POONA COLLEGE OF PHARMACY

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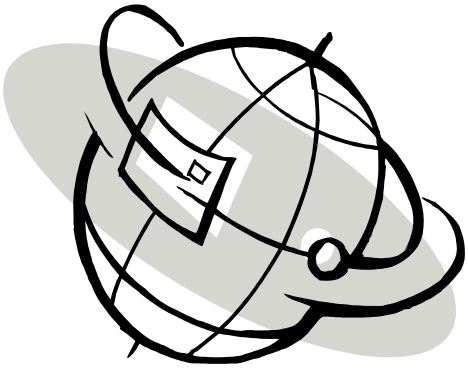
BVDU-PCP

Pharmawiz Newsletter

INSIDE THIS ISSUE:

New drug launched to treat Neutropenia

Gennova Biopharmaceuticals, a vertically integrated arm of Emcure Pharmaceuticals Ltd, has launched indigenously developed PEGEX (Pegfilgrastim) in India.



PEGEX (Pegfilgrastim) is indicated to reduce the duration of neutropenia and also the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for treatment of cancer. Neutropenia is the reduction of neutrophils, a type of white blood cells. PEGEX (Pegfilgrastim) involves just one injection per chemotherapy cycle with similar safety and efficacy profile as filgrastim.

CDSCO draft guidance for industry in reporting serious adverse events in clinical trials

As part of further streamlining the clinical trials sector in the country, the CDSCO has framed guidelines for reporting serious adverse events occurring during the time of trials. The move is intended to bring in uniformity in the process as at present different pharmaceutical companies and contract research organizations are using multiple and different formats and procedures to report serious adverse events.

"Two studies reported that selective serotonin reuptake inhibitors (SSRIs), a common class of antidepressant medication, increase the risk for congenital malformations and developmental disorders among children when taken by mothers during pregnancy."

CDSCO draft cont….

"Though most reports adhere to Appendix XI of Schedule Y, multiple formats and missing information, including improper referencing for submission of follow-up reports have lead to difficulties in segregation and further processing of these reports by the CDSCO. Hence, this guidance document has been developed to achieve uniformity and completeness of data received by this office with respect to SAE reporting in clinical trials," according to the draft.

The adverse event has been defined as any untoward medical occurrence (including a symptom/disease or an abnormal laboratory finding) during treatment with a pharmaceutical product in a patient or a human volunteer that does not necessarily have a relationship with the treatment being given.

"An adverse event that is associated with death, in-patient hospitalisation (in case the study was being conducted on out-patients), prolongation of hospitalisation (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening," the draft said.

All SAEs occurring in clinical trials should be reported as per the details provided in Appendix XI of Schedule Y (Annexure I) within the applicable timeline (14 calendar days), to, the Drugs Controller General (India). Pharmaceutical company/the sponsor/CRO (Investigator in investigator-initiated studies) is responsible for reporting SAEs within the applicable timelines, it said.

"As per the regulations (Schedule Y of Drugs & Cosmetics Rules), all Unexpected SAEs (serious adverse events) have to be reported to CDSCO within 14 calendar days. Every report (both initial as well as follow-up reports) should be submitted along with a covering letter. Unexpected SAEs have to be submitted to this office as per Schedule Y of Drugs and Cosmetics Rules, 1945. The assessment report should clearly mention whether the SAE occurred is related or not related (Situations like unlikely, possibly, suspected, doubtful etc. should not be used)," draft said.

DEPARTMENTAL ACTIVITES: Introduction of Drug Information "Helpline" service

Poona College of Pharmacy, BVDU, Pune has taken initiative in launching one of its first kind of drug information "HELPLINE" service for the common people in Pune. The objective of such service is to provide unbiased and legitimate information related to drugs prescribed by the physician to an enquirer. Information related to drug action, administration techniques, its side effects, adverse effects, drug cost and availability etc. are provided either verbally over our helpline no. **(020) 40555555 Ext.308. or through mail.(bvpcp.dic@gmail.com)Till date the following is the Drug Query provided:**

"Helpline" service cont……

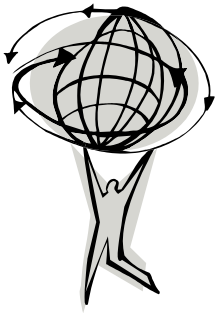
Drug Queries	Patient Counseled	Category of Drug Queries					
		Indication	ADR	Admn	Cost	Uses	P'cology
59	59	5	13	6	12	7	16

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

Topical MINOXIDIL Induced scalp itching, irritation, or burning and skin pigmentation

A mother of a 25 years old male patient enquired regarding allergic reactions. On history taking we found that patient was prescribed with Mintop 2 % solution (Minoxidil) once daily application at night on the scalp and Tablet Kover-H (Biotin, N- Acetyl Cystene, Calcium Pantothenate with Minerals) OD related to partial baldness. After 4-5 days of use the patient was affected with minor dermatitis, burning sensation surrounding the applied area. With this particular problem the patient continued applying near about one & half month that lead to blackening of skin almost around scalp & face wherever the solution reduced eyesight. She was enquiring whether any of these medicines were responsible for such problems. Upon literature survey and through various database search (Micromedex) revealed Minoxidil to be associated with such ADR's.



"Leptospirosis is a common disease that occurs during the monsoon season in the rural belt. Read more: 104 Die of Leptospirosis in the Last 2 Months in Surat | MedIndia http://www.medindia.net/news

Clinical Pharmacy Activities

Drug Information				ADR's identified and documented
Indication	**Poisoning**	**Efficacy/Safety**	**Others**	
11	1	7	11	23

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Poison Query

A Pediatric physician asked query on **Naphthalene ball poisoning.**

A 3 years old male child was admitted in pediatric ward with complaints of vomitting and belly pain with mild diarrhea. It was a case of accidental ingestion of Naphthalene balls. Weight of the patient was 17.1 kg.

Nature of Poison: In a young child, one Naphthalene moth-ball may destroy blood cells, and four may cause fits.

Content: Para-dichlorobenzene and Napthalene

Signs and Symptoms:

Naphthalene- If swallowed: Nausea, vomitting, diarrhea and belly pain, Sweating, fever, Yellow skin caused by changes in blood, Urine becomes dark and may contain blood, the patient may stop passing urine, fits, unconsciousness (In the eyes and skin), redness and irritation

Para-dichlorobenzene- If swallowed: Nausea, vomitting, diarrhoea and belly pain, In the eyes- redness and irritation, On the skin- redness and irritation

Therapy: Supportive care including oxygen and mechanical ventilation. If hemolysis evident, IV fluids should be given to reduce renal failure.

For repeated fits iv inj. Diazepam 200-300 mcg/kg of body wt. (children)

Finally, the patient was treated with IVF 0.45% DNS 1050 cc over 24 hrs with 5cc of kesol with a satisfactory prognosis.

BOOK LAUNCH

A hindi edition **"Dawayein Lete Samay"** of *Aushadhe Ghetana (Marath edition* : Gautami Prakashan Pune authored by Dr. Atmaram Pawar (Prof. & Head of Pharm.D) was launched on January 2011. This is another pride hold by the PCP faculty in authoring such a book on information of drug administration and precautions while administration was published for the community.

Departmental News

1. Department conducted a 2 day ICMR sponsored seminar on "Pharmacovigilance: Collaborative role of Industry and hospital in Patient Safety" on 29th and 30th March, 2011
2. Awareness rallies for community was conducted related to Swine Flu partnering with Pune Municipal Corporation.
3. An awareness rally on arthritis was jointly organized with Sancheti Hospital, Pune on "World Arthritis Day".
4. Mrs. Devyani Bobade,Asst. Prof, attended an International Symposium on "The Future Vision & Challenges in Pharmacy Profession" during September 18-19, 2010, Jaipur and achieved Young Scientist Award for oral presentation on A survey on Diabetes awareness in urban population of Pune city"