Drug Information Bulletin

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Regulatory Affairs Division (RAD), IPA

Pharmacists Day 25th September

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Content

Editorial

Pharmacists of India are going to celebrate 5th Pharmacist Day tomorrow with great enthusiasm. Pharmacy Council of India has decided that they will celebrate this day as Pharmacists Day in India every year and requested all State Pharmacy Councils, Pharmacy Institutions and professional organizations to celebrate the occasion since 2013.

*Like previous years Indian Pharmaceutical Association is going to celebrate this event throughout the country on 25th September to project the role of Pharmacist in the healthcare system with a theme **"Research to Healthcare: Your Pharmacist is at your Service".** Hope this celebration will make some social impact regarding the important role played by the Pharmacist in the healthcare system.*

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Safety News:

Finasteride Rare reports of depression and suicidal thoughts

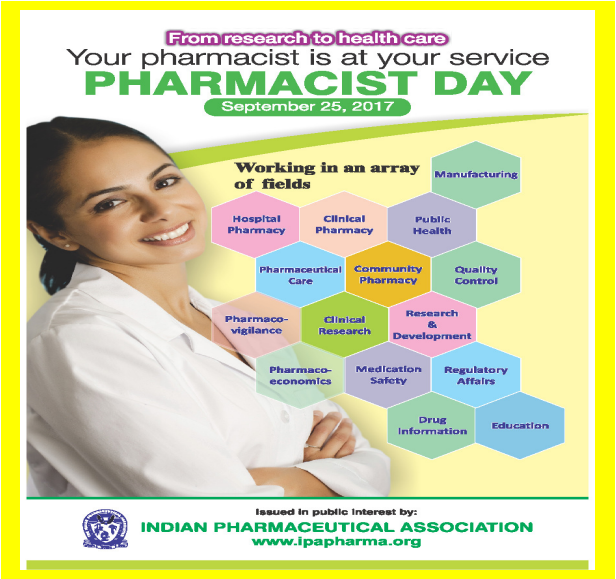
The MHRA has stated that depression and, in rare cases, suicidal thoughts in men taking finasteride (Propecia® and Proscar®) have been reported. Finasteride at a dose of 5mg is used to treat and control benign prostatic hyperplasia, whilst at a dose of 1mg it is used for treatment of androgenic alopecia. Some men have reported episodes of depressive illness and suicidal thoughts in association with the use of finasteride for male pattern hair loss. Depression and suicidal thoughts have been reported in men with and without a previous history of depression. Depressed mood has been previously recognised with finasteride. A recent review of the evidence has su ggested more significant depression can occur. The MHRA advises health-care professionals to tell patients to stop taking finasteride immediately if they develop depression and to inform a health-care professional

Reference: Drug Safety Update, MHRA, Volume 10, issue 10:1, 24 May 2017 (www.gov.uk/mhra) (See WHO Pharmaceuticals Newsletter No.1, 2016: Risk of suicidal thoughts and behaviour in Canada)

Nivolumab and pembrolizumab Reports of organ transplant rejection

The MHRA has advised health-care professionals to consider the benefit of treatment with nivolumab or pembrolizumab versus the risk of possible organ transplant rejection for individual patients. Nivolumab (Opdivo®) and pembrolizumab (Keytruda®) are indicated for the treatment of various cancers including: malignant melanoma, nonsmall-cell lung cancer, and relapsed or refractory classical Hodgkin's lymphoma. A European review of global data concluded that nivolumab and pembrolizumab may increase the risk of rejection in organ transplant recipients. The review assessed all cases received up to November 2016 and identified nine patients who had a transplant rejection after receiving nivolumab and pembrolizumab. Of the five patients receiving nivolumab, three had kidney transplant rejection, one had corneal transplant rejection, and one had skin graft rejection. Four patients receiving pembrolizumab had kidney transplant rejection.

Reference: Drug Safety Update, MHRA, Volume 10, issue 12:3, 20 July 2017 (www.gov.uk/mhra)



Tramadol Breastfeeding whilst taking tramadol is not recommended

The Medicines and Medical Devices Safety Authority (Medsafe) has stated that breastfeeding while taking tramadol is not recommended. Small amounts of tramadol are found in breast milk and the effect of this on infants and new-borns is not fully known. Tramadol is used for moderate to severe pain in adults and children from the age of two years. In New Zealand, the Medicines Adverse Reactions Committee (MARC) reviewed the use of tramadol in children in June 2016. Although very small amounts of tramadol and its active metabolite are found in breast milk, its safety in new-borns and infants has not been studied. There is a theoretical risk of breathing problems in the baby due to the opioid effects of tramadol. The Centre for Adverse Reactions Monitoring (CARM) has received one case report in a one-month-old where exposure to tramadol via breast milk was suspected to have caused a red rash. The baby was reported to have recovered and the rash was not considered severe or serious.

Reference: Safety Information, Medsafe, 7 July 2017 (www.medsafe.govt.nz/) (See WHO Pharmaceuticals Newsletters No.3, No.2 and

No.1, 2017, No.6 and No.1 in 2016, No.6, No.5, No.4 and No.3 in 2015, No.5 and No.4 in 2013, and No.5 in 2012 for related information)

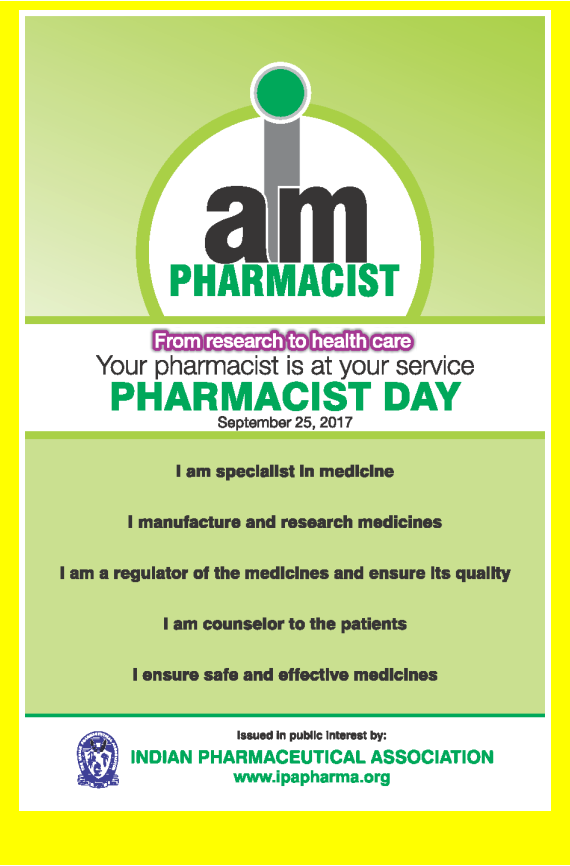
Regulatory Issues:

Sulfasalazine Risk of Stevens Johnson Syndrome and toxic epidermal necrolysis

The Pharmacovigilance Program of India, Indian Pharmacopeia Commission (PvPI, IPC) has made recommendations to the Central Drugs Standard Control Organisation (CDSCO) about revising the drug safety label for sulfasalazine to include Stevens-Johnson syndrome and toxic epidermal necrolysis as potential adverse drug reactions. Sulfasalazine is indicated for the treatment of severe rheumatoid arthritis, ulcerative colitis and Crohn's disease. Between 2011 and 2017, PvPI received 15 reports of Stevens Johnson syndrome and seven reports of toxic epidermal necrolysis with sulfasalazine use. The cases were reviewed by Signal Review Panel (SRP)- PvPI, IPC who concluded that there was a strong causal relationship between sulfa salazine and StevensJohnson syndrome and toxic epidermal necrolysis.

Reference: Based on the communication from IPC, NCC-PvPI, India, July 2017 (www.ipc.gov.in)

Ref. **The Economic Times (India)**



Compulsory license for Gilead's hepatitis C drug issued by Malaysia

A compulsory license was issued by the Malaysian government for generic versions of Gilead's Sovaldi, or sofosbuvir, as a treatment for patients with hepatitis C. The license will increase access to and offer a less-expensive version of generic hepatitis C drugs.

For details. http://www.raps.org/Regulatory-Focus/News/2017/09/15/28484/Malaysia-Issues-Compulsory-License-for-Gilead-Hepatitis-C-Drug/

Australia TGA tightens GMP clearance application rules

Australia's Therapeutic Goods Administration revised its policy on compliance verification applications, tightening rules on when supporting evidence may be submitted. After Sept. 26, incomplete applications will be evaluated without allowing applicants to add missing data, and if applicants fail to deliver requested information during the assessment phase by the TBA-stated deadline, the assessment will proceed without it.

Ref. Regulatory Focus

Drug-price notification bill approved by California assembly

The California State Assembly approved a bill already passed by the state Senate that would require drug makers to notify payers at least 60 days before raising prices in excess of 16% over two years and explain the reason for the price hike.

Ref. San Jose Mercury News (Calif.)

Drugmakers exploit regulatory loopholes to protect patents

Regulatory loopholes allow branded-drug makers to prevent competition, costing consumers billions of dollars each year, writes antitrust attorney David Balto, former policy director at the Federal Trade Commission. Drugmakers abuse the FDA's Risk Evaluation and Mitigation Strategy program, citizen petitions and the Hatch-Waxman Act, and product-hopping is used to prevent the substitution of lower-cost alternatives, Balto writes.

Ref. The Hill

Specialty-drug prices continue rising

Retail prices for some of the most commonly prescribed specialty drugs rose by 9.6% from 2014

to 2015, while prices for branded drugs rose 15%, and generic-drug prices dropped by 19.4%, according to an AARP analysis of data from Truven Health Research Databases. The average annual cost of specialty drugs studied was $52,486, compared with $5,800 for traditional drugs and $523 for generics, the report showed.
Ref. MedPage Today (free registration)

Research & Development:

WHO urges greater effort on antibiotic development

The WHO in a new report says not enough antibacterial drugs are under development to meet the threat of drug-resistant infections, noting that only eight of 51 in development can be termed novel treatments. "There is an urgent need for more investment in research and development for antibiotic-resistant infections including TB," said WHO Director-General Tedros Adhanom Ghebreyesus, who added that if the need isn't met, "we will be forced back to a time when people feared common infections and risked their lives from minor surgery."
Ref. The Economic Times (India)

UK firms plan cancer antibody conjugate development

UK drugmakers IONTAS and Glythera are collaborating on the development of antibody drug conjugates to treat difficult cancers. The technology enables monoclonal antibodies to deliver treatment inside targeted cells, improving efficacy while sparing healthy tissue.
Ref. PharmaTimes (U.K.)

Australia tackles childhood cancer

Australia is launching a nationwide effort called the Zero Childhood Cancer initiative to diagnose and offer personalized treatment of childhood cancers. A clinical trial is projected to enroll more than 400 children in the next three years as physicians and scientists collaborate on research and treatment.
Ref. BioSpectrum Asia

Japan & India expand biotech cooperation

Japan and India signed a memorandum of understanding to expand biotechnology research underway at Japan-based DAILAB, a collaboration of India's Department of Biotechnology and Japan's National Institute of Advanced Science and Technology. Joint research, training and networking levels will be boosted under the expanded DAICENTER, which will be created under the new agreement.
Ref. BioSpectrum Asia

Discovery could improve efficacy of malaria vaccines

A study by researchers from the Walter and Eliza Hall Institute in Australia showed that carbohydrate tags on proteins that allow the malaria parasite Plasmodium falciparum to infect mosquitoes and humans play a key role in that process. Accounting for those tags in vaccine development could improve efficacy, according to findings published in the journal Nature Communications.
Ref. Genetic Engineering & Biotechnology News