g**uilty about your drinking or drug use?
- Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover (**e**ye-opener)?

Scoring: Item responses on the CAGE questions are scored 0 for "no" and 1 for "yes" answers, with a higher score being an indication of alcohol problems. Even one positive score indicates the presence of an alcohol / drug problem that requires treatment in the form of rehabilitation.

The disease of Addiction is thus the great social leveller.

~By Dr. Sujatha Nair

Parkinson disease and Ayurveda

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ABSTRACT
Parkinson's disease, a degenerative brain disease of dopamine secreting brain cells **Substantia nigra** is increasing progressively and presents therapeutics -levodopa, carbidopa, MAOB inhibitor, COMT inhibitors ,surgery and deep brain stimulations though improve presenting feature but not quality of life.

Present study using herbal composite containing **Mucuna pruriens, Herpestis monnieri, Acors calamus, Nardostachys jatamansi and Withania somnifera** taken in equal part shows better quality of life in all most all with marked improvement in movemement disorder in 92% cases as compared to 39% cases on conventional therapy.

In addition Herbal composite also improve the haematological, hepatic and Renal function by bioregulating body biomechanics and neural cell function, revitalizing neural cell damage in substantia nigra check distruction of dopamine and facilitate optimal level of Dopamine for normal brain function.

(Key words : Parkinson disease ,Substantia nigra ,Dopamine ,Livodopa ,Carbidopa ,MAOB inhibitor ,COMT inhibitor , Deep brain stimulation)

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Dr Shankar is working as **Chairman , National Institute of Health & Research** (Previously RA. Hospital and Research Centre), an autonomous organisation .

Introduction :

Parkinson disease is a chronic progressive and degenerative disease of Central Nervous System and presents with movement disorders which prompt handicap in long time . [1,2,3]

This is considered as a combination of genetic susceptibility, exposure to one or more disease triggering environmental factor .[4,5]

Clinical manifestations are solely due to degenerative change in substantia nigra, a seat of an important neuro transmitter synthesis i.e.- Dopamine and 60-80% loss of dopamine secreting cells presents with dreaded presentation of movement disorder i.e.- tremor , rigidity, bradykinesia ,postural instability. In addition changing dietary habits and lifestyle causes free radical accumulation also triggers the clinical presentation .[6-14]

The commonest diagnostic tool remain the clinical acumen but MRI is considered commonly prescribed investigation as CSF examination remain non conclusive .[15]

Commonly prescribed therapeutics are **levodopa, carbidopa, MAO B inhibitor and COMT inhibitor**, Presently surgery and deep brain stimulation are also quite in vogue.[16,17]

Long term Levodopa use is frequently associated with serious impact on patents quality of life, inhibition of peripheral amino acids decarboxylase is administered to achieve proper dopamine concentration in Central Nervous System .

Inspite of all the available therapeutic modalities incidence of Parkinson's disease increasing and affects 1% of the people above the age of 65 years and presently it is 247per lakh. There is no homogenous and large epidemiological data on PD from **India**. Razdan et al., reported a crude **prevalence** rate of 14.1 per 100,000 amongst a population of 63,645 from rural Kashmir in the northern part of **India**. The **prevalence** rate over the age of 60 years was 247/100,000.

Thus today's need is safe affordable and curative therapeutics .

Objective of the study :
Evaluate the comparative therapeutic efficacy of herbal composite in management of parkinsons disease .

Design of the study : comparative
Interest of Conflicts : None
Ethical committee : Ethical committee approves the evaluation of status of safe herbal composit in management of Parkinson disease .

Material & methods :
Material :
Patients attending neuro clinic of RA Hospital & Research Centre Warisaliganj (Nawada) and Aarogyam Punrjeevan ,Patna having complaints of movement disorders were considered for the proposed study. Patients with severe debility, bed ridden and associated other disease like diabetes mellitus and hypertension were excluded from the study .

Methods :
Selected patients and their attendants were thoroughly interrogated for their presenting features, their duration, age of onset, disease progression, treatment taken, their effects and adversity .

Patients were clinically examined and investigated for their basic bioparameters to adjudge the effect of drug or drug related adversity.

Selected patients were graded as per clinical presentation (as per Hochu and Yahr sstaging)

Stage	Characteristic
I	Symptoms of one side of the body
II	Symptoms on both side of the body, no balance impairment.
III	Balance impaired, physically independent
IV	Severe disability and still able to walk or stand
V	Wheel chair or bed ridden

Stage Characteristics

Selected patients were classified in two groups having equal number of patients with similar status and each group were advised –
Group A; conventional treatment with Levodopa /Carvidopa
Group B : herbal composite

Each Capsules of 500 mg constitutes equal part of –

Mucuna pruriens seed	100mg
Withania somnifera root	100mg
Herpestis monnieri leaf	100mg
Nardostachys jatamanshi	100mg
Acorus calamus rhizome	100mg

Mucuna pruriens Seed

Withania somnifera

Herpestis monnieri

Nardostachys jartamansi

Acorus calamus

Acorus calamus rhizome

Dose schedule : 1 cap every 8 hours
Each patients were given a follow up card to enter the changes in movement ,stability and handwriting with an instruction to attend the centre on every alternate Friday for first 6 months and every 3 months afterward .Patients were followed by the Medical social worker of the organization to ascertain the changes in clinical presentation .To adjudge the improvement in CNS function handwriting was analysed digitally on tab .
Clinical response was adjudged as –

Clinical grade	Characteristics :
Excellent	complete absence of movement abnormality without any adjuvant ,drug adversity and withdrawal or relapse
Good	marked improvement in clinical presentation with occasional dystonia No drug adversity
Poor	only transient relief with frequent recurrence and adversity

Observation:
Selected patients were of age group **40->60 years** with male predominance over the female. 73.7% male and 26.3% female were of age group 55-60 years ,6.6% of 40-45 years,26.3% were of >60 years. (Fig 1 &2)

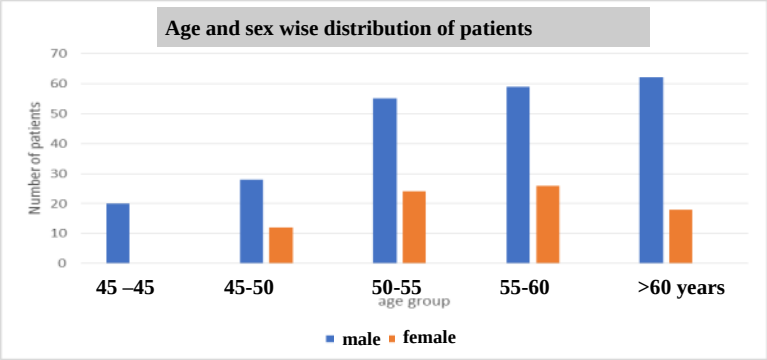

Figure -1: Bar diagram showing age and sex wise distribution of patients

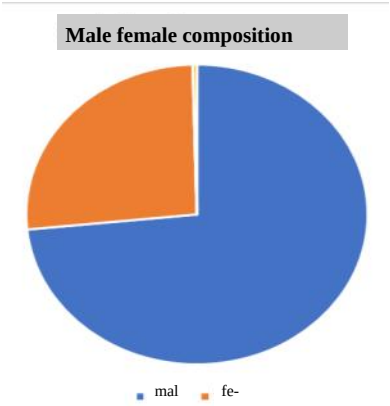

Figure -2: Pie diagram showing male : female composition

Out of all 12.5% were taking treatment since last 1-2 years, 27% since 4-5 years while 24.3% since >5 years (Fig -3)

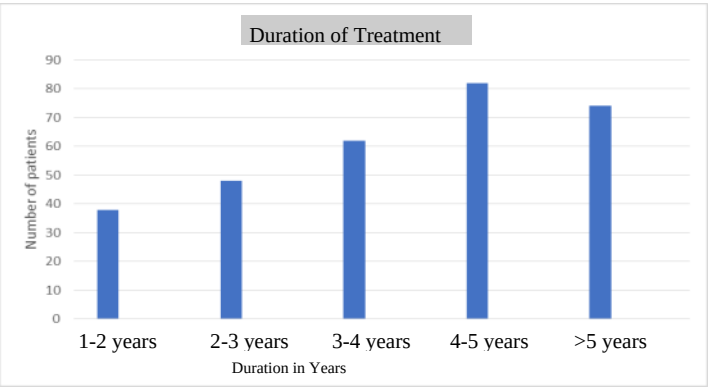

Figure -3: Bar diagram shows duration

22.4% were presenting with movement disorder, 45.4% with movement disorders on both side and 29% with balance disorder (Table -1)

Clinical presentation	#of patients
Movement disorder on one side of the body	68
Movement disorder on both side of the body	138
Balance impairment	88
Severe debility	10
Wheel chair Or bed ridden	44

Table-1 : Showing distribution of patients as per their presentation

As per clinical severity 22.4 %,45.4% ,29% and 3.2% are of stage I ,II,III and IV respectively (Figure -4)

Out of all basic bio parameters of the selected patients 77.6% patients had haemoglobin <10 gram %, Serum bilirubin >1mg%, SGOT and SGPT >30 IU, Alkaline phosphatase > 130 in 5.3% ,blood sugar (Fasting) >100mg% in 3.3% cases .

RESULT :

Patients on herbal composite shows early and better movement improvement as adjudged by handwriting or hand movement (ascertained digitally) than other group i.e.- 92% patients on herbal composite had normal hand writing while on conventional therapy only 39% cases (Fig -5)

Therapeutic outcome is better in both cases i.e. herbal composite alone or herbal composite with conventional drug than mere conventional therapy ,almost 100 % than 22.4% on conventional therapy .Post therapy bioparameters get improved in all the cases on Herbal composite than 02 patients on conventional therapy had worsening of parameters (Table -4)

CONCLUSION:

Herbal composite constituting equal parts of Mucuna pruriens ,Herpestis monnieri ,Acorus calamus ,Nardostachys jatamansi and Withanis somnifera proves worth in patients of Parkinson's disease in alleviating clinical presentation and improving quality of life without any untoward effects or withdrawal manifestation .

DISCUSSIONS:

Parkinson disease affecting elderly and more male than female result in handicap and bed ridden in spite of advanced therapeutics like surgery and deep brain stimulation ,current therapeutics though control movement disorder but fails to improve quality of life.

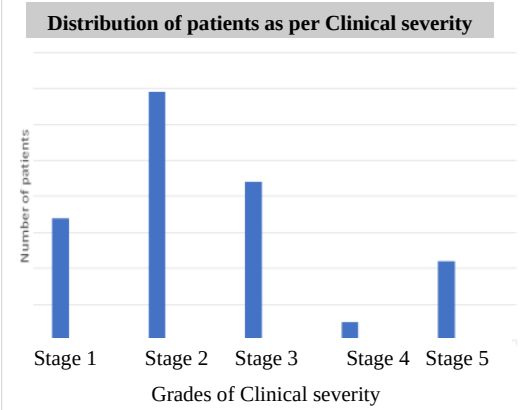

Figure 4 Distribution of patients as per clinical severity

Present study of comparative evaluation of herbal composite versus conventional therapeutics shows superiority of herbal composite than conventional i.e.- 92% patients on Herbal composite had grade I clinical recovery and better quality of life without any adversity or disease related sequel or required any adjuvant as compared to 39% on conventional therapeutics and is attributed to –

Mucuna pruriens : Provides Natural Levodopa to suppliment Dopamine

Herpestis monnieri :Revitalize damaged neyral cells in substantia nigra

Nardostachys jatamansi :

Check degeneration of neural cells in substantia nigra
Acorus calamus: Check metabolism of existing Dopamine
Withania simnifera : Bioregulate body biokinetics -improve quality of life

Hence combinely produce sustained improvement and bioregulate movement synegy ,check degeneration of neural cells in substantia nigra ,trevitalize damaged cell with provision of natural Levodopa .(Figure -7)[18-33]

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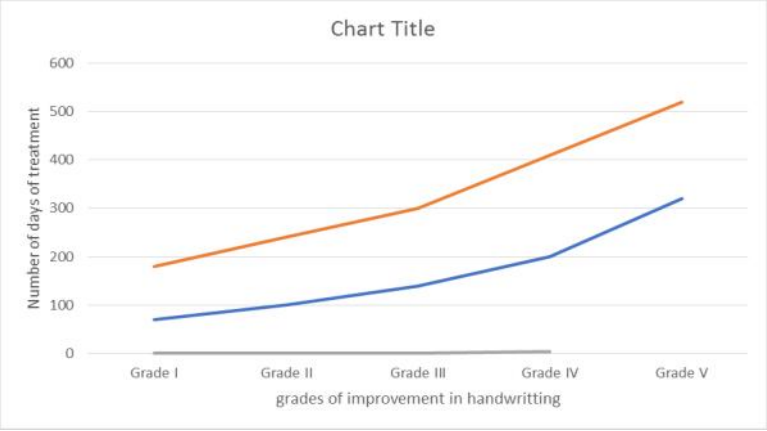

Figure -5 : Graph showing improvement in handwriting in mean duration of treatment

Table -2 : Showing basic bio -parameters

Basic bio parameters	Number of patients
Haematological :	
Haemoglobin :	
<10 gm %	236
>10gm%	68
Hepatic profile :	
Serum bilirubin :	
<1mg %	236
>1mg%	68
SGOT:	
<30 IU/L	236
>30 IU/L	68
SGPT:	
<30 IU/L	236
>30IU/L	68
Alkaline phosphatase	
< 100	288
>100	16
Diabetic profile :	
Blood sugar :	
Fasting :	
<100mg%	294
>100mg%	10
Renal profile :	
Blood urea :	
<30mg%	304
>30mg %	--
Serum Creatinine :	
<1.5mg%	304
>1.5mg%	--

Handwriting Abnormalities in Parkinson disease

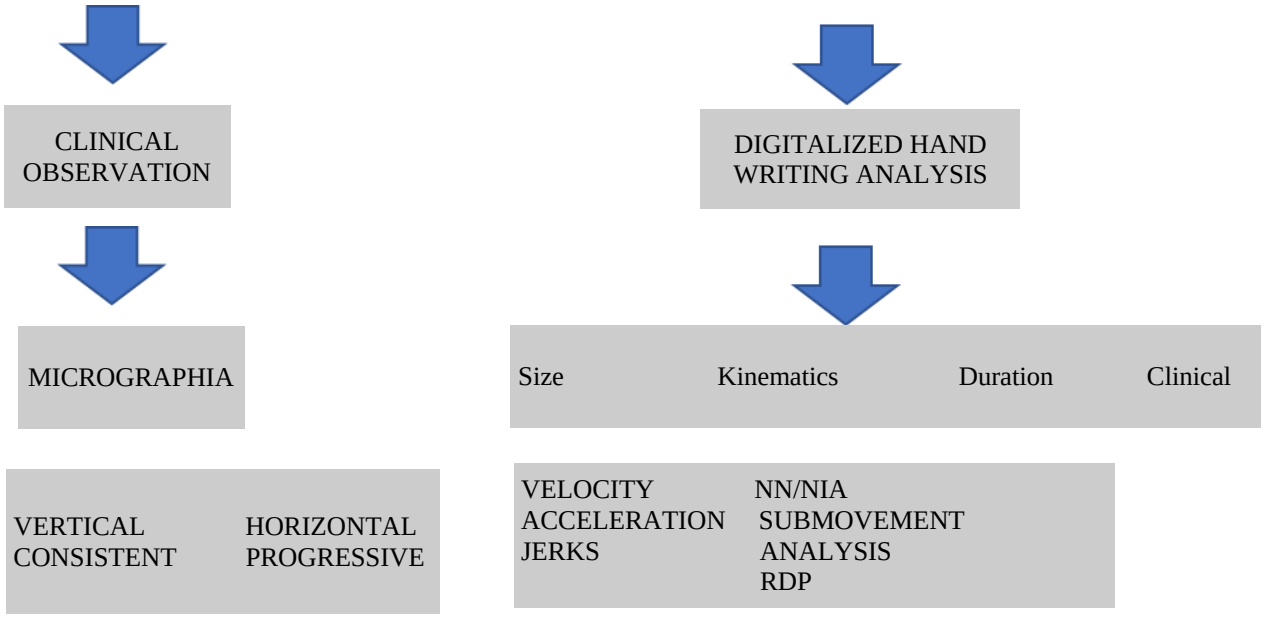

Fig -6 : showing hand writing changes

PARKINSON DISEASE

Stage I	Stage II	Stage III	Stage IV	Stage V
68	138	88	10	44

Selected patient
304

Group A (152) — Trial drug

Group B (152) — Conventional therapy

A1 Only trial drug

A2 Trial drug plus continuing drug

Outcome :	A1	A2	B
Grade I	75	76	34
Grade II	01	-	110
Grade III	-	-	08
Post therapy bio parameter:			
Unchanged	76	76	150
Changed	-	-	02
Urine albumin			01
Raised SGOT &SGPT	-	-	02
Decreased Hb	-	-	02

Figure -7: Out come of the study

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~By Dr Avinash Shankar

Mucuna pruriens

(Provides Natural Levodopa to suppliment Dopamine)

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(Revitalize damaged neyral cells in substantia nigra)

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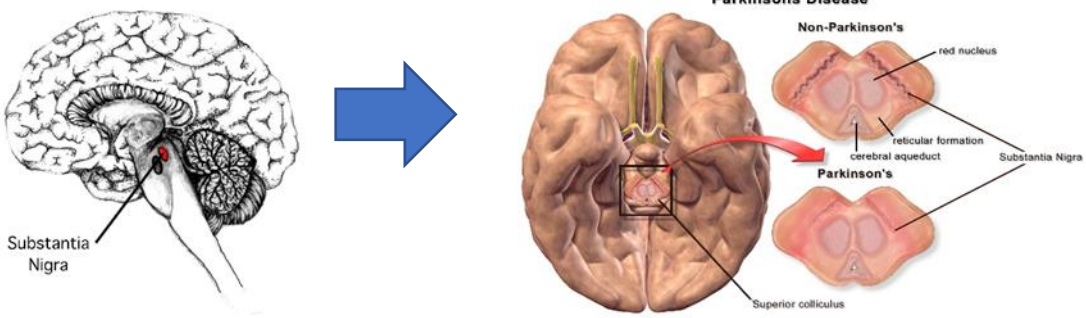


Withania simnifera

(Bioregulate body biokinetics -improve quality of life)

Combinely produce sustained improvement and bioregulate movement synegy ,check degeneration of neural cells in substantia nigra ,trevitalize damaged cell with provision of natural Levodopa .

(Schematic presentation of Herbal composite kinetics)

E-Pharmacy v/s Brick and mortar pharmacist

ONLINE WAR FOR BATTLE OF SURVIVAL

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 on-line 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

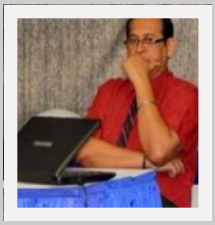
It is uniformly contended that purchasing the medicines through on-line is physically easier than going to the pharmacies especially for the senior citizens, i.e., the age group that spends most on drugs, the consideration is an important one. The on-line medium offers modern medical care tools and as such, their reminder information about the medicines and also render round the clock assistance. On-line pharmacies allowed the patients to purchase the drugs discreetly without face to face interactions. The rise in on-line 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.

Disadvantages to a purchaser of on-line.

- 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.
- 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.



DEBASISH M BANERJEE

Pharma/Healthcare Professional with proven ability to Conceptualize Innovative Strategies, Nurture talents, Build large teams and lead business operations. A dynamic and result driven professional with over 40 years of progressive work experience in Pharma / Life Sciences vertical (start-up/growing/LIC/MNC), having internalized best practices with core competence in Sales, Business Development, Training, D&IC, Compliance, Administration & Marketing at All India Level across key functions.

Proven proficiency in Pharmaceutical Consulting: Consulting assignment & business development, strategic planning & marketing across various sectors of Indian industry.

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 time-efficient, it affords more privacy than the brick and mortar pharmacy.

AIOCD PERSPECTIVE

Rajiv Singhal, General Secretary, AIOCD had earlier informed that all e-pharmacies 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 e-pharmacies. January 2019 witnessed a raise your 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 e-pharmacies to be promoted through the government's application. The AarogyaSetu App platform listed four e-pharmacies – 1MG, PharmEasy, NetMeds and MedLife.

AIOCD's main contention has been internet pharmacies and the illusion that e-pharmacies 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.

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 brick-and-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 off-line 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 on-line 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, on-line 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 on-line 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.

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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 value-added 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.

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 e-pharmacy contributes ~1% of the total therapeutic sales but according to NetMeds, 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 e-pharmacy 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.

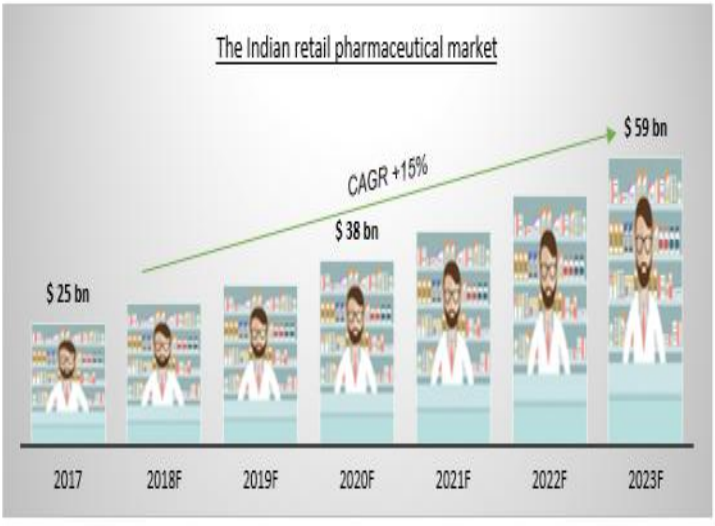
Co-founder of one digital platform had said that the priority would be to make clarifications to the court. Hoping against hope they expect the draft is released soon so that there is continuous supply of medicines to millions of families which are now dependent on online platforms for purchasing monthly 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 e-medicines 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.



Source: IBEF and EY

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 Prescription Exchange
Dispensing medicine by registered pharmacist	Medicines shall be dispensed under the personal supervision of a pharmacist according to D&C Act and Rules and Pharmacy Practice Regulation.	Prescription is required by a registered medical practitioner and sold through licensed 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 Conduct, 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.

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

spending from the current 1.6% to 2.5% of the GDP until FY 25.

There is significant opportunity for improving the healthcare services across the country, where penetration of quality and affordable outpatient & inpatient care services is limited.Moreover, increased awareness levels amongst consumers is further going to drive higher healthcare consumption levels. Driven by the same, the Indian healthcare market will grow at a healthy 17% CAGR and reach $353 Bn by FY 25. This will lead to an overall (Govt. and Private) increase from 4.6% to 7.1% spending on healthcare (as % of GDP) in a span of 6 years. The private spending will witness a ~2.6x increase during this period to reach $228 Billion. This along with $125 Billion government spending, will lead to $255 healthcare expenditure per capita in FY 25, significantly up from the current $99.

Source: Secondary Research & Articles / blogs and AIOCD bulletins/news

~Debasish M Banerjee

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The success cycle

What is that one thing that you strive for day and night from the day you came to your senses to the day when you'll lose them all (your last day on this planet)?

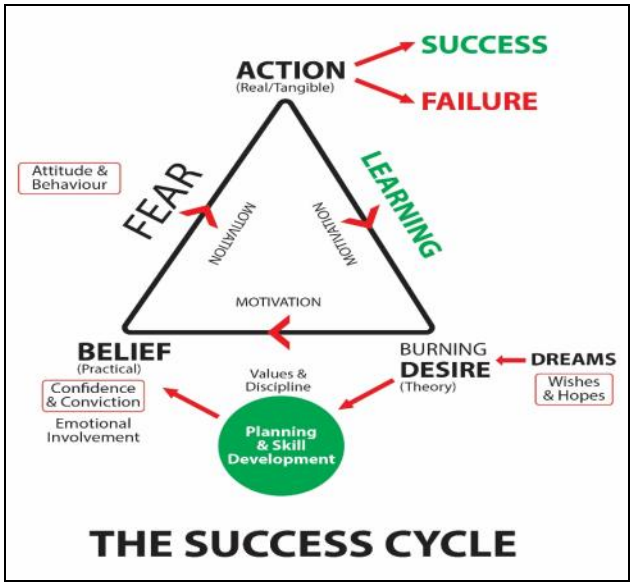
And in one form or another, every reply can be summed up to just one word - **SUCCESS**

Since we all have a different and our own personal definition of success, we all have a different meaning for success. Definition of success is derived from our own experiences and in most of the cases even after achieving our so-called success we don't feel successful. This is because we have not defined it correctly at the first place.

So before we start our journey to understand the 'Cycle of Success' we must first define it correctly. One of the most appropriate definitions of success is given by *Earl Nightingale*, which says

"Success is the progressive realisation of a worthy goal/ideal".

This is such a clearly stated definition that understanding it alone will give us much clarity about what success is. According to this definition, ***success is not a destination, but a journey (thus called progressive).*** The journey to keep moving forward in whatever we do, achieving more or better over time. this can only be done by improving our performance and performance can be improved by improving our own self. Secondly, we should progressively work towards some **'worthy goal/ideal'.** Have you ever thought what could be your worthy goal or ideal? ***A worthy goal must be larger than life, a goal which seems almost impossible with the available current resources, a goal which not only positively benefits you but also the people around you, your society, state, country or even the world.***



Most of the times we feel that "I am not worthy of that big goal", "How can I be that successful?", but the real question should be - "Is that goal worth my entire life?" Is my life worth spending entirely to purchase a home etc.? Just think over it, because remember - **'Whatever you put your energy to, it grows'**. Lastly it is important to understand that 'realization' of your goal is also important to call it a real success. Success should be real, that can be felt by you and the people around you.

It is commonly seen that a person who is good at one thing is also good at most of the other things and otherwise. Success, therefore, has to do something with the process or cycle which can be applied to any one and to any field. The diagram shown below depicts the cycle of success which is simple to understand but requires dedication, hard work, persistence and passion to implement it. If you are reading this line, I am sure you are qualified to implement the same.

Every achievement or success starts with a 'dream' **(Dream is not something that we see while we are asleep but something that won't let us sleep - *Dr.A.P.J. Abdul Kalam*).** Most of us fail at the very first step, as we are afraid to dream big and this is so because without understanding the intermediary steps to transfer it into success we jump to the last step where we visualize ourselves failing, and of course that seems true. It is just the same as we dream of topping the examination without knowing what it takes to be a topper, of course we can't expect success. it is my humble request that you should always dream big without coming to any rational conclusion about how you are going to achieve it, as 'HOW' is none of your business. once you dream big and start building a strong desire to make it happen, the 'HOW TO' will start appearing. Just dreaming and not desiring to move ahead with it in the success cycle will be called as 'Wishes and Hopes'.

Gurdeep Singh
Bachelor of Pharmacy (Gold. Medallist)

Mr Gurdeep Singh has started his profession in Pharmaceutical sales from Cadila and worked for Ranbaxy, Glaxo and Allergan at various positions. Handled training for over 10 years, where he has trained hundreds of professionals in sales and marketing. Also worked as a Product Manager at Win Medicare, Delhi. Started his own pharmaceutical company by the name Astron Lifesciences Pvt. Ltd. in 2005 and Marketing & Promotion Consultancy company by the name Ziva Resources LLP in 2016. With the passion of sharing knowledge that he gained during his education and professional years, He was also involved in delivering seminars and conducting workshops for professional college students and pharma professionals. He has written on various topics like Personal Development, Interpersonal skills, Communication skills, Success principles and related topics.

Your dreams are mere wishes and hopes if they are not converted into a burning desire. This burning desire is the theory based on which you start your planning and developing the skills required to achieve that goal. This process requires a high level of value system and discipline. This is the stage where you look for motivation that keeps you going despite the fact that you are unable to see the results of the hard work you are putting in, this is the stage where you are preparing the soil to plant the seeds in order to reap the fruits in future. This is the stage where you should never listen to the negative motivation from the people around you. If you really feel that you have a dream worth living for, then just close your ears and keep focussed. This is where your theoretical dream will get converted into a burning desire because you may not know how but you know why you have to achieve that goal, you have set for yourself.

Now since you keep moving forward this desire gets converted into your **'BELIEF'.** This is the stage where you start seeing the things practically happening in your mind. You will be able to see the things others can't and this is where people will try to drag you down and will try to convince you that your dream is practically impossible and you are wasting your time pursuing it. But remember, this is your dream and only you can visualize the results, this is why others can't see it. It is time to remember the golden words said by Mahatma Gandhi (on when you pursue you dreams, the challenges posed by others):

At first, they will laugh,
Then they will ignore,
Then they will fight,
And then you will WIN.

So be prepared to go through every line in your life, if you really want to achieve success.
This is the stage (BELIEF) where you get emotionally involved with your dreams and this is one of the most important stages of achieving success. With confidence and conviction, you start preparing yourself for acting upon the plans that you created during your preparation days. Believing in yourself comes to you when you work on your dreams and develop yourself.

The next stage of the success cycle is one of the most important stages because despite of all the preparations and belief that we have in ourselves, the fear of acting constantly stop us to reach out and be successful. This fear, is the fear of failure. This is the time to work upon your attitude and behaviour and realise that success and failure are just two faces of the same result. As explained by a famous speaker Zig Ziglar, FEAR is defined as:
F-False
E-Evidence
A-Appearing
R-Real
It is time to understand that, all the hard work you have put in to realize your dreams will never go in vain. If you are successful in achieving your dreams then you'll learn from it and then you'll reach to the same place from where you started, that is dreaming another big dream, but in case you fail, then again you'll get a learning from it go to the same stage from where you've started, your dream and rework on your plans and required skills, from where the cycle starts again. Now you can see here that the entire cycle results in one thing and that is **'LEARNING'**, because success and failure are not that important as learning is, because learning makes us a better person and this is the real goal of our life.

~By Gurdeep Singh

Pandemic India Versus Pragmatic India

IESECCI-COVID YODDHA A VETERANS INITIATIVE

This article is devoted to the ongoing effort of **IESECCI (Indian Ex Defence Service Employees Chamber of Commerce and Industries), a Veterans platform**, in working and synergising with like minded veterans, NGO's, volunteers, individuals, institutions etc. to create an ENABLING environment, empowering India's economic progress despite the ongoing challenge of COVID-19 Pandemic. A lot has already been and continue to be written, analysed, discussed and debated about COVID-19 by various experts. I feel that it is a new normal for atleast another one year from now and may be even more. Given the crumbling/crippling affect on Global and Indian economy and status of India's health care infrastructure, or rather the lack of it, especially in small towns and rural area, and seeing the first hand experience in ongoing health management and death tolls in major cities like Mumbai, Delhi etc. ,it is safe to presume that the following are the immediate steps for us as Veterans and civil society to undertake:-

A. **Social Distancing as a norm rather than exception**:-
The most telling affect of this Covid spread, has been and will be the ability to isolate and distance oneself socially. Also reverting to generic medicine, ayurvedic products,age old traditional medical recipes, Yoga, Jal Neti etc. are the game changer.

B.**Create Self Help groups**:-We all need to equip our self and ensure the same to our housing society,locality and group,with basic self help medical equipments like Oxymeter, Oxygen Cylinders,Ambulance Service,Telemedicine etc.Also the Covid Kavach and Covid Rakshak Insurance scheme is a great option and can be afforded by very large diaspora of economically marginalised population.

C.**Digital enabling:**-With the present job and economic down turn the best option for individuals without jobs or seeking economic empowerment is to enable themselves Digitally,and for that accessibility of Internet Service and Video Streaming platform is the necessity.

D.**Reviving Agro Industry**:-
We in recent times have neglected our National and civilisational strength of Agriculture and Agro Skills, especially in terms of lacking to create WAREHOUSING and also in providing the mechanism which enables a Agri product to reach the Indian and Global market,with least MIDDLEMEN interference especially in pricing of product.The present pandemic should motivate us to create the advantage of ITES and E-Commerce backed logistics support for the Agro industry and also we should utilise our farming capability and using of available agricultural land for market required CASH crops.

E.**Enabling Digital Education**:-The pandemic has given rise to the urgent demand of Digital education, which faces the great challenge of lack of Mobile connectivity compared to standards of globally developed nation. However this is also an opportunity for creating last mile mobile connectivity and also digitally enabling more Indian youth getting access to quality education of Global standards.

F.**ATMA NIRBHAR BHARAT**:-
The recent Govt initiative of promoting self manufacturing especially in Defence Industry and other Govt initiatives, is a great opportunity, which however can only be fulfilled by creating Skill based CLUSTER of Indian MSME and SME, which have the necessary Technology support .

G.**CSR as Social Impact tool:**-
The estimated Corporate Social Responsibility funds annually is more than 20,000 Crores. We should engage cohesively to access these funds as an enabling tool for Digital enablement, Health Care, Community .

Commander Angsuman Ojha(Retd.), Advocate and Co-Founder,IESECCI(Indian Ex Defence Service Employees Chamber of Commerce and Industries) and Life Member of Navy Foundation,Mumbai Chapter.
Commander Angsuman Ojha(Retd.),was Commissioned in Indian Navy on 01 January 1993 as a Permanent Commissioned Officer,in Executive Branch. He is a dedicated and resourceful Security & Safety, Administration, Legal Management, HR Management and Crisis Management Professional, offering diverse experience of over 21 years in the areas of Security, Safety, Legal and HR Management in different capacities. His past Indian Navy experience includes participation in OPERATION MADAD(Somalia UN Operations), OPERATION TASHA (Anti LTTE Operation), OPERATION VIJAY,OPERATION PARAKRAM (both are Indo Pak hostility operations). He has served in various Indian Navy war ships for 9 years. His Naval service also includes nearly 12 years continuous service as a Naval police specialist in various sensitive Defense organizations. Presently, other than being a practicing Advocate since 2014, Cdr. Ojha is Co-Founder ,Spokes person and Legal consultant of IESECCI ,a Registered Society of Veterans welfare, whilst being on the advisory capacity of all the other aspects that the IESECCI deals with . An excellent Disaster Management specialist, having First Hand experience of Tsunami relief Operations in Andaman & Nicobar. A ,quintessential deal maker, result driven and focused individual with immaculate work habits, with unusual capability to transfer this knowledge in empowering leaders and enabling aggregators, and group synergy .All thoughts shared in the article is the author's personal opinion only.

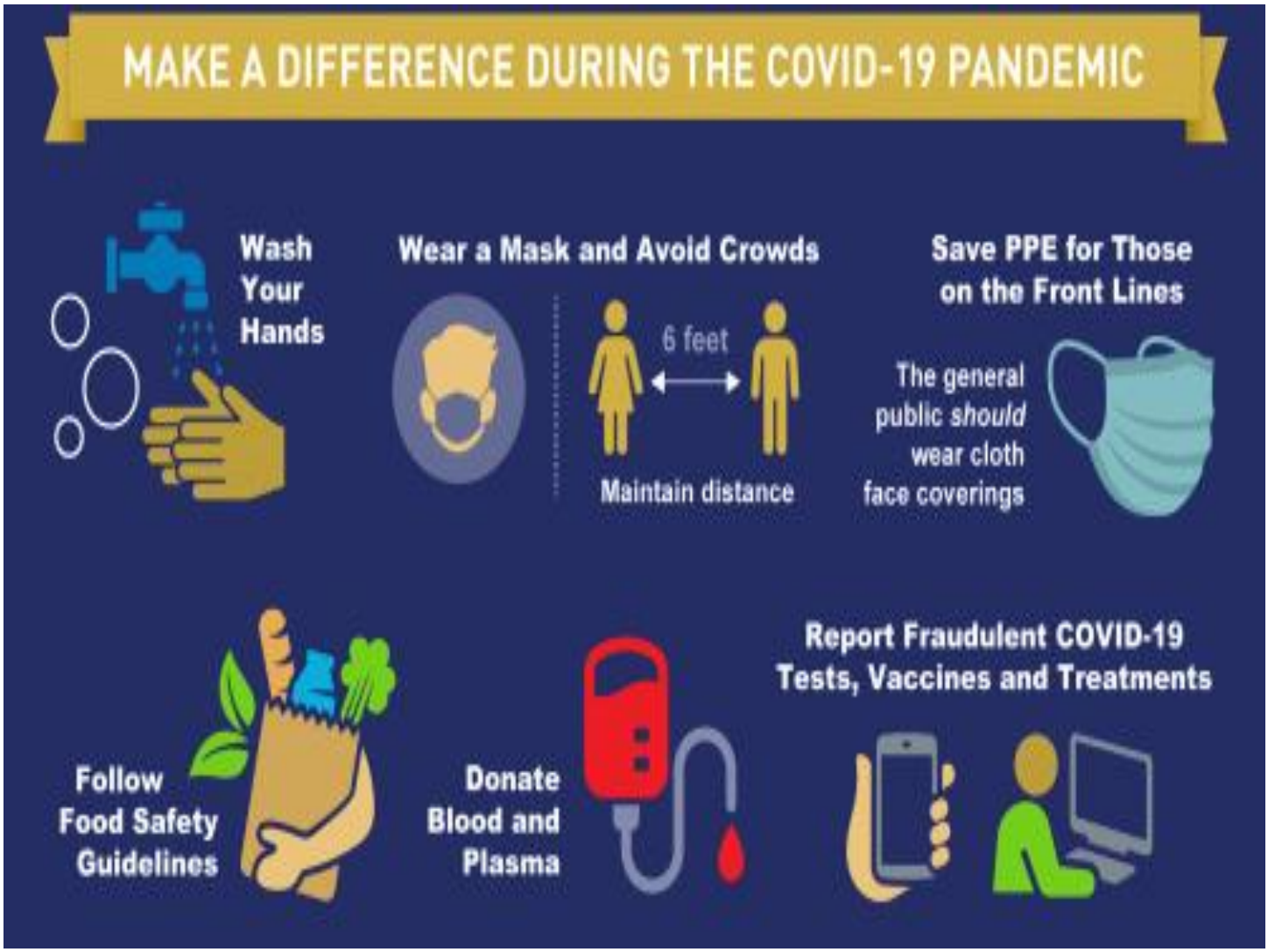
Capacity building etc.,so that the voluntary groups of Civil society can get the necessary monetary muscle to execute the task of reviving the India Growth story,in a socially inclusive manner.The plight of immigrant labourers returning from various cities,in abject dismal condition of financial distress,should be a lesson for all of us Indians,that we failed in our responsibility to uphold the dignity of life,liberty and livelihood of lakhs of citizens.

2.IESECCI,a registered Society for Ex Serviceman Welfare, as well as a Trust was formed in 2013., IESECCI in essence, is chartered to bridge the gap between ex-defence service personnel and businesses to have a mutually enriching role in commerce and industry. Approximately sixty thousand Indian Armed forces personnel leave service every year, and settle all over India.They are well trained, bear a positive attitude, in the prime of their life and conditioned to adapt to new roles and multitask. This pandemic has given us the opportunity to chart out a pragmatic approach by reaching out to our collective FAUJI community strength of adapting and synergising.

We have embarked in a slow but steady journey of Nation Building despite the COVID-19,with the true spirit of a COVID-YODDHA.

WE INVITE ALL TO JOIN HANDS WITH US IN THIS NOBLE JOURNEY. "BHARAT PRATHAM HAMESHAA SARVADAA" "INDIA FIRST ALWAYS AND EVERYTIME"

~ By Commander Angsuman Ojha (Retd.),



The evolution of FSSAI

The FSSAI (Food Safety and Standards Authority of India) may have begun its operations by regulating the over-regulated 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, globally-bench-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, ice-creams, 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.

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

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 e-commerce portal www.bodysatva.com

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 versions 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.

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.

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.

Conclusion

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

Value added auditing techniques

Hitendrakumar Shah
CEO - NADH^{+} GXP Compliance Services

Now a days, auditing is key for all pharmaceutical business either for evaluation of vendors, contract manufacturer, and service provider or for benchmarking and assessing the compliance level of the organization.

The GMP requirements are continuously changing (cGMP).To comply the cGMP requirements, the pharmaceutical company auditors or the professionals who pursue to become auditor should know the value added auditing techniques.

The traditional audit is having the compliance approach. Normally, it mainly focuses on compliance of quality management systems with the customer requirements, statutory and regulatory requirement, relevant quality standards, organization procedures and policies etc.

The traditional audit approach does not take in to account about effective implementation of the process. It just checks the compliance with respect to the compliance to specific clauses of the regulatory guidance.

Now, a days, there is need to do some value addition in the auditing so that it won't be just fault finding exercise. The main purpose or benefit of value added auditing is to develop a review procedure of specific system or process so as to ensure the process or system is effectively implemented. This value added auditing techniques helps organization in improvement with respect to cGMP compliance.

It also enables the risk based thinking process. The risk assessment strategies are traditionally applied for defining the frequency of the audits, however, we can apply the risk based thinking for identifying the critical checks/systems/ procedures to be reviewed. The criticality can be assessed based on supplier issues, customer complaints, feedback or changes made in process, product specification, specific requirements etc

The value added auditing techniques supports combination of horizontal and vertical audit rather than only horizontal audits. To achieve the goal of this auditing, the auditor can go upward (following the process flow) or downward (reverse of the process flow).

The one major focus of value added auditing is to review the processes which are interconnected. This helps in evaluation of compliance as well as finding the gaps, reason of gaps and provide suitable solutions in the filling the gaps or compliance improvements.

This technique can be applied for supplier auditing also. Because, overall improvement in the compliance level of the supplier can lead to improvement in the product quality in which the ultimately the auditor (Auditor's organization or country) is interested. Of course, this technique can have added advantage for self-inspection so that a common goal of compliance improvement can be achieved.

~By Hitendrakumar Shah

When Should Formal Quality By Design Documentation Begin?

When is the best time to start quality by design (QbD)? This question is asked most frequently among many small firms. A better way to phrase it is: When should I formally document my QbD activities?

The short answer: *Document the current state of knowledge and risk before the registration campaign begins.* In reality, QbD activities begin before Phase 1.

This article discusses three reasons why the registration campaign is the perfect time to formally document the quality risk assessments (QRA) for the drug product and manufacturing process. The principles of QbD have become embedded into industry thinking.

"Debunking the Top Three Myths About Quality by Design (QbD)."

Reason 1: Capture The Current State Of Knowledge

Small firms run lean and rely heavily on contract development and manufacturing organizations (CDMOs). Luckily, most CDMOs understand the basics of QbD. Early development activities are carried out with the critical quality attributes (CQAs) in mind, even if they are not formally documented. Knowledge of the product and process is usually contained in a fixed set of project management deliverables from the CDMO, such as campaign reports, weekly project updates, change controls, and deviation investigations. It is not uncommon in early phases to have process development runs executed just prior to a production campaign. In many instances, the parameters are tweaked between batches of the campaign.

Products and processes are not locked and there is a heavy reliance on end-product testing to demonstrate fitness for use. At this point, most readers are probably thinking, "Tell me something I don't know."

The registration campaign is a natural point to formally assess the current state of knowledge and plan the next phase of development. Registration material is typically made for Phase 3 studies or for late Phase 2 studies for products on a fast track. Either way, the registration campaign means the product and the manufacturing process have defined materials and equipment. While further optimization and QbD studies will be executed in the following months, the amount of change from this point forward is greatly reduced. The registration campaign is the perfect time to determine what is known versus not known and is not the time for assumptions. The QRA reflects the current state of process understanding and serves as a gap analysis between current knowledge and what is still needed.

It is commonly understood that risk is inversely proportional to process knowledge. I use preliminary risk assessments that measure uncertainty as a risk component. Uncertainty is a measure of the quality and depth of data supporting the risk decision. The more uncertainty, the greater the risk because of the lower confidence in the final risk decision. Uncertainty is particularly useful with QRAs in development, which work with limited data sets. I ask SMEs to reference the data upon which their conclusions are based. Three main questions really gauge the level of knowledge:

- What do you know?
- How do you know it?
- How good are you?

Table 1 is a subset of the uncertainty criteria showing a major difference in the level of knowledge. Category 3 reflects expert opinion and experience, while category 2 indicates experimental data supports the conclusion. When data supports the conclusion, one can go to the study, report, or other document where data is captured.

Sometimes, the study is well written and executed. In these instances, the uncertainty is low, and the conclusions are fully supported. Other times, data is present and gives a good sense of direction but does not suffice for the final data. It can be for a variety of reasons, including a statistically poor sampling plan or unvalidated analytical methods. On rare occasions, the conclusion is based on data assumed to be available but that, in fact, is not. It is not the expectation that everything be final with fully characterized processes or perfect data sets. The important point is understanding the known from the unknown.

The QRA process allows the SMEs to compile and present the knowledge in a logical format, which grounds the project team on a common understanding.

Kevin Wall

Kevin Wall is principal consultant and owner of **Cincero Consulting**. He has worked with five virtual pharmaceutical companies to move eight of their drug substance and drug product projects through development. He applies "fit for phase GMP" from Phase 1 to commercialization. Wall's process for identifying critical quality attributes (CQAs) and critical process parameters (CPPs) forms the basis for the CMC section of the regulatory submission (ICH Q11). He led the Johnson & Johnson development and global deployment of quality by design (ICH Q8) and quality risk management (ICH Q9) in pharmaceutical development and operations. He helped define and deploy Janssen's risk-based qualification and process validation systems (ICH Q7). .

Table 1: Uncertainty Criteria

Category	Uncertainty
2	Specific Knowledge i) The parameter has been experimentally evaluated on a sufficiently similar product (same API dosage form, formulation, process etc). Ii) The parameter has been experimentally evaluated on this particular product, but further investigation is still necessary.. Iii) Data demonstrates a casual relationship between the parameter and CQA
3	General Knowledge The effect of the parameter can be inferred based on general prior knowledge (Knowledge of pharmaceutical technology, empirical argument, etc) Corelation between parameter and CQA is based on expert opinion.

Table 2: Preliminary Risk of Drying

Factors / Drug Product CQAs	Drying			
	Uncertainty/Probability	Severity	Risk	Reference
Potency	3	4	High	1
Impurities	3	4	High	2
Dose Uniformity				
Water	2	4	High	3
Dissolution	2	3	Medium	4

Reference	Description
1	Incomplete drying causes low potency, due to replacing active with water, further study required. Compressing to weight is a risk with high water.
2	Impacted by heat and time, impacts impurities at release and shelf life. Limited data on impurity profile.
3	Firm water specification not established, IPC for water content.
4	Limited process knowledge at water upper limit. More studies required for increased knowledge. Current control is IPC +/- 1%.

In my experience, it has been one of the most value-added activities on a project.

Reason 2: Align With Your CDMO

Engaging the CDMO on the QRA prior to the registration campaign has multiple benefits. Your CDMO likely has been heavily involved in developing the process and it certainly knows its process flow and equipment. Formally documenting its knowledge moves it from the realm of tribal knowledge to institutional knowledge. It makes the QRA better and ensures the sponsor is on the same page as the CDMO.

A formal meeting with all functions present is essential. Many details are overlooked if sponsors do the risk assessment in isolation. It is not a good idea to simply have the CDMO review your output. Risk assessments work best with collaborative interaction, as the group chemistry, with back and forth discussion, teases out information that would otherwise go unnoticed. The discussion should be cross-functional. It is the time to understand the manufacturing process from different perspectives.

I particularly like to have these discussions at the CDMO's manufacturing facility. Going to the production line to see the equipment and ask questions gives a better appreciation of the process. This QRA process moves from theoretical to fact-based. The main goal is documenting the current state of knowledge, and that happens best where the action takes place. The factory setting makes the discussions more concrete and specific and lays the foundation for better communication with the CDMO. Effective communication is the key intangible that ensures success.

Get The Best Results

I find it works best to have a facilitator lead the QRA meeting. Ideally, it would be someone with a technical background. It should definitely be someone who understands the risk assessment process. Having an independent facilitator accomplishes a few things:

1. Facilitators allow the SMEs to focus on the details.
2. Facilitators help the team ask the right questions.
3. Facilitators keep the team from getting bogged down in weeds, knowing when to table some of the discussion.
4. Facilitators help ensure a consistent output.

Reason 3: Prepare Development Plan For Commercialization

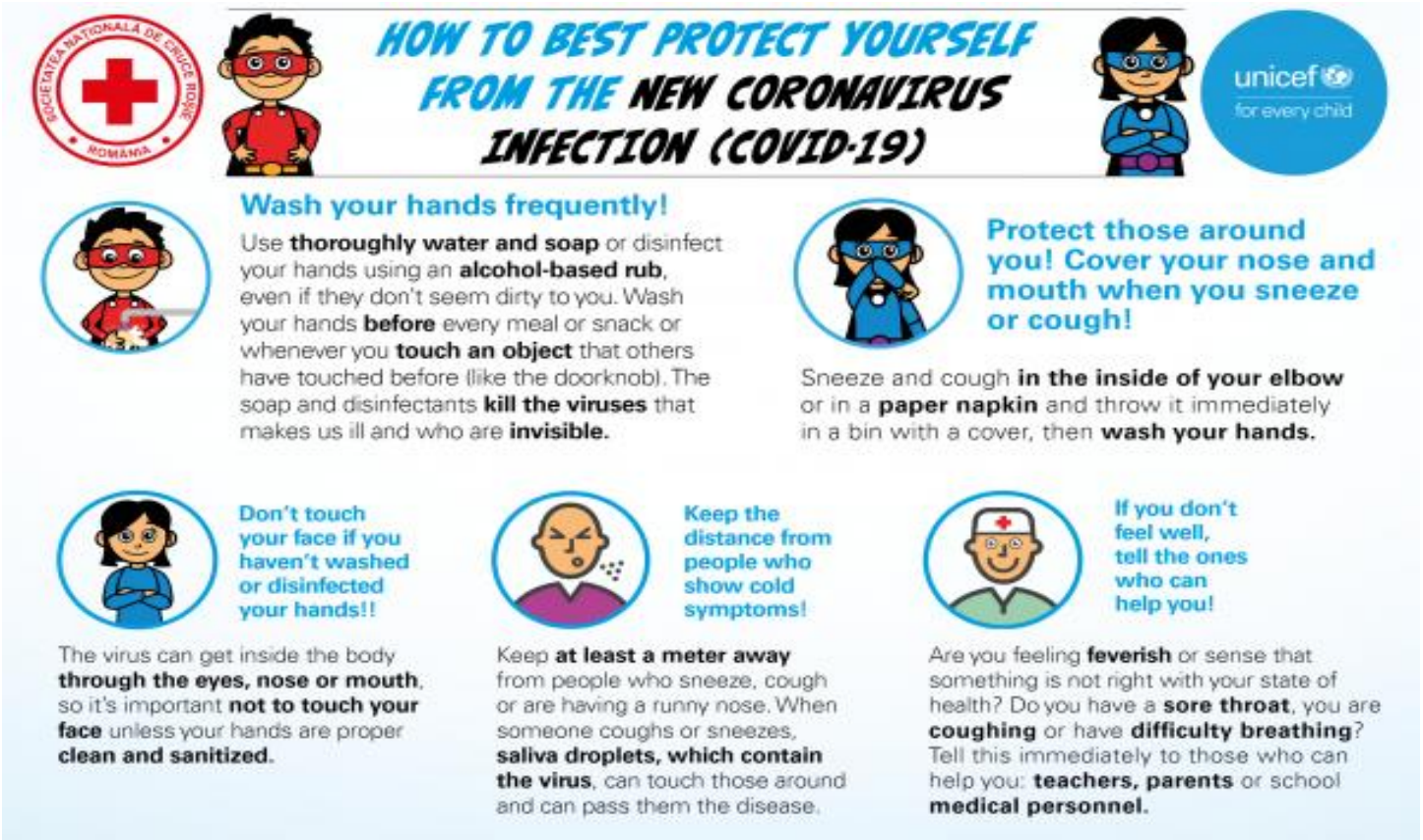
By far the best value of the preregistration campaign QRA is ensuring the campaign produces the best quality of information to close *specific* knowledge gaps. The registration campaign provides an opportunity to sample multiple locations and time points. Don't miss the opportunity to further characterize the process. On many occasions, the process risk is high because the level of knowledge supporting the decision has high uncertainty. *Table 2* represents a preliminary risk assessment for drying after wet granulation for an immediate release tablet. In this case, the formulation scientist has extensive experience with the excipients and the particular manufacturing equipment. The project has progressed quickly, with limited data collected. Expert opinion with some preliminary data is the basis for most knowledge. The elevated risk rating reflects the level of uncertainty. The QRA identified some key areas of study for the preregistration engineering batches and the registration campaign itself. In particular, the team decided to challenge the time and temperature impact on impurities during the engineering batch. They would collect data on impurities with the newly validated method. They also ensured the test plan included correlating moisture with potency and dissolution. The important lesson is the project team determined how to best gather data to fill in holes in the risk assessment. They went into the campaign with clear data-gathering objectives based on the initial risk evaluation.

The QRA should be updated after the registration campaign to incorporate the new learning. The updated QRA provides the basis for the development activities conducted between the registration campaign and process validation. The iterative nature of the QRA allows the project team to adjust experiments to focus resources where they can be most effective.

Conclusion

The registration campaign is a huge investment, and getting the most from it makes business sense. The best practice is to work with the CDMO to assess the risk. Planning data collection beforehand ensures the most valuable data is collected. Good risk management execution not only ensures a successful registration campaign, it lays down the path for development activities, culminating in process validation.

~By Kevin Wall



Patent Opposition in India

A patent is an **exclusive monopoly** granted to the inventor, for an **'invention- product or process'** to lawfully exclude others from **making, selling or using the invention**. The processing of a patent application is a multi-stage process that involves-

- Filing of an application
- Electronic data processing
- Screening and classification
- Publication
- Examination
- Hearing, if required
- Pre-grant opposition
- Grant/refusal
- Post-grant opposition

The procedure for filing patent application and its processing up to grant/ refusal, maintenance etc. are governed by **The Patents Act, 1970.** *This article focuses on the opposition system in Indian Patenting procedures.* Opposition proceedings, in fact, in any jurisdiction are fundamentally required to confine the grant of wrongful or frivolous inventions by third parties before or after the grant of a patent. Every jurisdiction follows certain laws to impede such illegitimate grant of patent. The Indian Patent Act provides the provision of both pre-grant as well as post-grant opposition. Section 25 of the Act as amended in 2005, governs the provisions for opposition proceedings to grant of patents.

Pre grant opposition

The provisions of section 25(1) of the Indian patent (Amendment) Act 2005 governs the filing of a pre grant opposition by third parties against a patent application, based on the grounds provided under this section. Under this provision any person or third party may, in writing, represent by way of opposition to the Controller against the grant of pending patent application after it has been published. The Indian jurisdiction provides third parties a time period of 6 months from the date of publication of the application to the grant of a patent, to file the representation for opposition in Form-7(A) along with a statement and evidence in support of the opposition. However, the Opponent may file the representation only after the request for examination of the application has already been filed by the Applicant.

The Controller then notifies the Applicant, based on the virtue of representation by the Opponent, and the Applicant is required to submit a reply statement within three months of receipt of the notice along with evidence, if any. The Controller then after considering the written submissions and hearing both parties, may either dispose-off the opposition and proceed with the grant of patent, or ask the applicant for certain amendments in the complete specification and/or other documents before allowing for the grant of patent, or may refuse the grant of patent by passing an order under Section 15 of the Patent Act, 1970.

Post grant opposition

The provisions of section 25(2) of the Indian Patent (Amendment) Act 2005 governs the filing of a post grant opposition by any 'person interested' after the grant of the patent but before the expiry of a period of one year from the date of publication of grant of the patent, by way of notice of opposition made in form 7 and sent to the controller in duplicate. The Opposition may be made on any of the grounds disclosed in section 25 (2). The "person interested" as per section 2(1)(t) is defined as including a person engaged in, or in promoting, research in the same field as that to which the invention relates.

On receiving the notice of opposition, the controller constitutes an opposition board, comprising three members, where one of them is a chairman. The opposition board conducts the examination of the notice of opposition and the documents filed under rules 57 to 60 and submit its recommendations to the controller within three months. Further a hearing is scheduled between both parties by the controller and decision for the patent to be revoked, maintained or amended is taken.

It is to be noted that the pre-grant opposition under section 25(1) is wider than the post-grant opposition under section 25(2), as the latter allows only 'person interested' to file the representation. The grounds of opposition for both the pre grant and post grant oppositions are similar.

Both Pre grant and Post grant opposition can be made on the grounds listed below:

- Wrongfully obtaining the invention
- Anticipation by prior publication
- Anticipation by prior date, prior claiming in India
- Prior public knowledge or public use in India
- Obviousness and lack of inventive step
- Non patentable subject matter
- Insufficiency of description of the invention
- Non-disclosure of information as per the requirement or providing materially false information by an applicant

Patent application not filed within 12 months of filing the first application in a convention country

Tanu Singh

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- Nondisclosure/ wrong mention of source of biological material. Invention anticipated with regard to traditional knowledge of any community, anywhere in the world.

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- Obviousness and lack of inventive step
- Non patentable subject matter
- Insufficiency of description of the invention
- Non-disclosure of information as per the requirement or providing materially false information by an applicant
- Patent application not filed within 12 months of filing the first application in a convention country
- Nondisclosure/ wrong mention of source of biological material. Invention anticipated with regard to traditional knowledge of any community, anywhere in the world.

Some remarkable judgements in opposition proceedings

Novartis Ag vs Natco Pharma Ltd. on 25 January, 2006:

In this case, the patent application of **Novartis Ag, 1602/MAS/1998** was refused under section 15 during the opposition proceedings. The invention titled **"Crystal Modification of A.N.-Phenyt-2-Pyrimidineamine derivative, processes for its manufacture** and its use was challenged by a way of representation under section 25(1) by Natco pharma on the grounds that imatinib mesylate is known from the US Patent No: 5521184 and was also cited in another prior publication. Further, non patentability under 3(d) was also raised as one of the grounds, as the applicant has claimed a polymorphic form of already known imatininb mesylate. The opponent established that the affidavits submitted by the applicant do not prove any significant enhancement in the efficacy, and also proved the grounds based on prior publications & wrongful priority claim. The application was, thus, rejected by the Controller.

American biosciences INC vs Natco pharma:

The application titled "Sterile Pharmaceutical Composition" was challenged by a way of opposition as per section 25(1) under the grounds of section 2(1)(j), 3(e) and 10. After examining all the documents submitted by both the parties and the arguments made by them during the hearing, the claims were found non patentable u/s 2(1)(j), 3(e) and 10 of the Patents Act, 1970, and therefore, the instant application was refused u/s 15 for grant of patent. The Applicant filed an appeal in 'Intellectual Property Appellate Board' (IPAB) against the said decision, where the Hon'ble IPAB reconsidered the case and set aside the order of the Controller, further remanding the matter to the Assistant Controller for fresh consideration.

The opponent filed a fresh representation u/s 25(1) on 28/03/2014 under the grounds of section 25(1)(g) and 25(1)(f) limited to section 3(d).

Difference between pre grant and post grant opposition

Parameters	Pre-Grant Opposition	Post Grant Opposition
Filed By	Any Person	Person Interested
Form	Form 7A	Form 7
Time period for filing	Any time after the request has been made but before the grant of the patent.	Within 1 Year after the grant of the patent.
Fee	No fee	Fee prescribed in the Patent Act 1970
Infringement Proceedings	No infringement proceedings	Infringement proceedings are considered
Coat and time consumption	More economic, effective and faster disposal of cases	High cost incurred, and time consuming proceedings due to trials and extended hearing in court.

After considering all the submissions, the Controller concluded that amended claims 1 to 12 lack inventive step and do not constitute an invention u/s 2(1)(j) of the Patents act, 1970. It was also presented that the pending claims fall u/s 3 (d) and 3(e) of the Patents Act, 1970. The application was finally refused for grant of patent.

Recent Trends in Pre-grant opposition

The Indian Patenting system allows any person (third party) to file a pre-grant opposition and that too free of cost. The idea behind this provision is to aid the examination procedure of an invention, and to encumber granting of wrongful or frivolous inventions, as was held by the Hon'ble Delhi High Court in ***UCB Farchim vs. Cipla Ltd. & Ors.***

"....This Court finds merit in the contention that the pre-grant opposition is in fact ***"in aid of the examination"*** *of the patent application by the Controller...."*

However, quite frequently nowadays, it is observed, that the third party tries to misuse their rights in delaying the grant of several important patents using illegitimate strategies. In several patent applications made at Indian Patent Office, a multiple number of pre-grant oppositions are filed by the Opponents one after another without providing useful insights into the matter by citing any new references or necessary evidence over the already considered responses to examination report or already file representation of oppositions. This line of attack is merely to delay the grant of a patent.

Apparently, such strategies do not comply with the judicial intent of assisting the examination of the application and is an exploitation of the legal system of patenting procedures.

Conclusion

The Opposition system prevalent in our country may be "a boon or a bane" in the patenting procedure of a new invention. To make it a "boon", some changes in our legal system are definitely required. The Controller needs to efficiently identify the merits in the opposition being filed before notifying the Applicant about the same. If the subsequent representation of oppositions by other opponents carries no further merits than what has already been held in the examination reports or former oppositions, the representation should be dismissed *in-limine*. Further, some penalty must be imposed on such fraudulent opponents to ensure a legitimate proceeding of any application as governed by the Patents Act, with the opposition truly serving as an 'aid' in the examination procedure towards the grant/refusal of a patent.

~By Tanu Singh

Indian legal position on impact of post grant opposition procedure on patent enforcement

It has been six years since the landmark decision of the Hon'ble Supreme Court ('SC') in ***Dr. Aloys Wobben and Anr. Vs. Yogesh Mehra and Ors.*, AIR 2014 SC 2210**. In this case, SC laid down dicta concerning post-grant opposition mechanism laid out in Section 25 (2) of the Patents Act, 1970 (as amended) that:

"18. ...If and when, challenges raised to the grant of a patent are disposed of favourably, to the advantage of the patent holder, the right to hold the patent can then and then alone, be stated to have crystallized. Likewise, if no notice of opposition is preferred, within one year of the date of publication of the grant of a patent, the grant would be deemed to have crystallized. Thus, only the culmination of procedure contemplated under Section 25(2) of the Patents Act, bestows the final approval to the patent. Therefore, it is unlikely and quite impossible, that an "infringement suit" would be filed, while the proceedings under Section 25(2) are pending, or within a year of the date of publication of the grant of a patent."

Notably, the said SC decision was rendered in the context of multiplicity of proceedings for revocation of a patent and it was held therein that all the available remedies cannot be availed for the same purpose, simultaneously.

Implications of SC's Dicta in *Dr. Aloys Wobben and Anr. (supra)*

The SC dicta above had important implications for the potential influence of post grant opposition procedure on the enforcement of patent rights as certain critical questions arose out of it - which were left unaddressed therein. The obvious questions were:

- Can mere filing of a post-grant opposition be permitted to freeze or keep in abeyance the rights of a patentee keeping in mind the statutory scheme of the Indian patent law which doesn't even provide for stay of the patent infringement suit after a post-grant opposition or revocation petition or counter-claim is filed?;
- Would any such interpretation not cause immense hardship for a patentee where frivolous post-grant opposition is filed intended only to freeze the rights of the patentee particularly when Indian patent law doesn't provide for patent term extension?;
- Can there be any blanket immunity for a potential infringer from liability for patent infringement in instances where a post-grant opposition is pending or opposition period has not lapsed?; and
- Can mere pendency of post-grant opposition period/proceedings, and revocation of a patent have exactly the same consequence of non maintainability of the suit for infringement of the patent itself?

With all due respect to the Hon'ble Apex Court, while the language of the SC dicta above is quite clear, it appears that the Hon'ble Court was not apprised about ground realities involving time-consuming patent grant and post-grant opposition procedures and the likelihood of misuse of said dicta by the malafide infringers who could use it blanketly as a strategy to delay the enforcement of a patent.

Examining Subsequent Jurisprudence

The said SC dicta has been cited in several decisions since then and therefore it is really interesting to see how it has been interpreted by the Courts over the past half decade.

The issue of impact of post-grant opposition procedure on enforcement of a patent was recently dealt with by the Hon'ble High Court of Delhi ('DHC') in the two cases of ***Novartis AG & Anr. Vs.*** [Order dated May 2, 2019 in CS (COMM) 229/2019], and *CDE Asia Ltd. Vs. Jaideep Shekhar & Anr.* [Decision dated February 24, 2020 in CS(COMM) 124/2019].

In Novartis AG & Anr. (supra), the Single Judge ('SJ') of the DHC was faced with an issue of grant of an ad-interim relief to the plaintiff-patentee Novartis during the pendency of a post-grant opposition filed by the defendant Natco against Novartis' patent concerning its anti-cancer drug **Ceritinib**. The SJ in this case discussed a situation where launch of an allegedly infringing product occurred prior to the decision in the post-grant opposition. In this case, the suit patent was granted on September 28, 2015 and the suit was filed in May 2019 when the Controller's order itself was reserved on said post-grant opposition.Natco placed reliance on the said SC decision to argue that once a post-grant opposition is filed, the rights therein are yet to be crystallized,

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since the post-grant opposition is pending. While taking note of the fact that Natco chose to commercially launch the impugned product during the pendency of the post-grant opposition, the SJ held that during this period, the rights of a patentee subsist – though they may be crystallized once the opposition is actually decided. The SJ observed that Natco ought to have awaited the decision in the post-grant opposition before launching its product. The SJ distinguished the said SC decision by holding as follows:

"17....While the Supreme Court in Aloys Wobben (supra) held that the rights would be crystallized once the post grant opposition is decided, launch of an allegedly infringing product, prior to the said decision in the opposition by the entity opposing the Patent, did not arise in the facts of the said case. Section 48 of the Patents Act grants rights in favour of a patentee, which are not affected during the pendency of a post-grant opposition. ..... During the pendency of the post-grant opposition, the rights of a patentee subsist – though they may be crystallized once the opposition is actually decided.."

Finally, while observing that Natco, having been well aware of the facts that the suit patent stood granted and that the post-grant opposition was pending adjudication, ought not to have launched the product during the pendency of said opposition, the SJ restrained Natco from carrying out any fresh manufacturing of pharmaceutical preparations comprising of the patented active pharmaceutical ingredient Ceritinib temporarily.

On the other hand, in *CDE Asia Ltd. (supra)*, the SJ was faced with an issue of maintainability itself of a patent infringement suit within one year of grant of a suit patent in view of the interpretation of Section 25(2) of the Act by the SC in *Dr. Aloys Wobben and Anr. (supra).* The SJ, in this case, discussed a situation where infringement of a suit patent entitled **"System/ Device Process for Classification of Various Materials"** occurred or was alleged soon after the grant of patent. In the instant case, the suit patent was granted on February 12, 2019 and the suit was filed on March 6, 2019 i.e. within one month of the grant of the patent.

DICTA—(Plural of DICTUM) A remark, statement, or observation of a judge that is not a necessary part of the legal reasoning needed to reach the decision in a case.

The SJ held that a suit for patent infringement within one year of grant of the patent would be maintainable and would not be liable to be rejected as premature. The decision came as the SJ dismissed an application filed by the defendant seeking rejection of the plaint on the grounds, inter alia, that the same is barred under Section 25(2) of the Patents Act.

The defendant argued, *inter alia*, that the rights of the patent holder do not crystallize on mere grant of patent but do so only after the lapse of one year period provided for giving a notice of opposition under Section 25(2) of the Patents Act and thus, the suit filed on the strength of grant of the suit patent is not maintainable in view of the interpretation of Section 25(2) of the Patents Act by the SC in the decision *Dr. Aloys Wobben & Anr. (supra).*

The SJ, however, distinguished the said SC decision by holding as follows:
"12....It is for the reason that two parallel remedies cannot be invoked by a party which may result in conflicting decisions and the fact that 'any person interested' had a right to file a post-grant opposition within one year of the grant of patent, Supreme Court held that by grant of patent itself the rights in favour of the patent holder do not crystallize finally, for the reason 'any person interested' of grant of a patent and, if and when challenge raised to the grant of patent are disposed of favourably to the advantage of the patent holder, the right to hold patent can then and then alone be stated to have crystallized...However, the situation where infringement of the suit patent occurs or is alleged soon after the grant of patent was not discussed by the Supreme Court, the same being not an issue before the Supreme Court, thus it did not hold that a suit for infringement within one year of grant of the patent would not be maintainable and would be liable to be rejected as premature.."

The SJ observed that the plaintiff has a right as a patent holder under Section 48 of the Patents Act and said right is not affected during the pendency of a post-grant opposition. The SJ opined that as the rights in favour of a patentee enure to its benefit on grant of the patent under Section 48 of the Patents Act, even though the said right may not have finally crystallized, pending post-grant opposition, in view of the subsistence of the right of the patentee, and there being an alleged infringement, the patentee is not required to wait for one year period to sue for infringement.

In 2015 case of *CTR Manufacturing Industries Ltd. Vs. Sergi Transformer Explosion Prevention Technologies Pvt. Ltd. and Ors.*, 2015 SCC OnLine Bom. 5538, the SJ of the Bombay High Court ('BHC') had occasion to consider the impact of the said SC decision as the SJ was faced with precisely the situation that the SC therein said was unlikely to arise: where a patent infringement suit is filed, while the post-grant opposition proceedings are pending. By way of this decision, the SJ decided CTR's application for ad-interim injunction restraining Sergi from infringing its patent concerning explosion and fire detection technology for use in electrical transformers and held for CTR and against Sergi on the issue of infringement of CTR's patent.

The SJ, however, found it unnecessary at the prima facie stage to consider the impact of the said SC decision and observed that if the grant of patent is not determinative and doesn't yield an injunction for the asking, it must follow that the mere pendency of an opposition cannot defeat an injunction claim either.

This decision was carried in appeal before the Division Bench ('DB') of the BHC in the case of *Sergi Transformer Explosion Prevention Technologies Pvt. Ltd. and Ors. Vs. CTR Manufacturing Industries Ltd.*, 2015 SCCOnLine(Bom) 6984 and the DB while admitting the appeal, stayed the SJ order.

In appeal, Sergi raised an objection to the maintainability of CTR's suit due to pendency of post-grant opposition in view of the said SC decision and argued, inter alia, that said objection was not dealt with in appropriate manner by the SJ. After hearing the appeal extensively at admission stage, perusing the said SC decision and taking note of the facts that Sergi's postgrant opposition was still pending before the Controller of Patents and that in the meanwhile Sergi had been manufacturing the transformers and selling the products in the market, the DB took a view that the appeal deserved consideration on merits and accordingly stayed the interim order passed by the SJ and allowed Sergi to continue to manufacture and deal in transformers. The DB also directed the Controller General of Patents to expeditiously dispose of the post-grant opposition proceedings initiated by Sergi.

However, this stay was later overturned by the SC in Civil Appeal No. 014655-014657/2015 as CTR moved it from the DB stay order. The SC observed that the DB has not looked into the merits of the respective contentions of the parties and has only gone by the fact that insofar as grant of patent in question to CTR is concerned, Sergi has filed post-grant opposition thereto which is pending before the Controller of Patents and on this ground alone the SJ order is stayed. The SC finally put in place its own earlier order of May 25, 2012 in Civil Appeal Nos. 4791-4792 of 2012 which contained direction to the effect that till the CTR's application for ad-interim relief is not disposed of by the SJ, Sergi will continue to manufacture and sell its products as per its patent but without infringing CTR's patent. The SC also requested the DB to dispose of the appeal as expeditiously as possible.

The Way Forward

The SC decision in *Dr. Aloys Wobben and Anr. (supra)* has clearly impacted the patent infringement litigation involving situations where post-grant opposition proceedings are pending. It gave defendants a new and unprecedented ground of defense that could be asserted early in litigation. In turn, the patentees have had to take this new ground of defense into account in their litigation strategy. While the SC dicta above appears to have been diluted or narrowed down to a certain extent by subsequent case law, it may possibly still be treated differently by the different Benches of the same High Court or by the different High Courts thereby leading to uncertainty around its treatment. Given the possible practical implications of said SC dicta, it is hoped that a fitting case involving its reconsideration will come up before the SC sometime in the near future, allowing jurisprudence on the subject to be revisited and relevant statutory provisions to be interpreted in a manner suited to the true intent behind their promulgation, thereby providing needed clarity and legal certainty in patent infringement litigation.

Abstract

This article attempts to look at the Indian legal position on the contentions issue of patent enforcement during post-grant opposition proceedings covering therein relevant case law developed subsequent to 2014 landmark Supreme Court case of *Dr. Aloys Wobben and Anr. Vs. Yogesh Mehra and Ors.*, AIR 2014 SC 2210, holding, *inter alia*, that only the culmination of post-grant opposition procedure contemplated under the Indian patent law, bestows the final approval to the patent.

~ By Dinesh Kumar Sharma

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Basudeo N. Singh

Executive Chairman—Alkem Laboratories Ltd.

Basudeo N. Singh
Executive Chairman
Alkem Laboratories Ltd.

Mr. Basudeo Narain Singh is the **Executive Chairman of Alkem Laboratories Ltd.** In 1973, along with his elder cousin Late Mr. Samprada Singh , he founded Alkem Laboratories.

Their journey began from a small pharma retail store in Patna. In 1973, both brothers shifted to Mumbai and decided to get into drug manufacturing. In 1973 **Alkem** began as a healthcare marketing company, with a seed capital from relatives. The big break came in 1989 with the launch of **Taxim**, which today is a leading brand in the anti-infective segment and have a significant market share. In fact, Taxim, became the first anti-infective in India to cross Rs.100Crore in sales. After Taxim there was no looking back and Alkem went on to create iconic brands in the industry like **Clavam, Pan, Pan-D, Taxim-O, Gemcal, A to Z** and many more. Currently Alkem is the **5th largest company** in Indian formulation market with a market share of 3.6%. The Company has an impressive portfolio covering **acute, chronic, specialty and OTC business**.

Alkem products are also sold in more than 50 countries globally. Amongst them USA, Australia, Chile, Philippines and Kazakhstan are the key markets.

Mr. B N Singh, a Post Graduate in Political Science, has nurtured Alkem since its early days. With his dynamic vision and strategic leadership, he has professionally managed Alkem's progress in becoming one of the leading Pharma companies in India. He is a great source of motivation for the entire Alkem family and is well recognized for the exemplary work ethics and the discipline he brings about in the day to day functioning of the organization. A great entrepreneur, he always focuses on basics, which has made Alkem a fast growing company and an **"Employer of Choice"** for over three decades.

His sterling leadership qualities and ingenious work process earned him the opportunity to be the president of the Indian Drug Manufacturers' Association from 2007 to 2009, the largest Pharma Association in India representing large, medium and small scale units manufacturing pharmaceutical dosage forms, active ingredients, intermediates, biological, vaccines and herbal drugs. In this capacity, Mr. Singh led the IDMA activities in shaping the Indian Pharma Industry's future in becoming a global player.

Many awards and accolades won by him includes; '**Business Leader of the Year 2014'** at the 7th Annual Pharmaceutical Leadership Summit and **the Pharma Leaders Business Leadership** Awards 2014. He was also bestowed with the **'EY Entrepreneur of the Year in Life Sciences'** award for the year 2016. Recently, he received the title **'Chief Mentor of the Year'** by the Indian Drug Manufacturers' Association.

Apart from his contribution towards the Company and the pharmaceutical industry, Mr. B N Singh has also strived towards the well-being of the society and bringing a positive impact through CSR activities in the areas of healthcare, education, environment conservation, rural empowerment, vocational training and encouraging sports.

M.K. Singh

Managing Director-Indchemie Health Specialities Private Limited

M K Singh
Managing Director
Indchemie Health Specialities
Private Limited

"*While a good leader allows his team to be in comfort zone, a great leader relentlessly pushes his team out of this zone".*

We are fortunate to have a great leader at **Indchemie Health Specialities Private Limited**; a narrative given by many team members describing **Mr.M.K.Singh Managing Director** of Indchemie and **Executive Director** at **Alkem Labatories Ltd**.

The reason for Indchemie's inception and its existence starts with the strong **Vision and Values** set in 1988 of touching millions of lives & alleviate human suffering and misery. Under the watchful guidance of ***Shri Samprada Singh****, Chairman Emeretius, Alkem Laboratories and* ***Shri B.N. Singh****, Executive Chairman, Alkem Laboratories,* Mr.M.K.Singh *began his journey in the Pharmaceutical world armed with a Masters Degree in Business Administration.*
The consistent 10% growth of 1.27 lac crore Indian Pharmaceutical Industry now for more than two decades has further bolstered and resonated this vision and values at Indchemie. The **vision** statement that flows throughout Indchemie is to be a **Rs.1000 crores** organization by the FY 2024-25 with **minimum 20% of the turnover to be its PBT levels.**

The thought process and the magnanimity of the vision set by this entrepreneur can be well understood from the excerpts of the interaction we had on his journey to build Indchemie and Alkem Group to be the amongst the top three pharmaceutical companies in India.

When Mr.M.K.Singh decided to build Indchemie; he assumed **complete responsibility and accountability** for all the people associated to the organization, internal as well as external customers including the medical fraternity, the creditors and debtors. His understanding was very clear that the professional and moral commitment is to create great value to all associated stakeholders.

Profitability is a basic obligation of Leadership at Indchemie and for all those who are responsible to create values for internal customers, external customers and distribution partners. Reinvesting the profits in creating human capital better than competition, patient friendly world class formulations and a high performing organization is the way forward.

Building Indchemie and achieving a 1000 crores vision FY 24-25 at the set deadline is all about **growth**. Growth of existing as well as new brands and people associated, the distribution channels, building world class formulation units and more than complete utilization of the production capacity. It is all about inclusive growth.

Attracting and retaining professional talent is the key towards creating a great organization. Helping the individual team member achieve his personal and professional visions has been the mainstay in achieving the set time bound goal.

One thing that would be imperative to achieve this set growth and vision is to build a system focused Indchemie. Our business is people centric and people intensive and for Indchemie to achieve exponential growth what is required are the self-regulating systems that can be monitored as well as ensure fiscal competencies.

Indchemie is currently poised at a turnover of more than Rs.450 crores and is well embarked on the journey of achieving Rs.1000 crores by being the fastest growing Indian pharmaceutical Company. With a sales team of more than 2500 personnel, Indchemie ensures the coverage of close to four lakh medical professionals across the country. Many leading brands including **Cheri, DV60K, Codesoft** and **Zecal** feature among the Top 10 brands of their respective therapeutic segments.

Indchemie's International footprint is slowly & steadily increasing. Mr.M.K.Singh has a dream to establish Indchemie on a global platform in its various therapeutic segments. Indchemie's products are today available in Africa, Asia, Latin America & Caribbean Islands. A highly dedicated team of professionals ensure that Indchemie's products are registered in various countries with present approvals crossing 125 in more than 17 countries.

Indchemie's state of the art manufacturing facilities are approved internationally and many of its plants employ advanced **Without Human intervention** technology. More than 25 bio-equivalence studies endorse the International Quality Standards.

Mr.M.K.Singh strongly believes that every individual working for Indchemie is to be closely associated with business generation process wherein all additions have to be direct, visible and measurable. Moreover, Indchemie should be known by the customers and the Therapeutic Specialties it builds. The focus is to create brands that reflect in TOP 300 of the industry, brands that bring in profits, brands that propel and shape the immediate vision of 1000 crores.

Dr Rajesh Jain

Managing Director-Panacea Biotec

Dr. Rajesh Jain
Managing Director
Panacea Biotec

Dr. Rajesh Jain, Managing Director at Panacea Biotec, a leading Biotechnology company focused on affordable access to innovative medical products to enable people to live well and live longer.

One word that describes me: ***Cheerleader.***

Dr Rajesh Jain focus on developing people, letting them fail, and giving them all the credit when they succeed. You'll often find him cheering his competitors when they got it right. Dr Rajesh Jain has been working closely with international partners as well as spending time in research, development, and supply chain.

"We're having fun making a difference. Ensuring that people can access high-quality medical treatment at an affordable price." says Dr Rajesh Jain

Dr Rajesh Jain firmly believes that sitting alongside the right partners, the best distribution and moving forward to a global R&D process is the most vital part of a business's success – the team. "When our scientists travel the world and come back, they not only learn from different ecosystems but also impact their colleagues and their families through their habits, values, evolved world view and thinking."

Some of his key contributions are:

- **Chair** Confederation of Indian Industry (**CII) National Committee on Biotechnology** for **2019-20**
- **Co-Chair at the Confederation of Indian Industry (CII),** National Committee on Biotechnology for **2017-18.**
- **Earlier served as Chairman during the periods: 2011-12 & 2012-13**
- **Vice President – Indian Pharmaceutical Alliance (IPA) for 2017-19 and 2019-2021.**
- **Recipient of India Innovation Award in 2016 and 2015 (Top 50) by Clarivate Analytics** (Formerly Thomson Reuters)
- **Hon'ble Member of Indian Pharmacopeia (**IP) **Expert Working** on Vaccines and Immunosera for Human Use of in the year 2017
- **Member-Research Council of CSIR**–Central Drug Research Institute (CSIR-CDRI), Lucknow
- **Startup India: Board Member for Innovation and Incubation Foundation - Delhi Pharmaceuticals Sciences and Research University (DIPSR)**
- **Member of Academic Council** of **DPSRU** for three years w.e.f. Sept., 2018
- **External Member of the Board of Studies in Pharmacology, Biotechnology, Clinical Pharmacy and Hospital Pharmacy of DPSRU** for three years w.e.f. Sept., 2018
- Member **"DPSRU Vision 2030"**
- **31 granted patents and 33 under prosecution**. Dr. Rajesh Jain's commitment and actions towards making affordable vaccines for mass
- Appreciated and valued globally by **GAVI and Bill & Melinda Gates Foundation** during the pledge conference in June 2011 & in January, 2015
- **Mr. Bill Gates has himself lauded the efforts of by Dr. Rajesh Jain towards this noble cause.**

Released following two Position papers:

- CII recommendations for Guideline Changes in Vaccine Approval Procedures
- The Make in India Imperative – Position Paper on Regulatory and Policy Changes required for Sustained competitiveness of the Indian Vaccine Industry.

Dr. Rajesh Jain is amongst Top 40 Global most influential persons as per the list put together by **World Pharmaceutical Frontiers published in SPG Media, London.**

Dr Rajesh Jain is a board member for Innovation and Incubation at the Delhi Pharmaceuticals Sciences and Research University (DIPSR). "Since joining DIPSR, his commitment has been to increase extracurricular activities in the curriculum, promote higher academic-industrial partnerships, and encourage students to take risks while they are young.

As Chair for the CII National Biotech Committee, Dr Jain encouraged wider participation and diagloue on how India should manage its healthcare system efficiently while catering to the inherent nature of the business.

Dr. Rajesh Jain has over 31 granted patents and another 33 patents under various stages of application. These stem from novel pharmaceuticals and vaccines to 'how restaurants can improve their operational efficiency while focusing on increasing customer satisfaction and waste elimination'. Dr Jain was also recipient of the **'Top 50 Innovators in India'** by Clarivate Analytics.

Ketan C Zota

Managing Director Zota Healthcare

Ketan C. Zota,
Founder Chairman – Zota Healthcare Ltd.
Joint Secretary – JITO Surat Chapter
Trustee Shraman Arogyam – JITO

Who says one needs to be a Doctor to serve society a healthy life? Hardwork and Dedication is just enough to create miracles.

One person who has always been on his toes for the betterment of the needy is Mr. Ketan Zota, the director of Zota Healthcare Ltd. Since 1995, Zota Healthcare is in the business of manufacturing and marketing quality medicine with an aim to provide medicines to people at an affordable price.

In 1995 he started company with 5 products only & today it a basket of more than 3000 Branded products & it is the highest number of products managed by a single company in india. With a calm and composed persona, Mr. Ketan Zota is always focused on achieving the mission to make his company a globally acclaimed pharmaceutical company.

Having done his Diploma in Pharmacy from L. M. College, Ahmedabad in the year 1983, Mr. Ketan has contributed years in this industry. He started his career with a small retail medical store in the year 1984. His drive for giving people a healthy lifestyle at an affordable price became the reason of Zota Healthcare's birth.

Dynamic Leadership and 24 years of experience is one of the main roots that led to the firm's success. He believes that the pharmaceutical industry goes through a slow growth process as the approval of products are not done on time. Apart from being strong and clear about his work, Mr. Ketan has made good health accessible to local communities and society by setting up Heath Camps. Blood & Medical Donation Camps have been held in villages and other remote areas of the nation. Through such CSR activities Mr. Ketan has always uplifted the thought of Living Long and Healthy. He has also been honoured with a life time achievement award at Pharma Ratan Award 2016 for his extra ordinary contribution to the pharmaceutical industry.

Keeping yourself fit and fresh, Mr. Ketan truly does it with Cricket and Music. A fit personality and a fresh mind fuels your soul with positive vibes and for him Cricket and Music does it all. Mr. Ketan's sheer determination and journey throughout these years gives us an insight to one of the quote said by Buddha,

"Health is the greatest gift, contentment the greatest wealth, faithfulness the best relationship."

Harish K Jain

Director Embiotic Laboratories (P) LTD Bangalore

**Harish K Jain,
Director, Embiotic Laboratories
(P) LTD, Bangalore.**

Mr. Harish K Jain is the **Director of Embiotic Laboratories (P) LTD, Bangalore.** Mr Jain, a B.Pharm 1989- Govt. College of Pharmacy, Bangalore and M. Pharm 1991- Pharmaceutics, College of Pharmacy, New Delhi (Now called as DIPSAR) with GATE 1989 Score of 99.74 Percentile is the Pharma Entrepreneur with 27 years' experience in the Industry. His sterling leadership qualities and ingenious work process earned him the opportunity to be the 3rd Consecutive term as Secretary, Karnataka Drugs & Pharmaceutical Manufacturers Association '**KDPMA'** (Also served in past as Treasurer). He has effectively represented KDPMA in various State & National Forums/ Committee's to put forward views of SSIs w.r.t. various issues like Ban on Gelatin Capsules & its implications on Export of Formulations, Delegation of \Licensing Powers to SLAs of Unapproved/Banned Drugs & FDCs without NOC from CDSCO for Export purpose, Licensing pathway for FDCs approved by Kokate Committee,Draft Pharma Policy etc.

He has been the

- Member, **Vision Group of Pharmaceuticals, Minimum Wages Advisory Board** of Govt of Karnataka. Member,
- **Sub Therapeutic Committee, Karnataka Drugs Logistics & Warehousing Society** of Govt of Karnataka, Member 2020-2025,
- **Strategic Planning Group**, Faculty of Pharmacy, JSS Academy of Higher Education & Research, Mysore, India,
- Advisor to **Shengjie (Shanghai) Business Management & Consulting Co. Ltd, Shanghai**.
- Delivered High Quality talks on Technology and Business during Conferences being held in Shanghai. Guest of Honour and Delivered Key Note Address at **World Congress on Pharmaceutical Sciences** with the theme Empowering New Era Technologies in Pharmaceutical Technologies Organised by Operant Pharmacy Federation held on 2nd and 3rd Dec 2019 at Bangkok,
- Co-opted expert member, Panels on MSME & Africa – **PHARMEXCIL** (Pharmaceutical Export promotion council of India – Set up by Ministry of Commerce and Industry, Govt of India)
- Successfully conducted Workshops/ Programs on UCPMP, Moving from Schedule M to PICs, DPCO 2013, GST Implementation, Pharma Parks etc.
- Executive Committee Member- **IPA-KSB, FOSIPMA, NAPA**
- Regulatory Advisor – **Federation of Pharma Entrepreneurs (FOPE), Delhi**
- Active member of **CIPI**
- Member of **IPA (Central Committee)- Industrial Pharmacy Division** 2018-20
- Member, Steering Committee of Department of Pharmaceuticals for Organizing '**India Pharma & Medical Devices Expo**' event in Bangalore every year.
- Joint Secretary, Organizing Committee of Golden Jubilee Celebrations of Govt. College of Pharmacy, Bangalore
- Co-Chairman, Exhibition Committee, **63rd IPC, Bangalore.**
- Regional Co-ordinator, **68th IPC, Vizag.**
- Recipient of **Skoch Achiever's and Order of Merit Award 2014** as India's Best SME.
- Certified 'Corporate Director' by Institute of Directors

Sahil Dharia

Founder & CEO Soothe Healthcare

Sahil Dharia
Founder & Chief Executive
SOOTHE HEALTHCARE

Sahil Dharia is a global executive turned entrepreneur with over 15 years of experience setting up, scaling & leading -Financial Services business with a multinational corp. as well as a consumer goods (FMCG) venture. He is the founder of **Soothe Healthcare,** a consumer health care company engaged in manufacturing, marketing and distributing women's personal hygiene brand **Paree -sanitary pads.**

He started his career on the 'buy-side' in New York at UBS Investment Bank & then managed the high visibility derivatives desk at Reuters, New York.

His success in building high performance teams that deliver results, catapulted him among the youngest in leadership & entity management roles across functions in a fast-tracked career. At the time of founding Soothe Healthcare, Sahil Dharia was the Global Head of Operations, Investment Research Content, at Thomson Reuters, supporting operations with US$ 200 mn revenue footprint. He helped set-up & rapidly scale Reuters, Bangalore to peak size with emphasis on building management depth. Sahil won the **Global CEO's Award of Excellence** for successfully leading strategic change management programs as part of the $ 6 billion merger of Thomson Reuters across Business & HR functions in India.

He launched his first entrepreneurial venture at age 21. This entrepreneurial streak & solid operations experience motivated him to start-up Soothe Healthcare- that has achieved high growth, phenomenal media attention & multiple rounds of investment from PE & Strategic investors owing to its disruptive product portfolio in affordable healthcare.

Sahil is a charter member of **TiE startup community, a FICCI Young Leader & on the Executive Council of CII Young Indians.**

He is passionate about building thought leaders and serves as visiting faculty at leading educational Institutions. Sahil studied Economics at the Zicklin School of Business, New York, NY

Deepak Sahni

Founder & CEO Healthians

Deepak Sahni
Founder & CEO
Healthians

Mr. Deepak Sahni started his entrepreneurial journey with a computer business immediately after completing his education. Academically his schooling happened at St Margaret School in Delhi followed by Bachelors & Masters in Computer Application from Sikkim and Manipal University.

In 2003, he discovered the field where his interests lay which is healthcare. He established a digital healthcare agency which gave him a chance to interact with myriad health professionals across the globe and learn the nuances of the healthcare business.

It was his experience with renowned hospitals across the world and the healthcare systems in the developed nations that equipped him with business acumen and insights necessary to establish a business that was unique and differentiated.

The idea of starting a tech enabled and customer centric diagnostic service has its roots in his learning from the previous business. In India, there is marked difference in what healthcare services are available and what people need. The entire health ecosystem of India is based on a reactive approach, rather than a proactive one and all research, marketing and solutions are focused on the post disease phase, where the costs, efforts and stress are extremely high.

Also, the diagnostic space of the country is dominated by B2B players dependent upon franchises and doctors to reach its customers. With the growing incidence of non-communicable diseases, there is growing need for a preventive healthcare. All these reasons were indicators that there was a huge opportunity in creating a business that would deliver cost-effective, standardized and accurate diagnostic service that would enable them to lead healthier lives.

Achievements

Mr. Sahni's clear vision and passion to offer a standardized service in a highly disorganized and fragmented market has ensured that in just a span of five years, Healthians has become the largest at home diagnostic service in the country with a presence in over 38 cities across the country.

Healthians is India's first B2C diagnostic company with NABL certified labs that have more 200+ quality checkpoints to ensure accuracy of results. The company was founded on the core philosophy of promoting wellness and having a preventive rather than reactive approach to healthcare. With Healthians, Mr. Sahni's aim is to add 10 healthy years to every Indian's life by making screening and tracking of health parameters a norm rather than exception.

A proactive approach to health and a focus on prevention is the core philosophy of the company and all its initiative including those for the betterment of the society are also addressed towards raising awareness and enabling people to get access to better facilities. During the Covid-19 pandemic, Healthians was one of the first private diagnostic labs that started covid sample collection. It offered unique solutions to address customer needs while keeping safety as a priority.

Mr. Sahni has represented India in the Medical Tourism Congress in the US for three consecutive years. The company and **Mr. Sahni** himself have won numerous awards including the **Young Entrepreneur of the year, The Top emerging brand in innovative Healthcare, Home Health-care Brand and Innovative startup in diagnostic healthcare.**

Bodh Raj Sikri

Key promoter ABS group

Bodh Raj Sikri
Key promoter ABS group

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.

Shinde Jagannath Sakharam

Chairman – MSCDA LTD , AIOCD LTD & President The Maharashtra State Chem & Drug Association

SHINDE JAGANNATH SAKHARAM
Chairman – MSCDA LTD ,
AIOCD LTD & President
The Maharashtra State Chem &
Drug Association.

Shri Shinde Jagannath Sakharam has experience of over 20 years of relentless working in the field of Indian Pharmaceuticals Trade for the betterment of more than **850,000 Retailers** and Pharmaceutical **stock fraternity of India** by understanding and solving their trade related issues by negotiating and setting the trade practices between the trade and pharmaceutical manufacturers by using the forum of **All India Organization of Chemists & Druggists (AIOCD Association).**

His areas of interest is to minimize the trade related disputes by setting and effectively implementing trade practices/ norms for mutual benefit of trade and pharmaceutical companies. Improving and uplifting the standards of services rendered to consumers by retailers by conducting continuous training programs for them encompassing patient counseling, disease management, behavioral and personality development and working capital management. He has ambitious plans to convert existing mom and pop stores into a large organized retail chain, supported by state of art IT infrastructure and world's best in class SOP in handling all types of storage conditions to ensure the full potency of the product is delivered to end customer and with complete transparency.

Sh. Shinde inspired all members to form a corporate entity to leverage their true strength and bringing in huge value to them by entering into the business of: ***Organized Distribution, ** Organized Retail Chain, ***Market Research Data**

Professional & Organizational Achievements

He has relentlessly worked for over 20 years at all India level for building the cohesive force and strong bonding between all the State level associations and worked for bringing the status and stature of AIOCD at today's enviable position. He has travelled almost across India for developing AIOCD's network through its stock and retailer members at various remote and inaccessible places.

- In Maharashtra, he built the organization from grass root level by creating three tier of association i.e. Taluka Associations, District Associations and State Level Associations. His major contribution is he identified, developed and nurtured a pool of vibrant and efficient leaders at all levels.

- His amazing style, persuasion and network convinced Government of India to revise VAT on medicine from 12.5% to 4%.

- He convinced Central Government and most of the State Governments to keep medicine dealers out of purview of Value Added Tax (VAT) and collect VAT on MRP for the initial period. Our retailers are benefited by this decision and they are free of all types of problems.

- He has formed the Educational & Welfare Trust of MSCDA to help the chemists and their families in the hour of need. Arranged monitory help for educational, hospitalization and to fight the natural or accidental calamities. However, this help is also extended to the other needy people of Maharashtra State

- He has inspired all the district associations to form Chemists Credit and Capital Societies to finance small and needy chemists and made them self-sufficient and to promote the spirit of Co-Operation. In Maharashtra 9 such cooperative societies have been formed at Ratnagiri, Kolhapur, Satara, Sangli, Jalgaon, Nandurbar, Dhule, Nashik, and Yeotmal.

- He has inspired to form M/S.Green Cross Healthcare Pvt. Ltd. to run retail chain stores under the Company Act and based on a franchisee business model. Company is running 26 stores successfully in Mumbai.

- He encouraged computerization of retail medical stores along with the wholesalers and bring them on line to keep inventory and expiry, non-moving under control. This has already started to make it happen.

- With the help of state pharmacy council, he developed a syllabus for a professional pharmacy course for upgrading knowledge of practicing owner pharmacists under AIOCD Ltd. Currently over 6000 participants have attended various training programs in Maharashtra.

- Under his leadership all the district level association offices are now connected via internet and emails. He has inspired all district associations to establish their own offices and build own buildings as Chemists Bhavan and at some places Dawa Bazar. In Maharashtra, all the associations have their offices and 24 district level Chemists Bhavans and Dawa Bazar at 5 places.

World Health Organization

Home care for people with suspected or confirmed COVID-19

Take care of yourself and your family

All members of the household

Wash hands with soap and water regularly, especially:

- after coughing or sneezing
- before, during and after you prepare food
- before eating
- after using the toilet
- before and after caring for the ill person
- when hands are visibly dirty

Avoid unnecessary exposure to the ill person and avoid sharing items, such as eating utensils, dishes, drinks and towels.

When coughing or sneezing, cover mouth and nose with flexed elbow or use a disposable tissue and discard immediately after use.

Monitor everyone's health for symptoms such as fever, cough and if difficult breathing appear, call your health care facility immediately.

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