

SHREENATH
PHARMA
M *MAGAZINE*

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From The Editor's Desk

Dear Readers,

Coming to the third issue. I firstly thank all the readers, subscribers and contributors to motivate my team at the beginning of this publication. It feels good to see increase in the number of readers.

This issue of August 2019 contains the interview of Mrs. Monisha Sarage, imparting guidance on entrepreneurship by sharing her experience. We also describe Tetrahydrocannabinol as the molecule of the month. Along with the above mentioned articles we have Pharma news updates from the industry and campus for our readers.

September starts with Ganesh festival and ends with the start of Navratri. Requesting all readers to share their experience and we will be glad to share.

Wishing all readers a Happy Ganesh Chaturthi!

Happy reading

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Sun Pharma lowers the shutter on clinical pharmacology units

Sun Pharma has been in the limelight for more than a month now. It was in the news lately for their promoter and Managing Director, Dilip Shanghvi foregoing 99% of his salary, as the company optimised operational costs due to pricing pressure and moderating growth in US. The latest development is the company has decided to discontinue operations at two clinical pharmacology units in Vadodara (Gujarat). Sun Pharma, the world's fifth largest generic pharmaceutical company, which is known for delivering market beating results year after year has taken this step to bring in efficiencies in cost and processes, and to ensure optimal utilisation of Clinical Pharmacology Units (CPUs) that conduct bio-equivalence studies. This has left 85 employees without a job.

According to a spokesperson, the bio-equivalence studies from these centres will be transferred to other Sun Pharma R&D units. Full support is being offered to the affected employees and that the company is also helping them with placement services.

Sun Pharma files application for drug in Japan

A day before the closure of the R&D units, Sun Pharmaceutical filed an application with the Pharmaceuticals and Medical Devices Agency (PMDA), a Japanese health authority for manufacturing and marketing authorisation of Tildrakizumab, a drug used to treat psoriasis and psoriatic arthritis.

Sun Pharma acquired Pola Pharma Inc, a Japanese drugmaker in January 2019 as a step in getting a foothold and strengthen its global presence in dermatology, with drug Tildrakizumab as its lead product.

Reference:

https://www.business-standard.com/article/companies/strides-pharma-announces-jv-with-chinese-firm-to-launch-its-products-119072901648_1.html

Artificial Intelligence driven Pharma News-NewsCut App

GSK Worthing branch to let go of 200+ redundant employees

On July 30th, staff at GSK Worthington's Southdown View Way site were called to a meeting. In the meeting, employees were told GSK had reviewed its global antibiotics manufacturing operations and had come to a conclusion that the manufacturing of ingredients for sterile antibiotics and the injectable Augmentin product in Worthing was not cost-effective. Hence some of the pharmaceutical giant's manufacturing was to be transferred out of the town, resulting in redundancies. A GSK employee who was made redundant said with utmost despair to the Worthington Herald, "As soon as I'd heard the news I knew instantly I'd be one of the 250 jobs to go.

GSK being a major private employer in town, the axing of these many jobs will have an effect on Worthington as a whole.

China: The greener grass for Indian Pharma Companies?

A BofA-ML report stated that Indian pharma firms are scouting for partners that can make quantifiable business contribution, protect Intellectual Property(IP), ensure operational control and manage talent. Owing tough competition in the United States of America, the largest drug market, domestic pharma giants are eyeing the second largest drug market, China. China is hence one of the focus areas for future growth. There have been recent regulatory developments in China which have enabled fast track approvals of differentiated high-quality generics approved in key regulated markets. Aurobindo Pharma and Cipla are in the process of setting up facilities and plants, and setting up networks for China.

Cipla announced in July that it was in the process of setting up a Joint Venture(JV) with a Chinese pharmaceutical company to manufacture and sell drugs. Cipla is also looking at potential facilities in China for oncology.

Sun Pharmaceutical announced earlier in May that it had entered into licensing agreements with China Medical System Holdings to develop and commercialise drugs to treat psoriasis and dry eye in Greater China.

Strides Pharma Science Limited said that its step down subsidiary Strides Pharma Global Pte, Singapore (SPG) has entered into a joint venture (JV) with Sun Moral International (HK) Limited, a wholly-owned subsidiary of Sihuan Pharmaceutical Holdings Group Ltd (Sihuan), one of China's leading pharmaceutical companies.

As the recent regulatory developments in China has enabled fast track approvals of differentiated high-quality generics approved in key regulated markets, Strides' specialized basket of 140+ products qualifies for the program, and this JV will be able to leverage it in China, thus catapulting Strides into the market.

Pfizer-Mylan deal to Generics Gambit

Pfizer Inc. plans to merge its off-patent business, which includes Lipitor cholesterol pills and male-impotence drug Viagra, with Mylan NV. It is an all-stock M&A Pharma deal. Furthermore, the combined entity will become the largest generic drug maker across the globe. The merged entity will create a New Company (NewCo) with the goal of a new kind of focus on a global approach to the historically lower financial margin end of the drug spectrum in generic and name recognizable off-patent drugs.

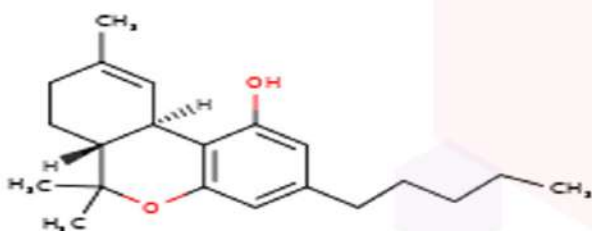
According to the terms, Pfizer shareholders will own 57% of the NewCo and Mylan shareholders will own 43% in the new venture. The NewCo will continue sales of Mylan's more than 7,500 products, including biosimilars, generics, brand and over-the-counter remedies. Although, the NewCo's sales will be off-patent or soon to be off-patent recognizable products from Pfizer's Upjohn unit. This will include Lipitor (atorvastatin calcium), Celebrex (celecoxib) and Viagra (sildenafil).

Reference for all:
Artificial Intelligence Driven Pharma News
NewsCut App

MOLECULE OF THE MONTH

Tetrahydrocannabinol

Cannabis has been in use in India since 2000 BC. In our society the common terms for cannabis preparations include charas (resin), ganja (flower) and bhang (seeds and leaves). Its use is documented even in the early scriptures. The British parliament levied a tax on cannabis in 1798, saying it would reduce the consumption. And, today bhang is legal and is commonly drunk on Holi. The buds and resins are stronger and it is against the law to grow the plant. William Brooke O'Shaughnessy's research on cannabis introduced the therapeutic use of Cannabis sativa to western medicine. He marked on its usefulness in treating convulsions, rheumatism and even cholera-170 years before the US FDA came to the same conclusion, at least in the case of convulsions.



This month the Delhi High Court dismissed a petition seeking the legalisation of cannabis for medicinal purpose. Although more and more states in the United States have legalized marijuana for medicinal use, the FDA does not recognize it as medicine.

Marijuana contains psychoactive substances such as THC (tetrahydrocannabinol). Its structure is similar to the brain chemical anandamide, because of which it alters normal brain communication. Anandamide functions as neurotransmitters and send chemical

chemical messages through the nervous system. They affect the areas of pleasure, memory, thinking, concentration, movement co-ordination and time perception. THC attaches to cannabinoid receptors and activates the reward system, which includes the regions that govern healthy pleasurable behaviours such as sex and eating by release of dopamine. This flood of dopamine at excessive levels contributes to the pleasurable "high" that those who use recreational marijuana seek. Marijuana is highly lipophilic which leads to its storage in adipose tissue, liver, muscle and spleen and redistributed into the users blood stream long after ingestion. Medicinally, suppository form of THC is available as an ovular capsule which can be inserted vaginally or rectally. In transcutaneous absorption, the transport across the skin layers is limited. Selection of a carrier eliminates this rate limiting step.

Since it can be smoked, eaten and brewed about ten percent of people who use cannabis become addicts. It is mainly used to reduce nausea and vomiting during chemotherapy, improve appetite in people with HIV/AIDS, reduce chronic pain and treat epilepsy. Psychotic symptoms consist of hallucination, paranoia, delusion. In people with pre-existing schizophrenia, it leads to higher rates of re-admission in bipolar disease and manic episodes. The other chemical in marijuana is cannabidiol and has no intoxicating property and can be used to treat seizures in children.

In essence we still don't fully understand the health risks associated with marijuana use. Being an illegal substance in India, we are yet to study the matter properly.



Walls closing in....

Pharmaceutical companies, on account of pricing pressure and an intense regulatory gaze, are investing in data analytical and digital tools to sharpen their marketing focus and improve compliance. The move comes in the backdrop of price competitiveness in key markets and regulatory actions leading to adverse audit observations and warning letters. "Businesses that digitalise will have a huge competitive advantage over others. At Cipla we are leveraging new-age technologies to drive efficiencies" said Kedar Upadhye, Cipla's global chief financial officer.

GSK Worthing: Redundancies planned among 673 employees. The employees were told GSK had reviewed its global antibiotics manufacturing operations and concluded it was "no longer cost competitive" to manufacture ingredients for sterile antibiotics and the injectable Augmentin product in Worthing. Reports from several GSK employees said around 200 permanent employees were set to be made redundant, plus around 50 temporary employees.

Sun Pharma Vadodara: 85 employees from R&D unit get terminated. According to the people aware of the matter the employees got no prior information and were given three-month salary and told to leave. The company refutes posts doing rounds on the internet about bouncers being employed to control the situation. In the first quarter, Bayer said about 200 jobs would be lost with the closure of an Indiana logistics centre. Roughly the same number of positions are getting culled at the California offices of AbbVie's Stemcentrix. In Colorado, AstraZeneca laid off 210 workers across a pair of manufacturing sites. According to BioPharma Dive's analysis, since the start of 2018, thousands of jobs lost.

"Under our new marketing model, we are accelerating the use of credible scientific, data analytics and digital tools across our operations. We increased the hiring of experts in digital technology and data analytics this year",

Digital data analytics are bringing other benefits too, PwC partner Sujay Shetty says using data analytics is helping drugmakers to improve distribution, increase sales force productivity and effectively manage working capital. For companies, cost optimisation is critical because growth is under pressure because of price erosion. Domestic sales growth slowed to 7 percent year-on-year on May, the slowest in the last seventeen months. GSK Pharmaceuticals are using the same tool to drive customers insight and improve engagement with doctors. "Under our new marketing model, we are accelerating the use of credible scientific data, data analytics and digital tools across our operations. We increased the hiring of experts in digital technology and data analytics this year", GSK Pharmaceuticals said in its latest annual report.

"Businesses that digitalise will have a huge competitive advantage over others. At Cipla we are leveraging new-age technologies to drive efficiencies" said Kedar Upadhye, Cipla's global chief financial officer.

Zydus Cadila is using digital applications for improvements in supply chain process, product development and sales marketing. These help the company to plan sales. Another solution provides real-time visibility in project milestones because it helps in updating and tracking product development and launching initiatives across regions.

It comes down to these slim situations during the financial ups and downs and future planning's of a company. As it is said, "Something good and profitable will never be saturated, as long as the ones deriving the benefits understand and invest into its implied dynamic nature." It is a seat grabbing experience in the whirlwinds of laws and market norms, amidst patent expirations to see a company thrive. Is the future of a pharmacy degree in the dark...

A.Magdum



Articles 101

Polycystic ovary syndrome (PCOS) is one of the most common endocrine disease found in reproductive womens which is mostly due to the hormonal imbalance . The cause of the disease is still unclear. The syndrome is characterized by chronic anovulations , hyperandrogenism and irregular menstruation. Some metabolic complications of PCOS are insulin resistance,hyperinsulinemia,obesity and metabolic syndrome. There is increase in androgen production,reduced sex hormone binding globulin and increased level of testosterone due to hyperinsulinemia and insulin resistance.Women's suffering from PCOS showed fertility problems i.e lack of ovulation and other beauty consequences like alopecia,acne,hirustism,obesity due to hyperandrogenism.

Non pharmacological treatment includes lifestyle and changes and weight loss are first line treatment. Food with anti-inflammatory properties improve androgenic profile of womens. Polysaturated fatty acid (PUFA) particularly the type of omega-3 with important bioactive properties act as metabolic regulators. Long chain n-3 fatty acid have been founded to improve several disorders such as insulin resistance,lipid profile glucose,liver fat content and blood pressure in women with PCOS.Moreover the cost,monitoring and side effects of omega-3 fatty acid are comparatively less than other medical treatment.

SOURCES OF OMEGA 3 FATTY ACIDS:

Soybeans (Roasted) ,Walnuts,Salmon,Canola Oil,Sardines,Chia Seeds,Mackerel,Flaxseed.

HOW OMEGA FATTY ACID IS USEFUL IN PCOS:

BALANCE HORMONES:

Women suffering from PCOS show high level of cortisol.The oil containing omega fatty acids helps in reducing the level of cortisol which is a stress hormone and is also responsible for the increased weight.

MANAGEMENT OF TESTOSTERONE LEVEL:

Excessively high level of testosterone are linked to most of the symptoms of PCOS.These omega-3-fatty acids helps to decrease the level of testosterone.

SHRINKAGE OF FAT CELLS:

Fish oil concentrate contains two important fat molecules called EPA (eicosapentaenoic acid) and DHA(docosahexaenoic acid). A study on mice was conducted where they were given high fat diet containing EPA . It was observed that there was a reduction in their fat weight and the size of the fat cell shrank. Experiments suuggest that humans also benefit in similar way.EPA also suppresses the process of inflammation. The problem is that many of those who have PCOS are blocked into fat building mode because of dysfunction of insulin and other hormones.

INSULIN RESISTANCE:

Insulin resistance play a important role in weight loss difficulties and they disturb the overall hormonal balance. They are the centre cause of PCOS symptoms. The study of DHA in overweight people showed decrease in insulin resistance.

LIFT DEPRESSION:

EPA and DHA are important components in brain as they perform a multitude of critical functions. Depression is the most common symptom of PCOS. Depressed people have low level of omega-3-fatty acid. Medical studies show that adequate level of EPA and DHA are necessary for optimal brain function. Studies show that depressed women had 32% lower level of DHA as compared to non-depressed women. Higher level of DHA is important for better verbal reasoning ,mental flexibility,working memory and vocabulary. Oil containing omega-3-fatty acid is an important personal health building program and they also reduce the risk of mania,dementia and Alzheimer like disease.

REDUCE HEART RISK IN WOMENS:

Omega -3-fatty acid are important for preventing cardiovascular disease in womens of all ages. Womens with PCOS have high risk of developing heart disease as compared to other womens. A healthy diet and daily exercise is obviously basic requirement for healthy heart but other additional supplementary food are also helpful. Medical studies have shown omega-3-fatty acid decrease the risk of cardiovascular disease.

CLEAR FATTY LIVER DISEASE:

Studies show that 55% of PCOS women have NAFLD (non –alcoholic fatty liver disease). Fatty liver disease is not restricted to overweight womens. Nearly 40% of women with NAFLD are lean. Omega-3-fatty acid helps in reducing liver fat content,triglycerides and blood pressure.

IMPROVES PREGNANCY:

Omega -3-fats ensures that a women's tissue conatins a reserve of these fats for the development of fetus and the breast fed newborn infants. Consumption of omega-3-fatty acid during pregnancy reduce the risk of premature birth and intellectual development of fetus .DHA is important for the development of unborn child.

HELPS MENSTRUAL PROBLEMS:

Omega -3-fatty acid play a positive role in the prevention of menstrual problems and post-menopausal hot flushes

REDUCE STRESS CONDITIONS:

Omega -3-fatty acid helps to prevent helps to prevent the development of certain cancer particularly breast and colon cancer and possibly may reduce uterus cancer.

Thus omega-3 fatty acids are essential polyunsaturated fats. They cannot be manufactured by the body and must be consumed through food or supplements. Three types of omega-3s include ALA (alpha-linolenic acid), EPA (eicosapentaenoic acid), and DHA (docosahexaenoic acid). The benefits of EPA and DHA are in the news often. These omega-3 fatty acid are naturally found in fatty fish such as salmon, herring, sardines, tuna, trout, and mackerel.Studies suggest that supplementing 1200 mg of omega 3 fatty acids daily may be beneficial.

"So let's fight this battle of PCOS and enjoy flawless skin ,fertile health and eat like a normal person because we are worth it ."

Reference:

Effect of omega-3 fatty acids supplementation on testosterone levels in women with polycysticovary syndrome: Meta-analysis of randomized controlled trials
Neda Forouhia, Sakineh Shab-Bidarb, Kurosh Djafarian.
[https://www.sepalika.com/pcos/omega-3-pcos.](https://www.sepalika.com/pcos/omega-3-pcos)

- Pradnya Shetty

Ninth Amendment, 2019

Law Lines

Earlier, the Drugs and Cosmetics (Fifth Amendment) Rules, 2018 notified the voluntarily labelling of high-risk medicines with caution and warning effective from November 1st 2018. The high-risk medicines includes the & Narcotic analgesics, hypnotics, sedatives, tranquillisers, corticosteroids, hormones, hypoglycemic, antimicrobials, antiepileptics, antidepressants, anticoagulants, anti-cancer drugs and all other drugs falling under Schedules G, H, H1 and Schedule X whether covered or not in the said schedules. However, the Drugs and Cosmetics



(Ninth Amendment) Rules, 2019 has announced this labelling requirements shall be mandatory from April 1st, 2019. Now, the import and manufacturing permission of drug formulation granted under Form 45/46 also requires Labelling of these formulation with a caution or warning, as applicable, depending on whether the drug is covered under Schedule G or Schedule H or Schedule H1 or Schedule X, as specified in rule 97, in legible black colored font size in a completely red rectangular box.

TALK

THE

TALK



Monisha Sarage
Founder - Seduction Las Vegas Cosmetics, Operation Head - Ms 365 Cosmetics



Seduction Las Vegas is a solid, strong name. Is there any story behind the name choice?

Basically we had shortlisted couple of names and we ran through those names through various women and men in the industry. What we saw was that there was a raised eyebrow when we took Seduction Las Vegas as a name and hence we derived that we need a brand name which will certainly raise eyebrows and increase curiosity.

How was the experience of going from a postgraduate to a director of a company with a Pan-India Vision?

While Pursuing MBA I always had a keen interest in cosmetics but I always thought i would work for one of those companies but fate turned out to be me starting up one. It is difficult journey because its not only money that's involved but also on the path you make lot of mistakes as lot of situations

Currently, you are one of the few (although not so few) Indian cosmetic companies. How do you deal with foreign competition, especially when they have a lot of capital?

This industry has space for everyone, agreed upon with the competition level

and the capital involved, it is always important as a brand to derive your niche, in our case we developed a spa/salon supply model which has been the reason for our success.

What orientation & boundaries are necessary for identity to an Indian market. What differentiates Indie start-ups from the outsiders?

Speaking about the orientation and boundaries it is essential to create even a small market share in this country is to work as per the customer, their traditions , their rituals which foreign companies generally take time to adapt to.

“I always thought i would work for one of those companies but fate turned out to be me starting up one.”

You have been spearheading two companies at the same time, how do you slip through the task profiles and time frames?

Entrepreneurship is always about multitasking and working in multiple roles.

“No day is a typical work day when you are an entrepreneur, because what each day will bring its set of own challenges, so its very difficult to sum it up as a typical day”

There are problems that young aspiring entrepreneurs don't consider while setting up a start up. Could you offer some advice to budding entrepreneurs?

Young entrepreneurs have a problem when it comes to micro level management, they try to do everything themselves which leaves them with no or little time for business development which is an essential when it comes to taking your company from a startup to a full fledged company.

What does a typical day of work look like?

No day is a typical work day when you are an entrepreneur, because what each day will bring its set of own challenges, so its very difficult to sum it up as a typical day.

How did people close to you react to your decision of entrepreneurship?

For me it was quitting a highly paid job and a PR in London and coming back to India to startup and hence it was quite terrifying for many. But my immediate family stood by me which was one of my major strengths.

What are the ingredients to brew a successful entrepreneur?

Don't try to be the know it all entrepreneur

Learn to delegate.

Followup of regular intervals.

How would people know you outside of your professional life? Who is Monisha Sarage?

People know me as fun loving and in the moment kind of person.

As told to S.Bhatia

Upcoming Events

79th FIP World Congress of
Pharmacy and Pharmaceutical Sciences
Abu Dhabi, United Arab Emirates
22-26 September 2019



New horizons: Navigating winds of change

New technologies, new roles, new opportunities for pharmacy

Do you want to be inspired to take on new roles and be prepared for success in a world of change? Wherever you practise, FIP can help you stay ahead of the game so that you can provide the best care for patients.

As we develop new skills to manage new technologies such as robotics and the digitalisation of health care, it is important that we do not compromise quality and safety. Come to the Abu Dhabi congress, which will help you develop the knowledge and attitudes to adapt to emerging new roles through networking with pharmacists and scientists from all areas of practice and from all around the world.

WELCOME TO ABU DHABI!

Abu Dhabi is a modern, cosmopolitan city with an ancient heritage where respect for the past informs the present and shapes the future. There are historic buildings, engaging tours and a packed calendar of events covering the arts, culture, sports and trade. Visitors will encounter a diverse emirate, with deserts, beaches, oases and mountains, and there are ultra-modern malls and small souk-like stores to cater for their every (tax-free) shopping need.

CONGRESS STREAMS:

A > New trends in science, practice and education

Focuses on new technologies, digitalisation of health care, robotics, individualisation of therapy, the provision of education via virtual classrooms, integrating science and practice in teaching, communication, people-centred care, and ethical challenges.

B > New roles, opportunities and responsibilities

Examines pharmacists' roles and the roles of individuals, looks at new services and the skills required to advance them, and highlights the importance of education and of collaboration not only with pharmacy colleagues but also with other health-care professionals.

C > Health now! Responding to the challenges of today

Recognises that challenges can be faced by looking at new research, ethical considerations, new values, access to health, health systems, sustainability, environmental sustainability, non-communicable diseases, empowerment of patients, empowerment of women, quality and assessment.

D > Targeting special interests

Looks at special interests in the different fields of pharmacy and pharmaceutical sciences.



ABU DHABI 2019
FIP WORLD CONGRESS
22-26 September

Please find more information:
abudhabi2019.congress.pharmacy

Note
Some congress sessions are accredited for continuing education. Check our website.



PHARMOCRACY
FOR THE PHARMACISTS, BY THE PHARMACISTS, OF THE PHARMACISTS

WHAT IS PHARMOCRACY

A PROFESSIONAL cum Student Body. Working towards bridging the gap between industry and academics

- PHARMOCRACY is involved in activities that identify the need of pharmacy students and provide possible solutions.
- A platform to conduct Community service activities and learn things beyond the curriculum for all pharmacy students.
- Brings the best out of pharma students aspiring to reaching the next level

Annual program starts from Sept 2019

Future Aspects

- Technical Events encouraging student to write review articles or research papers & getting them published in Pharmacy Magazines
- Community Services at Individual/Group or college level to promote the awareness of pharmacy as a profession and career

Annual Membership Fee: INR 799

MEMBERSHIP INCLUDES

- 8 Different events throughout the year
- Educational Seminars & Workshops
- Technical Competitions

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“If You Are Working On Something That You Really Care About, You Don’t Have To Be Pushed. The Vision Pulls You.” - Steve Jobs

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