A Quarterly News Letter of Krupanidhi College of Pharmacy, Bangalore
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KCP NEWSLETTER

VOL.5 ISSUE 2

SYNERGIA

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In this Issue...

ALERT!

Ministry of Health and Family Welfare Bans 344 fixed drug combinations including popular OTCs

MOHFW on 20 Mar 2016 banned 344 Fixed Drug Combinations (FDCs) through a gazette notification. These include several common cough syrup solutions, analgesics and antibiotic combinations, many of which are sold over the counter (OTC).

The ban came into immediate effect following recommendations of an expert committee formed to examine the efficacy of these drug combinations. The industry, though, may question the basis of the ban and seek judicial intervention.

The health ministry opined that unscrupulous operators in the pharmaceutical industry, in their quest for newer products and to circumvent DPCO, mix and match APIs into FDCs to market them as newer remedies.

This adhoc expert committee formed by MOHFW found the combinations lacked "therapeutic justification".

This ban affects many famous OTC brands and are likely to go off the shelves following this development.

From a clinical pharmacist point of view this development is significant since:

- being OTC products the side effects of these FDCs mostly go unreported since patients buy them without prescriptions and hence the crucial pharmacovigilance insights were found lacking in this domain.
- the long term abuse of these FDCs causes anti-microbial resistance leading to newer strains that are difficult to manage.
- there are reports of organ (renal and hepatic) failures supported by scientific publications

"We have reviewed products for several times and there is evidence from research papers and studies to show these medicines are irrational combinations", MOHFW commented.

The complete list of banned FDCs can be found in this URL:http://www.cdsco.nic.in/writereaddata/drugs%20banned%20in%20the%20country2.pdf

***Chandramouli R**, HoD, Quality Assurance Dept., Krupanidhi College of Pharmacy, Bangalore*

Editorial

Dear all,

I'm writing this to you amidst hectic times. Come April, the student community has a lots to do. Finish off syllabus, write those seemingly endless tests, finish records, prepare for exams, the list will go on...

But, at KCP we find time for everything. Be it displaying their talents, or sporting prowess or contributing our knowledge and expertise to the upliftment of the community that we live in, means a lot to KCPians, they have managed to take themselves off for a week to meticulously plan and organize the annual National Service Scheme Special camp which benefitted the communities of Mullur and Ambedkar Nagar, situated in the neighborhood of KCP.

The NSS team exhibited some exemplary leadership in doing community outreach and upliftment activities and with the help of like minded volunteers from MVJ Medical College & Research Hospital and Vydehi Institute of Dental Sciences, Bangalore.

As usual in the academic and professional development fronts too KCPians performed splendidly, bagging top 10 University Ranks in M Pharm, Pharm D and B Pharm courses. As a trendsetting event, the KCP's Center for Pharmaceutical Professional Advancement under Prof. Prakash Mallya's leadership is conducting a "*certificate course in Pharmaceutical Regulatory Affairs*" a first of a kind course of study which gives an immersive understanding of pharmaceutical regulatory affairs offered free to students and faculty, *Synergia* thanks the CPPA's efforts.

Rajeswari R
Editor

FDA Watch

USFDA New Drug Approvals

Approval	Indication
Kovaltry (antihemophilic factor (recombinant)) Injection	Hemophilia A
Evomela (melphalan) for Injection	Multiple Myeloma
Idelvion (coagulation factor IX (recombinant), albumin fusion protein) Injection	Hemophilia B
Odefsey (emtricitabine, rilpivirine and tenofovir alafenamide) Tablets	HIV Infection
Briviact (brivaracetam) Tablets, Solution and Injection	Epilepsy
Sernivo (betamethasone dipropionate) Topical Spray	Plaque Psoriasis
Cetylev (acetylcysteine) Effervescent Tablets for Oral Solution	Paracetamol Overdose
Zepatier (elbasvir and grazoprevir) Tablets	Chronic Hepatitis C
Zembrace SymTouch (sumatriptan) Injection	Migraine
Adzenys XR-ODT (amphetamine) Extended-Release Orally Disintegrating Tablets	Attention-Deficit Hyperactivity Disorder
Onzetra Xsail (sumatriptan) Inhalation Powder – formerly AVP-825	Migraine
Dexilant SoluTab (dexlansoprazole) Delayed-Release Orally Disintegrating Tablets	Gastroesophageal Reflux Disease
Emverm (mebendazole) Chewable Tablets	worm Infection
Zurampic (lesinurad) Tablets	Hyperuricemia Associated with Gout
Docetaxel Non-Alcohol Formula Injection	Cancer
Uptravi (selexipag) Tablets	Pulmonary Arterial Hypertension
Basaglar (insulin glargine) Injection	Diabetes Type 1, Diabetes Type 2

Source: Centerwatch, USFDA, Current as on 20 March

We would like to hear from you!

Please send your contributions, feedbacks and suggestions to: synergia.kcp@gmail.com

Case Report

Phenytoin Induced Toxic Epidermal Necrosis

INTRODUCTION

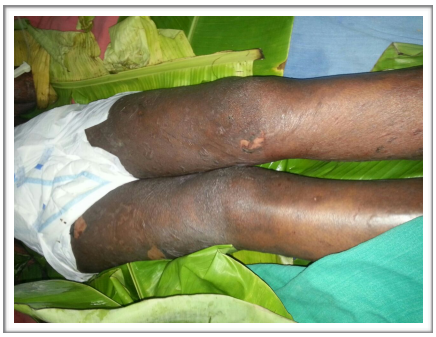
Severe Cutaneous Adverse Reactions (SCAR) are life-threatening conditions associated with significant morbidity and mortality. In Toxic Epidermal Necrosis (TEN) greater than 30% of the Body Surface Area (BSA) is involved. The incidence of TEN is estimated at 0.9 to 1.4 persons per million per year in the general population.

Phenytoin is the most commonly prescribed antiepileptic drug in adults. In a case-control study of 73 patients taking anti-epileptic drugs 14 patients were reported with the Stevens-Johnson Syndrome (SJS) associated with the phenytoin ingestion.

CASE REPORT

A 60 year old female patient was admitted with the complains of ulcer over lips, oral cavity, bilateral eyes and itchy blisters all over the body. She also had burning sensation of the chest, blood stained urine and swelling on the leg since 3 days. The patient had a history of left parietal craniotomy 3 weeks prior to admission and was put on Tab. Phenytoin, Tab Dexamethasone, and Tab. Diclofenac, post which she developed above symptoms and was brought to the emergency department.

On the day of admission the patient was conscious, oriented and her blood pressure was 140/90 mm of Hg. Upon cutaneous examination, multiple flaccid bullae were seen all over the body including scalp. Oral and genital erosions with multiple bleeding points were present. Purulent eye discharge was present. The suspected drug phenytoin was advised to discontinued and was kept under observation. From first day to the sixth day the patient was started with the Piperacilin and Tazobactum combination, Mupirocin, dexamethasone and nutrional supplements. Patient had fluid and electrolyte abnormalities, The fluid requirement during initial 24 hr calculated using Parklands formula. Patient had Purulent eye discharge which was taken care by eye drops. On seventh day the patient was shifted to MICU and started with higher antibiotics such as vancomycin and meropenem.



She also had respiratory distress, which was treated with nebulization of salbutamol and budesonide. on the eight day she had multiple organ dysfunction, metabolic acidosis, and sepsis where multiple life saving medication had been administrated but the patient expired after 8 days of admission.

DISCUSSION

Both SJS &TEN are debatably included in the same spectrum as Erythema Multiforme (EM). In both the condition hemorrhagic erosions of mucous membrane including eye, lips, mouth, pharynx, trachea, bronchi, glans penis, urethra and anus are present in about 95% of the cases. Maculo– papular eruption which may also present with oral lesions and conjunctivitis must be considered as differential diagnosis in early stage of disease.

Up to 60% of cases of SJS/TEN can demonstrate causality to a medication exposure, but other factors including infection (e.g., Mycoplasma pneumonia), genetic factors (HLA alleles) or graft versus host disease have been implicated in the development of this mucocutaneous condition, and up to 20% of cases remain idiopathic. The studies performed in Taiwan indicate a strong association between HLA-B*1502 allele and 15,16 phenytoin induced SJS/TEN and declared that the allele can be considered as a universal marker for phenytoin induced SJS/TEN, which is not supported by few studies. More than 200 medications have been identified as potential causative agents of SJS/TEN. Even though some drugs have been implicated in case reports, not all of these agents have demonstrated a strong association with the development of SJS/TEN.

Early diagnosis with the prompt recognition and withdrawal of all potential causative drugs is essential for a favorable outcome. Removal of offending drug, its metabolites or cytokines by plasmepheresis or hemodialysis can also be considered. Various immunomodulatory treatments for SJS/TEN have been proposed, such as glucocorticosteroids, intravenous immunoglobulins (IVIG), and cyclosporine. The cost of these treatment are high.

Patients will commonly have fluid and electrolyte abnormalities that require careful monitoring. Mouth care with disinfecting mouthwashes and mild ointments is essential in managing the mucosal lesions of the oral cavity and lips. In cases with eye involvement, ophthalmologic care of critical and specialized lid care should be provided daily in addition to anti-inflammatory eye drops Treatment can include prophylactic ophthalmic antibiotics (e.g., bacitracin or a fluoroquinolone), preservative-free emollients, antiseptic eye drops, and/or vitamin. The Government of India and regulatory authorities should create awareness among practitioners to report all the ADRs to the Adverse Drug Reactions Reporting Centers, with special emphasis on the drugs banned outside India.

Conclusion

If patient is affordable and willing, its better to screen for HLA alleles before starting treatment with anticonvulsants. Hence, the medication of anticonvulsants could be individualized. If HLA screening for HLA alleles became common, phenytoin associated SJS/TEN incidence might be reduced. As the adverse systemic reactions to AEDs are rare and severe, physicians should counsel patients on the importance of notifying their physician if they develop any new or unusual symptoms.

Laboratory Investigations

Parameter	Reference Range	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Haemoglobin	12–18 mg/dl	10.8			9.4			7.3
WBC	5000 – 11000 cells / cu mm	17,800	8,600		9,400			24919
Platelets	1.5 – 4.5 lacs / cu mm	5.3	3.4		1.86			1.1
ESR	0 – 20 mm/hour	12	10		18			15
Serum Urea	20 – 50 mg/dl	43				68	130	149
Serum Creatinine	0.6 -1.1 mg / dl	0.7				0.9	1.8	2.3
Sodium	136 -145 mEq/L	132		138			146	154
Pottasium	3.5 -4.5 mEq/L	6.7		4.1			4.1	4.4
RBS	70 – 100mg/dl	50					116	96
Post Prandial Glucose	110 -140 mg/dl	68		148				
Total Billurubin	0.3 -1.2 mg/dl	9.8		4.9		3.9	4.7	4.9
Direct Billurubin	0- 0.2 mg/dl	4.8		3.0		2.0	2.9	1.8
Indirect Billurubin	0.3 -1.0 mg/dl	5.0		1.9		1.7	1.8	1.2
SGOT	upto 31 IU/L	82				74	31	52
SGPT	upto 34 IU/L	96				43.0	17.0	13.0
ALP	42 – 98 IU / L	173						143
Total Protien	6.4 – 8.3 mg/dl	5.6		4.5		4.4	4.4	3.4
Albumin	3.5 – 5.2 mg/dl	2.0		1.7		1.3	1.3	1.0

Merphin Philip Thomas *5 Pharm D,* ***Dr. Aneesh S.*** *Assistant Professor, Department of Dermatology, MVJ Medical College and Research Hospital ,* ***Rajeswari R*** *Associate Professor,* ***Merlin T.S*** *Pharm D Intern, Department of Pharmacy Practice, Krupanidhi College of Pharmacy.*

Commonly prescribed drugs to treat attention-deficit hyperactivity disorder (ADHD) may affect bone density

Researchers found that young people who take stimulant methylphenidate have lower bone density than their peers. This could have serious consequences later in life, the study suggests. Using data from the U.S. National Health and Nutrition Examination Survey, researchers examined the effects of ADHD drugs on the bone density of young people between 8 and 20 years old. Among more than 6,400 survey participants, 159 were taking stimulant drugs.

Precision Medicine - an emerging field that aims to deliver highly personalized health care

Precision medicine is an emerging field that aims to deliver highly personalized health care by understanding how individual differences in genetics, environment, and lifestyle impact health and disease. According to the National Research Council, “personalized medicine” is an older term with a meaning similar to “precision medicine.”

In precision medicine, the focus is on identifying which approaches will be effective for which patients based on genetic, environmental, and lifestyle factors. Pharmacogenomics is a part of precision medicine. Pharmacogenomics is the study of how genes affect a person’s response to particular drugs.

Precision medicine gives medical professionals the resources they need to target the specific treatments of the illnesses we encounter, further develops our scientific and medical research, and keeps our families healthier.

Precision medicine allows us to be more effective than a "one-size-fits-all" approach. It is an emerging approach to promoting health and treating disease that takes into account individual differences in people's genes, environments, and lifestyles. This makes it possible to design targeted treatments for cancer and other diseases.

PROS

- New approaches for protecting research participants, particularly patient privacy and the confidentiality of their data.
- Design of new tools for building, analyzing, and sharing large sets of medical data.
- Improvement of FDA oversight of tests, drugs, and other technologies to support innovation while ensuring that these products are safe and effective.
- New partnerships of scientists in a wide range of specialties, as well as people from the patient advocacy community, universities, pharmaceutical companies, and others.
- Opportunity for a million people to contribute to the advancement of scientific research.
- Improved ability to predict which treatments will work best for specific patients.
- Better understanding of the underlying mechanisms by which various diseases occur.
- Improved approaches to preventing, diagnosing, and treating a wide range of diseases.
- Better integration of electronic health records (EHRs) in patient care, which will allow doctors and researchers to access medical data more easily.

CONS

- Precision medicine is still a young and growing field.
- Researchers will need to find ways to standardize collection of data from more than 1 million volunteers from hospitals and clinics around the country. They will also need to find efficient ways to store large amounts of this patient data in databases.
- With health data on such a large number of people, it will be critical to find ways to protect participants’ privacy and the confidentiality of their health information.
- Cost is also an issue with precision medicine.drugs that are developed to target a person’s genetic or molecular characteristics are likely to be expensive.
- Reimbursement from third-party payers (such as private insurance companies) for these targeted drugs is also likely to become an issue.

The potential of precision medicine, was demonstrated in an international study based at UT Southwestern Medical Center used next-generation DNA sequencing technology to identify more than 1,000 gene variants that affect susceptibility to systemic lupus erythematous.

Renoy Philip, *6 Pharm.D Intern, Department of Pharmacy Practice, Krupanidhi College of Pharmacy, Bengaluru,*

Free apps every Pharmacist should have

Lead Article

Imagine a life without smartphones! smartphones in your pockets are morphed itself into a multifunction device long ago. Now phone is your camera, media device - even professional references.
Now a days all paper based references are rendered obsolete by relentless onslaught of technology and a slew of apps are available for both the dominant players in the smartphone market - Android and iOS. This compilation here features some of the must have free and freemium apps that are essential for carrying out professional duties.

Google play

How we chose?

- While there are several premium apps available for a price – few hundreds to thousands – we chose the best ones there which are *Free or mostly free.*
- The *offline apps* – that do not require data connection – was given preference
- Apps for *iOS was not included* because of its low user share
- Apps which has *Indian relevance* was preferred over the rest.

MICROMEDEX FREE DRUG REFERENCE

Micromedex Drug Information is available since March 2011 and ranks among the best apps for pharmacists. Thomson Reuter's Micromedex has garnered high praise for its usability.

Medscape

Medscape from WebMD is the leading medical resource most used by physicians, medical students, nurses and other healthcare professionals for clinical information. registered users. The Medscape app for Android is available for free.

edT Drug Information on Mobile

edT® is an *offline* mobile application for healthcare professionals to access all important drug information without connecting to internet. Brand Related Information, Indian brand names are included

LC

Lexicomp is considered gold standard in the filed of Clinical pharmacy related information. But the premium features are not free. This app is sufficient for basic reference and is a source of current and exhaustive information.

CIMS India

CIMS – pharmacists can improve patient outcomes through safe and effective use of medication at every point of care, CIMS provides pharmacist with both concise and comprehensive drug prescribing information- in a quick-access mobile format.

1mg is a health app that tells you about your medicines, their cheaper substitutes and side effects. Know about a medicine's impact on pregnancy, lactation and alcohol. Over 100,000 Medicines listed in this app covering the Indian market.

Please share with us if you know better alternatives.

-Compiled by: ***Chandramouli R*** *&* ***Rajeswari R****, Eds.* Synergia

NSS Special Camp @Mullur Village 29 Feb - 4 Mar 2016

Supported by:



February 29, 2016 | General & Oral hygiene and Dental screening Camp | Mullur Govt. Primary school| Supported by volunteers of Vydehi Institute of Dental Sciences


March 1, 2016 |Visit to Ashabhavan-Swanthanaa (home for desitiute women and mentally retarded female children) | Donation of articles and money


March 2, 2016 | Vaccination and Diabetes awareness campaign | Mullur Village

March 3, 2016 | Seminar on Best practices on Waste management by SAAHAS & SwachhBharath Abhyan | Mullur Village



March 4 , 2016 | Free Medical camp- Screening of Diabetes, Hypertension, Eye checkup and Dental treatment | Supported by volunteers of MVJ Medical College & Research Hospital, Vydehi Institute of Dental Sciences, Krupanidhi College of Nursing, Krupanidhi College of Physiotheraphy | Diagnostic agents & Medicines sponsored by Nuwell Biotech

Sports Day

24, 25 Feb 2016

The two day sports meet involved the enthusiastic participation of all the students.The students actively participated in the indoor and field events. Track events- running race for boys and girls, lemon and spoon race and three legged race,were especially conducted for girls. Field events shotput throw, javelin throw,discuss throw, high jump and long jump. Throwball for girls, and volley balls for boys, was also conducted. Indoor games carrom and chess Special event for staff was organized; both teaching and non teaching actively participated The overall rolling shield was bagged by 3rd B.Pharm.

Talents Week

10 , 11 Feb 2016

KCP is home to stellar talents to foster them, Talents week is an annual fixture in KCP's cultural Calender; this year it was celebrated at Asia Pacific World School . The off stage events were conducted at KCP. The programs was inaugurated by the lighting of the lamp by the Vice – Chair Geetha Nagpal, Principal Raman Dang , Director CPPA Prakash Mallya, Vice Principal Sonal Dubey and Cultural co-ordinators Kavitha AN & Deepti V.

TeamSYNERGIA

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