Drug Information Bulletin

Drug Information Centre (DIC)
Indian Pharmaceutical Association
Bengal Branch
Tele fax: 033 24612776, E-mail: ipabengal.dic@gmail.com
Web Site: http://www.ipabengal.org
Contact: 09830136291

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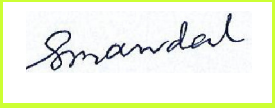
Content

Editorial

There is a misconception amongst various stake holders of health care system and the consumers that "Generic medicines" are not of good quality. There are several reasons, but some doctors had raised question of Bioavailability. During last few years the Drugs and Cosmetics Rules has amended that licensing of any product by any state Drugs Control Office require to submit data on safety, pharmacology and stability study. Formulations containing drugs belongs to BCS class II and IV require to submit Bioequivalence data like new drug. Therefore basic scientific questions have already been addressed by amending Drug Rules.

Therefore using generic drug is as safe as "Branded" and as efficacious as "Branded". Use of Generic medicines can reduce treatment cost and can help in improving access to health care. Steps taken by Central Government and several state Governments to promote generic medicines is a bold step towards improving access to health care.

However "Generic Drug" is not defined in the Drugs and Cosmetic Act and Rules, which are making the process of implementation more complex. Therefore definition of "Generic Drug" require to be inserted in the Drugs and Cosmetic Act and Rules immediately.



Dr. Subhash C. Mandal
Editor
E mail: subhash.mandaldr@gmail.com
Mob. 9830136291

Health authorities find global increase in drug-resistant HIV

Health authorities have discovered a worldwide increase in resistance to HIV drugs, according to *Nature*.

The World Health Organization surveyed randomly selected clinics in 18 countries from 2014 to 2018 to determine resistance levels among people who had started HIV treatment during that period.

They found over 10 percent of HIV-infected adults from 12 countries in Africa, Asia and the Americas had developed resistance to two drugs used against HIV, efavirenz and nevirapine. It is not considered safe to prescribe more HIV medicines above the 10 percent threshold, as doing so could further increase resistance.

Increased resistance may be due to people interrupting their treatment. More people were resistant when they restarted Efavirenz and Nevirapine after interrupting treatment, according to the WHO's report. The WHO recommends the affected countries substitute these two drugs with Dolutegravir, which is less likely to develop resistance.

Drug-resistant malaria strains increasingly common in Southeast Asia

Two recent studies in The Lancet Infectious Diseases found an increasing presence of drug-resistant malaria strains in southeast Asia. A combination of Dihydroartemisinin and Piperaquine failed to treat half of cases in four regions of Cambodia, Vietnam and Thailand that were studied.

Ref.: The Washington Post

USP new reference standard releases

Sodium Decanoyl Sarcosinate (30 mg) (Sodium N-decanoyl-N-methylglycinate)
Sodium Myristoyl Sarcosinate (30 mg) (Sodium N-methyl-N-tetradecanoylglycinate)
Benzalkonium Chloride (5 mL of approx. 4% aqueous solution)
Polyoxyl 9 Lauryl Ether (1 g) (Polyethylene glycol monolauryl ether (n=9))
Neodiosmin (30 mg) (5-Hydroxy-2-(3-hydroxy-4-methoxyphenyl)-4-oxo-4H-chromen-7-yl 2-O-(alpha-L-rhamnopyranosyl)-beta-Dglucopyranoside)
Polypropylene Glycol 11 Stearyl Ether (500 mg)
Star Anise Oil (500 mg)
Alginic Acid (100 mg)
Potassium Alginate (100 mg)
Sodium Alginate (100 mg)
Hydroxyethyl Cellulose (60 mg)
Low-substituted Carboxymethylcellulose Sodium (100 mg)

NPPA revises PMRU Scheme; Rechristens as CAPPM Scheme

In view of the changing scenario in the pharma sector and the recommendations of various committees including the Parliamentary Standing Committee, the National Pharmaceutical Pricing Authority (NPPA) has revised its Price Monitoring and Resource Units (PMRUs) scheme and has rechristened it as Consumer Awareness, Publicity and Price Monitoring (CAPPM) scheme. The PMRU scheme was started by the NPPA to monitor the prices of drugs.

The revised scheme will be implemented at the central level by the NPPA and at the State level by the registered societies of PMRUs.

The scheme will have two components viz., National component and State component. The national component covers the expenditure for publicity through print and electronic media, organizing seminars for consumer awareness, purchase of samples etc. Under the State Component of the Scheme, it is planned to set up PMRUs in the States. PMRU is a registered society under the Chairmanship of the State Drug Controller. The representatives of NPPA/State Health Department, civil societies and other stakeholders are members of the PMRU. PMRUs will be key collaborating partners of NPPA with information gathering mechanism at the grassroots level. PMRUs will also ensure that the benefits of the DPCO (revised from time to time) trickle down at the grassroots level.

The main objectives of the scheme are to disseminate message to the consumers and general public about ceiling prices of scheduled medicines notified by the government; permissible price increase for scheduled and non-

scheduled medicines; availability of medicines at reasonable prices and promotion of generic medicines; precautions to be taken while purchasing medicines from chemists/retailers such as checking the MRP (which includes all taxes), manufacturing and expiry dates, price list of medicines, obtaining bill for the medicines bought, etc; requirement for prescription of medicines by their generic names also; price control and monitoring and enforcement activities of NPPA; ad lodging complaints to NPPA for any violation including violation of DPCO, 2013 as well as unethical practices in the pharma sector.

The scheme is expected to create general awareness about the availability of medicines, prices of medicines, ceiling prices of medicines fixed by the government, precaution to be taken while purchasing medicines and about the functioning of NPPA. This will improve the accessibility of quality medicines at a reasonable price to the common people of the country and facilitate both clinically effective and cost effective treatment.

Source: Pharmabiz

Bombay High Court strikes down plea against online drug sales

The Bombay high court has struck down a public interest litigation (PIL) challenging online sale of medicines. The PIL was filed against the Union government and e-pharmacies. The HC noted that guidelines to regulate such entities would be announced soon and, hence, they would "comply with substantive laws".

The petition had said certain categories of drugs (schedules H and X) cannot be sold without a prescription, that is, only through physical stores. In other words, the case challenged e-pharmacies where these critical medicines can be ordered online even without prescription in certain towns and cities. (Schedule H drugs include key antibiotics, and schedule X drugs are related to opioid and psychotropic substances — both categories cannot be sold without the prescription of a registered medical practitioner).

This comes after a similar petition against e-pharmacies was withdrawn in the Calcutta high court in March, while the Patna high court in July questioned the government on delay in finalising guidelines for e-pharma companies. The deadline for amendments to the Drugs and Cosmetics Rules, 1945, which would regulate e-pharmacies, was July 31. With the government yet to notify the guidelines, e-pharma companies continue to face an uncertain regulatory climate, and mounting court cases.

In its reply, the government said the final notification on e-pharmacies is likely to be issued within four months. Retail trade channels under All-India Organization of Chemists and Druggists have been opposing e-pharmacies because of discounting as a standard practice by online players. On an average, most e-pharmacies offer a 15-20% discount on each order, while there is no such fixed practice among chemists and stockists, or they may offer up to 10% off on orders of a certain amount.

The order, a copy of which is available with TOI, says, "Purpose of PIL is served when omission in the existing law resulting in possibility of harm to the public, or large scale violation of existing laws, is brought to the notice of a court and based thereon the competent authority takes cognizance of the omission, and proceeds to take action to rectify the omission. At that stage, the public interest litigation has to be terminated."

"The fact that online sale of pharmaceuticals drugs is taking place has been noticed by the ministry of health and family welfare, which has proposed to amend the Drugs and Cosmetics Rules, 1945 by inserting Part VIB in the rules defining epharmacy portals and providing for registration of the same. The draft rules were promulgated on August 28, inviting objections and suggestions. We have perused the draft rules and note that an attempt is being made to ensure that epharmacy portals comply with substantive laws", the order adds. A Madras high court had last year stayed the ban on online sale of medicines, while another case in Delhi high court sought contempt action against the government for allegedly not taking any action against defaulting e-pharmacies.

Source: The Times of India

Hydrochlorothiazide Risk of non-melanoma skin cancer

Medsafe has announced it is working with sponsors of hydrochlorothiazide-containing products to update the product information to include information about the risk of non-melanoma skin cancer. Hydrochlorothiazide is used in combination with cilazapril, quinapril, losartan or amiloride, to treat high blood pressure and build-up of excess fluid in the body (oedema). While the mechanism is unknown, hydrochlorothiazide has skin photosensitizing effects. Patients who are at higher risk of developing nonmelanoma skin cancer (e.g. personal or family history of skin cancer) should take protective measures in any case. Also, health-care professionals should encourage patients taking a hydrochlorothiazide preparation to check their skin and lips regularly and report any changes or new skin lesions or moles.

Reference: Safety Communications, Medsafe, 15 April 2019 (www.medsafe.govt.nz/) (See WHO Pharmaceuticals Newsletter No.2, 2019: Potential risk of non-melanoma skin cancer (NMSC) in Canada and Singapore; No.1, 2019: Risk of nonmelanoma skin cancer in Egypt; No.6, 2018: Risk of non-melanoma skin cancer in UK)

Opioid pain medicines risk of uncontrolled pain and withdrawal symptoms following sudden discontinuation

The US Food and Drug Administration (FDA) has required changes to the prescribing information for opioid pain medicines to warn of serious withdrawal symptoms, uncontrolled pain, psychological distress and suicide following sudden discontinuation or a rapid decrease in dose. Opioids are used to manage pain when other analgesic treatments cannot be taken or are not able to provide enough pain relief. Common opioids include codeine, fentanyl, hydrocodone, morphine and oxycodone. Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin and other substances. Health-care professionals should not abruptly discontinue opioids in a patient who is physically dependent. When health-care professionals and their patients have agreed to taper the dose of an opioid analgesic, a variety of factors should be considered which include: the dose of the drug, the duration of treatment, the type of pain, and the physical and psychological attributes of the patient. There are no standard opioid tapering schedules that are suitable for all patients. A patient-specific plan should be created to gradually taper the dose of the opioid and patients should be monitored and supported to prevent serious withdrawal symptoms, worsening of pain or psychological distress.

Reference: Safety Alerts for Human Medical Products, US FDA, 9 April 2019 (www.fda.gov)