

SHREENATH **PHARMA** *MAGAZINE*

Volume 1, Issue 6, November 2019



Table of Content

| | |
|---|----|
| # From the Editor's Desk..... | 3 |
| # Pharma News..... | 4 |
| # Molecule of the month..... | 6 |
| # Digitalisation in Pharmaceutical World..... | 8 |
| # Articles 101..... | 10 |
| # Talk the talk..... | 12 |



From the Editor's Desk

Dear Readers,

We begin with the sixth edition bright as ever acknowledging the readers, contributors and the subscribers for their support and interest.

In this issue we shall brain storm over the digitization of the pharmacy world with an interview of Mr. Kamalraj Bhatia, and an article with statistics about the same. A drug caught in the cross fire- Ranitidine as the molecule of the month & the hidden key of life - The Nutraceuticals along with Pharma news updates from the industry and campus for our readers.

Looking forward to your contribution for this magazine. We will be glad to share your thoughts with our readers.

Happy reading

Forum Jalundhwala

Editorial Team: Atharva Magdum

Sahil Bhatia

Ravi Kukreja

Mayur Khiyani

Along with Pharmacad & Pharmocracy

Coverpage & Design: Vaishnavi Pawar

Ranitidine declared safe by USFDA statement

NDMA(N-Nitrosodimethylamine) found in Ranitidine are similar to the levels like grilled or smoked meats etc) says USFDA. USFDA also conducted tests that simulate stomach environment to check what happens to Ranitidine if exposed to acid in the stomach with a normal diet. Results indicate NDMA is not formed through this process. This is not a matter of worry anymore. Only if NDMA levels in Ranitidine are above the acceptable limits(96 nanograms per day or 0.32 ppm) USFDA is asking companies to voluntarily recall Ranitidine batches. If not, companies do not need to recall batches as it is safe. As a result, several pharma companies like Strides Pharma Science Ltd have relaunched Ranitidine in USA.

Reference:<http://www.pharmabiz.com/NewsDetails.aspx?aid=119464&sid=2>

Lupin launches potassium chloride for oral solution USP, 20 mEq

Lupin Limited launched potassium chloride for oral solution USP, 20 mEq which is the generic equivalent of Pharma Research Software Solution, LLC's potassium chloride for oral solution USP, 20 mEq. It is intended for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis in patients for whom dietary management with potassium- rich foods or diuretic dose reduction is insufficient.

Reference:https://www.equitybulls.com/admin/news2006/news_det.asp?id=259503



Macleods Pharma recalls nearly 32000 bottles of anti-diabetes drug in US .

Macleods Pharmaceuticals has recalled 31,968 bottles of pioglitazone hydrochloride in the US market after the tablets were found to be 'superpotent'. Pioglitazone hydrochloride tablets are used to control high blood sugar in type 2 diabetes patients. The tablets are sold under the brand Actos and are available in 15 mg, 30 mg, and 45 mg. The 15 mg bottles were recalled.

Reference:<https://www.livemint.com/science/health/macleods-pharma-recalls-31-968-bottles-of-anti-diabetes-drug-in-us-for-being-superpotent-11572260844615.html>

Pfizer's Abrilada gets USFDA Nod

Pfizer announced that the US Food and Drug Administration (FDA) has approved Abrilada (adalimumab-afzb), as a biosimilar to Humira (adalimumab), for the treatment of certain patients with rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis and plaque psoriasis. Biosimilars have been a significant catalyst for change for the healthcare industry over the last decade, with the potential to drive cost savings for healthcare systems.

Reference: <https://business.medicaldialogues.in/pfizer-abrilada-biosimilar-to-humira-gets-usfda-nod-for-multiple-inflammatory-conditions/>



FDA gives nod to first targeted therapy to treat patients with painful complication of sickle cell disease

U.S. Food and Drug Administration approved Adakveo (crizanlizumab-tmca), a treatment to reduce the frequency of vaso-occlusive crisis – a common and painful complication of sickle cell disease that occurs when blood circulation is obstructed by sickled red blood cells. Common side effects for patients taking Adakveo were back pain, nausea, pyrexia (fever) and arthralgia (joint pain).

Reference: <https://www.pharmatutor.org/pharma-news/2019/fda-approves-first-targeted-therapy-to-treat-patients-with-painful-complication-of-sickle-cell-disease>

Sun Pharma and AstraZeneca work together to develop oncology products for China

Sun Pharmaceutical Industries Ltd has entered into a licensing agreement with AstraZeneca UK Ltd to introduce certain novel ready-to-use infusion oncology products in China.

According to the agreement, Sun Pharma will handle development, regulatory filings and manufacturing aspect of the drug. AstraZeneca will be responsible for promotion and distribution of the drugs in China.

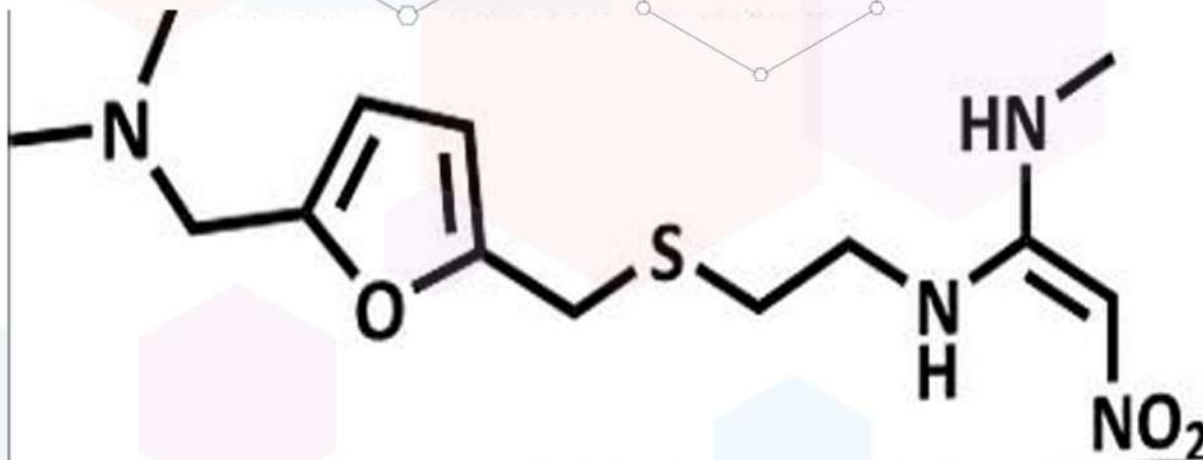
Reference: <https://www.livemint.com/companies/news/sun-pharma-in-pact-with-astrazeneca-to-develop-oncology-products-for-china-11573010941123.html>

MOLECULE OF THE MONTH

RANITIDINE

Ranitidine is a competitive, reversible inhibitor of the action of histamine at the histamine H₂ receptors found in gastric parietal cells. This results in decreased gastric acid secretion and gastric volume, and reduced hydrogen ion concentration. It is commonly used in the treatment of peptic ulcer disease, gastroesophageal reflux disease and Zollinger-Elison syndrome. There is also tentative benefit for hives. It can be taken orally, intramuscularly or intravenous. Bioavailability as high as 50% with an action setting up in an hour. Half-life from 2-3 hours as it is excreted from the kidney. It is one of the OTC marvels.

Ranitidine is given with NSAIDs to reduce the risk of ulceration. Proton-pump inhibitors are more effective for the prevention of NSAID-induced ulcers. It is part of a multidrug regimen for *Helicobacter pylori* eradication to reduce the risk of duodenal ulcer recurrence. For prevention of acid-aspiration pneumonitis during surgery. The drug initially increases gastric pH but has no effect on gastric volume.



Ranitidine was discovered in 1976 and came into commercial use in 1981. It is available as a generic medication. In 2016 it was the 50th most prescribed drug with more than 15 million prescriptions. It is on the World Health Organisation's List of Essential Medicines, the safest and the most effective medicine needed in a health system. In September 2019 the toxin N-nitrosodimethylamine (NDMA) was discovered to occur in ranitidine from a number of manufacturers, resulting in large scale recalls.

NDMA is a semi-volatile organic chemical produced as by-product of several industrial processes and present at very low levels in certain foodstuffs, especially those smoked, cooked, or cured. It is toxic to the liver and other organs and is a probable human carcinogen. It is also used to create cancer in rats for cancer research. At high doses, it is hepatotoxic and can cause fibrosis in the liver.

Some Indian Pharma companies have been impacted by the news flow regarding a potential ban on Ranitidine. While the impact on formulators is direct, API and chemical manufacturers can partially offset if they have a presence in alternative drug and application. The global formulation market of Ranitidine is estimated to be about Rs. 20,000 crore. Companies which are reasonably diversified in terms of exposure to formulations have a better chance to survive regulatory crisis like this. GSK Pharma has issued a recall.



Reference: https://www.google.com/search?q=gsk+pharma+ceases+ranitidine+distribution+and+sales+in+india&sxsrf=ACYBGNTnlUdgAxsWjSOF6nq0RRSNAEAV5Q:1574489648730&source=lnms&tbm=isch&sa=X&ved=2ahUKEwi28NuB1__IAhVEul8KHQ4XCQ0Q_AUoAnoECAwQBA&biw=1536&bih=706&dpr=1.25

-A.Magdum

Digitalisation in Pharmaceutical World.

In the days of clattering keyboards and clickety-clacking mice running errands for a pair of drowsy stressed eyes sitting across a lit screen, we now phase through. In times when we can get to know a person without actually meeting them, they said technology will and has done wonders. Through the wonder years of the twentieth century, data was generated and transmitted through the one-and-zeros, somehow... it seemed was a representation of the "can be" and "cannot be" leaving no grey area, a system so powerful, a system so perfect, a system so impeccable that today multibillion dollar industries rise and fall on a platform designed using this system, and the cycle goes on, like a guinea pig in the wheel.

But with great challenges come great opportunities. Digitalisation is fundamentally changing the healthcare outlook. The Pharma industry as a core part of healthcare is no exception to this change. Technologies and innovations are already enabling pharma companies to improve medicine development, understanding the patients profile and enabling patient care. The consumers on the other end of the tunnel are demanding better data on the medication efficacy and improvement in the quality of the patient's life. All this is a lot and cannot be fulfilled by the old textbook and pure traditional means. The increase in the price pressure due to tightening of the market regulations and patent expirations are forcing company strategies in order to survive. Global laws and regulations cause even more complexity in compliance of product supply infrastructure and operations. The Pharma Business is under a storm, multiple storms ...a transformation will not only challenge the long-time hosts, but also create opportunities for new entrants outside of the business whose innovations and business structure profiles clock speed on a completely different level.

Digitalisation has the capability to provide patients real-time information about their condition and collect data for care analytics to improve treatment. This system not only helps companies address the challenges in compliance and chronic disease management, but also help them generate hundreds of billions of dollars in value. Companies such as Novartis, GSK, Nova Nordisk are already investing in partnership and new business models with technology giants such as Google, IBM, Qualcomm. Traditional manufacturers like Apple, Samsung and Nokia are already researching beyond the wellness products and looking into the patient care market.

The Pharma manufacturing infrastructure implementation are already highly complex with an increasing number of connected equipment and system integrations, internally and externally. The fundamental ecosystem, business model and technology changes lead to a concept that experts regard to as the 'New Pharma Reality'.

With sales portals generated online, data acquisition becomes a smooth task, however incidences questioning the authenticity of the portal and the service provider often remain in the blur. Sales still prevails to drop a huge question mark as the list of regulations with the ever evolving technological systems and softwares cannot keep up. Softwares diagnosing patients on entries of the ailments have left the medical profession with star eyed gazes and awe's. generation of prescriptions on these very portals makes differentiation difficult as it keep within the boundaries of the 'Drugs & Cosmetics Act' which burdens a pharmacist. Numerous apps in place makes this digital market a competitive playground. The disappearance of online retailers on supplying false goods or expired goods has been reported in some parts of India, Malaysia.

Blockchain like systems are in place. Healthcare companies like United Heath Group(UHG) and others who handle a load of data of their clients and patients are looking to use blockchain for easier and quicker solutions. A lot of companies have already started pilot use of blockchain, especially in the United States. It is only applicable because it provides confidentiality and is a more secure way to handle data. It helps a lot to adhere to HIPAA regulations and that is why it definitely has an impact on the industrial future.

Digital marketing is a frontier for pharmaceutical companies as many of them are scaling up their consumer business and introducing consumer brands. Traditionally, there are a number of restrictions. Pharmaceutical companies have had little or no interaction with their end users since they are entirely dependent on health care providers for medical knowledge and advice. With the digital medium democratising information, there is a huge opportunity for the pharma industry to develop patient-centric strategies and transform the business. Patients are also not just passive recipients of prescriptions anymore. They play an active role in their healthcare. This easy accessibility has both, positive and negative sides to it. Digital pharma strategies can help brands develop authority by providing patients with accurate reliable information.

Constant pressure has pushed the industries into compounding the medicines of the future. Burning bright and vibrant an ever evolving market is like a swinging door, timing is the key. But a known fact states, 'when the steam is blown off, it's only the survival of the fittest'.

-A.Magdum

Article 101

HIDDEN KEY OF LIFE - THE NUTRACEUTICALS

Nutraceutical is a term derived from "nutrition" and "pharmaceutics." The term is applied to products that are isolated from herbal products, dietary supplements (nutrients), specific diets, and processed foods such as cereals, soups, and beverages that other than nutrition are also used as medicine.

In the US, the term "nutraceutical" products are regulated as drugs, food ingredients and dietary supplements. The term is not defined the same in different countries, but is usually defined as a product isolated from foods that is generally sold in medicinal forms not usually associated with food. A nutraceutical product may be defined as a substance, which has physiological benefit or provides protection against chronic diseases. Nutraceuticals may be used to improve health, delay the aging process, prevent chronic diseases, increase life expectancy, or support the structure or function of the body.

Nutraceuticals, in contrast to pharmaceuticals, are substances, which usually have no patent protection. Both pharmaceutical and nutraceutical compounds might be used to cure or prevent diseases, but only pharmaceutical compounds have governmental sanction.

Nutraceuticals covers most of the therapeutics areas such as anti-arthritic, cold and cough, sleeping disorders, digestion and prevention of certain cancers, osteoporosis, blood pressure, cholesterol control, pain killers, depression and diabetes.

The nutraceutical industry's three main segments include herbal/natural products, dietary supplements and functional foods. Among these, these most rapidly growing segments are the herbal/natural products and the dietary supplements. In 2007, the world nutraceutical market grew to reach \$74.7 billion, compared to that of 2002, when it reached \$46.7 billion.

Nutraceuticals can be organized in several ways depending upon its easier understanding and application, i.e. for academic instruction, clinical trial design, functional food development or dietary recommendations. Some of the most common ways of classifying nutraceuticals can be based on food sources, mechanism of action, chemical nature etc. The food sources used as nutraceuticals are all natural and can be categorized as mentioned below:

1. Dietary Fibre
2. Probiotics
3. Prebiotics
4. Polyunsaturated fatty acids
5. Antioxidant vitamins
6. Polyphenols
7. Spices

References –

1. Adelaja AO, Schilling BJ. Nutraceutical: blurring the line between food and drugs in the twenty-first century. *Mag Food Farm Resour Issues*. 1999;14:35–40. [Google Scholar]
2. Albert CM, Campos H, Stampfer MJ, Ridker PM, Manson JE, Willett WC, Ma J. Blood levels of long-chain n-3 fatty acids and the risk of sudden death. *New Engl J Med*. 2002;346:1113–1118. doi: 10.1056/NEJMoa012918. [PubMed] [CrossRef] [Google Scholar]
3. Anderson JW, Randles KM, Kendall CWC, Jenkins DJA. Carbohydrate and fiber recommendations for individuals with diabetes: a quantitative assessment and metaanalysis of the evidence. *J Am Coll Nutr*. 2004;23:5–17. [PubMed] [Google Scholar]
4. Brower V. Nutraceuticals: poised for a healthy slice of the healthcare market? *Nat Biotechnol*. 1998;16:728–731. doi: 10.1038/nbt0898-728. [PubMed] [CrossRef] [Google Scholar]

To get more info on the article, go to link:

docs.google.com/document/d/2IWpiOtwpDFeLXQjqV90BuT24GMxx-3nKNo9oM7mRM

TALK THE TALK

**Pharmacist Kamalraj Bhatia-
D.Pharm**

**Co-Proprietor of Bhatia Medical
And Superstores, a chain of 6
pharmacy-cum-supermarkets
based in Western Mumbai suburbs.
Co-Partner in The Pharma Hub, a
wholesale distribution firm for
medicines based in Marol, Andheri.
Black belt in Karate**



Are online pharmacies bad for the average retailer?

Yes. They are very bad for the average retailer. They are offering heavy discounts on medicines, as far as 20 to 25%, where the retailer margins are only 14 to 19%, which is fixed by the government. The only playing field of the online pharmacies is that they are offering huge discounts. If one levelled the playing field by preventing huge discounts, online pharmacies would be nowhere near as competitive as brick and mortar stores. The stores would offer more value in terms of dispensing advice, as compared to a lifeless and virtual online pharmacy.

How does it affect you specifically?

As a retailer myself, I can confidently say that it affects not only me, but all the retailers. To me, specifically, patients are trying to get the 20% discount by hook or by crook. This way, I tend to lose regular patients.

How can a regular retailer be a part of this process?

Honestly, online pharmacies are in a very grey area, as per the law. The government has still not framed proper guidelines for the online pharmacies. Online pharmacies during their inception in India tried to deal with local retailers, offering them a margin of 7.5%, and the retailer was supposed to give 20% discount on medicines to patients. However in today's day, the ties have been broken. The online pharmacies are operating via their own dark stores (like warehouses) with very low overheads, and have thus left the retailers with very low margin.

Will online pharmacies be the only way in the future?

Not at all. Retailers will never die. Brick and mortar stores have stood the test of time, and will never quite die out. No doubt that the online pharmacies have made their presence felt, but this is a threat only to a certain extent. In the past, I heard through sources, that malls have sprung up, so it's game over for the retailers. Everyone will only go to malls. Nothing of that sort happened. When online e-commerce stores came into the picture, it was said that malls will shut down, because online shopping is much more convenient. Again, nothing of that sort happened. Today if you check the market share pie charts, online shopping and e-commerce only occupy 2-3% of the total market share in India.

What are the shortcomings of online pharmacies as compared to regular pharmacies?

When a patient places an order online, he blindly orders what the doctor prescribes. The patient uploads the prescription to the app, and the laymen who fill these prescriptions will then deliver the order to you as per the prescription. In a reputed retail pharmacy, the pharmacist looks at the prescription, scrutinizes it properly. He then explains to the patient the correct dose. Also very few people are aware about the fact that a pharmacist can be superior to a doctor in terms of medicine.

The pharmacist is the person that will verify whether what a doctor has prescribed is accurate or not in terms of treatment of the disease. Only a pharmacist is capable of deciphering the doctor's handwriting, as well as catches any errors that might have crept in. The pharmacist also checks for any dietary restrictions or possible adverse drug interactions that are likely to occur. The pharmacist is also more likely to check the patient's medical history, and can correct any discrepancies or can also replace any drug if the patient is non-compliant. Online pharmacies are just traders, whereas pharmacists are at the

With razor-thin margins, is it better to open a retail business today as compared to the past?

Well, in the past, pharmacies were neat, clean, non-chaotic, and being a pharmacist was considered to be a White-Collar profession. In today's date, many pharmacies have sprung up today for the sole purpose of making a lot of money. These so-called pharmacies have very less knowledge about medicine and have no clue about what they are dispensing.

Do you plan on charging customers for dispensing advice along with medicines in the future?

I'm not sure about the rules regarding this. A little while ago, if I recall correctly, there was a rule where the pharmacist could charge "Consultancy fees" of some sort (do not quote me on this). Let's say that if I were allowed to charge money for my consultancy, I do not plan on doing it anytime soon. Maybe in the future, I might give it a thought. Honestly, serving patients since 1987, I never thought about charging money for giving advice. I thought it was more of helping humanity, than a service that has to be paid for. I would like to preserve this profession as a White-Collar profession. When patients come to my store, they actually wait to talk to me and inquire what and why the doctor has prescribed the specific medications, or whether the doctor has mentioned the right dose, or number of milligrams of the medicine. Such things can only be looked into by a skilled and ethical pharmacist. Hence, I would not prefer charging a patient for the above services.

"I would like to preserve this profession as a White-Collar profession."

Has your business put stress on any aspect of your social life?

Frankly, no. It's not a big deal, and does not disrupt any of my social life. I am perfectly able to attend any social functions, family functions, parties, and even go on vacation without too much worry. There are pharmacies where only one pharmacist has been employed. As per the norms of the Food and Drug Administration, if any medicine is being dispensed, it has to be under the supervision of a registered pharmacist only, or else the shop cannot dispense medicine. I myself am a pharmacist, and I have also hired additional pharmacists so the pharmacy can operate fluently even in my absence.

-As told to S.Bhatia.



***To contribute and for article specification connect with us on:
Email:pharmamagazine.shreenath@gmail.com
Facebook:Shreenath Pharma Magazine
Website:www.shreenathpharmamagazine.com***