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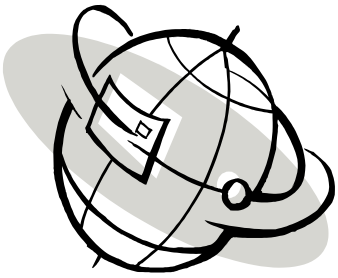
New drug launched



On october 19, 2010, the U. S. Food and Drug Administration approved **Dabigatran** indicated for prevention of stroke in patients with non valvular atrial fibrillation. The approval came after an advisory committee recommended the drug for approval on September 20, 2010 although caution is still urged by reviewers. Indian FDA approved the drug on December 12, 2011.

On February 14, 2011, the American College of Cardiology Foundation and American Heart Association added Dabigatran to their guidelines for management of non-valvular atrial fibrillation with a class I recommendation (Benefit>>>Risk, procedure/treatment SHOULD be performed).

The approved doses according to FDA are 150 mg twice daily for patients with creatinine clearance greater than 30 ml/min and 75 mg twice daily for patients with creatinine clearance greater than 15 ml/min and less than 30 ml/min.

75 & 110 mg capsules are prescribed for Prevention of venous thromboembolic events (VTE) in patients who have undergone major orthopedic surgery.

110 & 150 mg capsules are prescribed for Prevention of stroke, systemic embolism & reduction of vascular mortality in patients with atrial fibrillation.

Dabigatran is contraindicated in patients with active pathological conditions and in patients with history of hypersensitivity.

Clinical Trials in India – Present and Future

Sachin Narkhede
Clinical Operations Manager
PRA International India Pvt. Ltd, Mumbai

Clinical trials market in India is growing at a very fast pace and is expected to be more than double in 2015 from its size in 2011. Total number of trials registered in India till date is 1875. Number of new trials registered in 2011 had sharply declined from the number of trials registered in 2010. However, the market is not expected to be negatively impacted by the lower number of new trials registered in 2011. At present 513 clinical trials studies are being conducted in India which is far greater than the 331 studies being conducted in 2010 and 181 studies being conducted in 2009. Since trials of single drug

"The diabetes drugs glipizide, glyburide, and glimepiride each show a significantly higher risk for mortality compared with metformin, according to an analysis of more than 23,000 patients with type 2 diabetes presented here at ENDO 2012: The Endocrine Society 94th Annual Meeting."---- http://www.medscape.com/viewarticle/766729

FDA Issues Update on QT Prolongation Risk With Ondansetron

The 32-mg single intravenous dose of ondansetron should be avoided, as it may cause QT interval prolongation and could lead to a potentially fatal heart arrhythmia.

itself may take several years, the market will continue to exhibit steady growth even if the number new trials registered declines in a particular year.

The clinical research industry in India is expected to employ 50,000 professionals over the next five years, according to Indian trade association ASSOCHAM, *PharmaTimes* reported.

According to ASSOCHAM, introduction of electronic medical records in hospitals has also proved "a major attraction" for international CROs and multi-national companies looking to offshore trials to India.

Many of the new initiatives for regulating pharma industry in India has been in the charts for quite a long time. What required is speedy implementation and, necessary investment and infrastructure support. India should realize the fact that laws alone would not suffice; there should be a proper administrative and monitory mechanism to ensure its working. Lack of regulatory jurisdiction over private trial sites and absence of uniform application of the need for informed consent and proper ethics review have raised concerns about trials conducted in India. What we need here is to establish authorities such as the proposed Central Drug Authority and central licensing mechanism for manufacturing approvals. This would essentially help us keep a check over the activities of firms conducting drug trials in India.

India is the third largest producer of pharma products by volume and the industry is growing at a rate of 15-20% annually. The domestic pharmaceutical industry is pegged at USD 20 billion and is expected to touch USD 75 billion by the end of this decade.

On the regulatory front, Drug Controller General of India has implemented a robust process of reviewing the clinical trial application and data submitted for New Drug approval. DCGI has formed New Drug Advisory Committee (NDAC) for each therapeutic area which consists of 10 members from big government and private academic and research institutes. All the applications for Clinical trial conduct in India are sent to these members for review and provide the comments on the data supporting the application to ensure that the proposed Investigational product has gone through all the testing required as per Schedule Y and safety is well established in addition to DCGI's internal review process. As this process is recently been implemented by the authorities, this has increased the approval timeline in India and it will take some time to streamline the review process.

As a society, it is important for doctors, regulators, ethics committees and most importantly, patients to work together to ensure conduct of ethical research. There might surface instances that question our ability to conduct good clinical research. However, to throw the baby out with the bathwater is not the answer. We have fantastic doctors and researchers in India that are interested as much in the knowledge accrued from new research as they are in the ethical process of gaining that knowledge. It's time for India to take center stage in collaborative global pharmaceutical research. Talking openly about the clinical trial process and measures to strengthen those can only serve to further strengthen the foundations of our research infrastructure and mindset.

DEPARTMENTAL ACTIVITIES: "Helpline" service

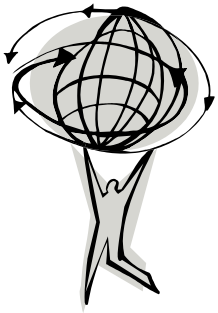
Drug Queries	Patient Counseled	Category of Drug Queries						
		Indication	ADR	Admn	Cost	Uses	P'cology	Others
27	27	1	5	4	1	2	8	6

1) WE DO NOT PRESCRIBE OR ADVISE TO TREAT ANY DISEASES. IT IS THE ROLE OF PHYSICIANS.
2) WE PURELY PROVIDE INFORMATION ON HOW A PRESCRIBED DRUG WORKS, DRUGS ADMINISTRATION TECHNIQUES, SIDE-EFFECTS, INTERACTION WITH OTHER DRUGS AND FOOD, COUNSEL ON DRUG PROBLEMS AND HEALTH PROBLEMS.
3) GUIDE PUBLIC REGARDING FALSE CLAIM MADE IN AN ADVERTISEMENT A DRUG OR DISEASE CURE METHOD BY DRUGS.
4) DO NOT PROVIDE ANY INFORMATION RELATED TO SURGERIES, ALLIED MEDICAL TREATMENTS. ALWAYS CONSULT THE RESPECTIVE HEALTH CARE PROVIDER.
5) WE DO NOT ASSIST IN EMERGENCY TREATMENTS.
6) WE DO NOT PROVIDE ANY INFORMATION ON POISONS OR HABITUAL DRUGS.

ALWAYS IN SERVICE TO KEEP PUBLIC INFORMED ABOUT DRUGS

Diclofenac Induced Angioedema

A 22 year old male visited the Drug Information centre with a prescription and some medications. The person visibly showed swelling over lips and right side of cheek. When the medical/medication history of the person was conducted, it was revealed that, he suffered with headache,fever and body ache from past 3 days. He visited a local doctor in a private clinic and was prescribed with Ibugesic Plus BD (Diclofenac+Paracetamol) ,Rantac150mg(Ranitidine) and multivitamins. After two hours of the first dose of these medications, patient developed the above symptoms. He wanted to know, whether any of the medications have lead to these adverse reactions. A detailed literature survey revealed the case as Diclofenac induced angioedema. It is a rare adverse reaction associated with Diclofenac (<1%). Causality assessment of this Adverse reaction as per WHO assessment scale reveals the reaction to be "**Certain**".



India, Brazil & China defend generic drugs at WTO....Amiti Sen, ET Bureau Jun 25, 2012, 01.03AM IST

FDA LABEL CHANGE (Ref: FDA medwatch issued ***December 2011***)

Captopril Tablets

BOXED WARNING

WARNING: FETAL TOXICITY (revised)

- When pregnancy is detected, discontinue Captopril as soon as possible.
- Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

List of drugs that are banned but available in India can be seen on

http://cdsco.nic.in/html/Drugsbanned.html

http://www.drugscontrol.org/ban_drugs.htm

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Critical Drug Review [Student Corner]

LINAGLIPTIN: In this review, I made a short attempt to focus on the advantages of linagliptin over other DPP4 inhibitors (saxagliptin, sitagliptin, vidagliptin etc.). Eight published **randomized clinical trials** were identified from PubMed database. Linagliptin is a new oral antihyperglycaemic drug of DPP-4 inhibitor class for type 2 diabetes mellitus. It is rapidly absorbed after oral administration, with C (max) occurring after approximately 90 minutes, and reaches steady-state concentrations within 4 days. Though it has a long terminal half-life (>100 hours), accumulation half-life is much shorter (approximately 10 hours). Clinical studies have revealed no relevant drug interactions when coadministered with other drugs commonly prescribed to patients with type 2 diabetes, including the narrow therapeutic index drugs warfarin and digoxin. In meta-analysis of Singh-Franco D et. el., concluded that linagliptin monotherapy was not more effective than metformin at reducing HbA1c or FPG. Patients who would probably benefit most are those with HbA1c <9%, already on an active agent, compliant with weight reduction strategies, and can recognize and manage hypoglycemia, fluid retention and upper respiratory tract infections. The pooled analyses of linagliptin predict its well tolerability with low risk of hypoglycemia. Pancreatitis is also a rare adverse effect observed in linagliptin clinical studies. It contrasts with other agents in its class by not requiring dosage adjustment in patients with renal or hepatic impairment. Oral doses of linagliptin 5 mg once daily have been shown to be clinically effective, well tolerated, and weight-neutral. The lack of head to head clinical data comparing the various dipeptidyl peptidase 4 inhibitors does not allow for specific recommendations if one agent is more effective or safer than another within the class.

By: Ms. Sneha Mirghe (VI yr, Pharm D)

BOOK LAUNCH

A book was launched by Hon. Dr. B Suresh during the UGC National conference on "The innovative research and developments in Pharmaceutical Sciences" 7th and 8th Jan 2012 at Poona College of Pharmacy. The book titled "**Handbook for Community Pharmacist**" was authored by Dr. A P Pawar, Vice Principal and HOD, Poona College of Pharmacy. This occasion was co-chaired by Hon. Vice Chancellor Dr. Shivajirao Kadam, Dr. K R Mahadik, Principal, Poona College of Pharmacy.

Departmental News

1. Ms Asawari Raut, Asst. Professor attended 5th international conference on "Clinical Pharmacology -Discovery, development and beyond" during 28th August 2011, Mumbai and **achieved first prize** in **oral** presentation on "Adverse Drug Reactions to Antibiotics in Medicine Inpatients"
2. Mrs. Priyanka Singh, Pharm D. (P.B), 3rd yr, attended 5th international conference on "Clinical Phamacology -Discovery, development and beyond" during 28th August 2011, Mumbai and **achieved second prize** in **poster** presentation on "Clinical Pharmacist and Clinical Physicians: A Team for rationalizing Therapy"
3. Guest Lecture on "*Introduction to Clinical Trials*", by Dr. Saji Vijayan, Research Scientist-Clinical Research, Lupin Bioresearch Centre.
4. An article written by Dr. Atmaram Pawar in "Maharashtra Times (9th & 27th April 2012)" initiated the public and drug regulatory body awareness regarding the unethical practice of sale of drugs by doctors in their clinics.