Drug Information Bulletin

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Editorial

Since enactment of Pharmacy act in 1948 In India one pharmacist require to be engaged in a community Pharmacy or Hospital Pharmacy and should not be engaged in two different institute at a time as this is a full time job. Further amendment of section 42 of Pharmacy Act in the year of 1981 effective from 1984 strongly established the fact. No person other than a "registered pharmacist" shall compound, prepare, mix or dispense any medicine on the prescription of a medical practitioner as per section 42 of The Pharmacy Act 1948, which states-"Dispensing by unregistered persons:- (1) On or after such date as the State Government may by notification in the Official Gazette appoint in this behalf, no person other than a "registered pharmacist" shall compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner. and it was further bolstered by the amendment of Rule 65 of Drugs and Cosmetics Rules 1945 in the same year.

Thereafter Pharmacy Council of India has taken two more steps to ensure Pharmaceutical Care in the country by Notification of –Notification No. 14-163/2010-PCI dtd. 11.09.2014 stated- A teacher working at more than one place simultaneously shall render himself liable to disciplinary action in the following manner : "……3.X. A report will be sent to the Central/State Drugs Control Deptt. for taking action under the Drugs & Cosmetics Act, 1940 if he is working in a pharmaceutical industry/sales or any other department of a pharmacy institution and industry. …….(d) In all such cases, the matter will be taken up with the State Pharmacy Council for taking action under Section 36 of the Pharmacy Act,1948 for deletion of his name from the State Pharmacy Register. The next notification No. 14-148/2012-PCI dtd. 15.01.2015 stated- Sec. 13 (e) of the Chapter 8 of the said act stated –"The following acts of commission or omission on the part of a registered pharmacist shall constitute professional misconduct rendering him/her liable for disciplinary action" …….e. Giving his pharmacist registration certificate at more than one pharmacies. Upon receipt of any complaint of professional misconduct, the Pharmacy Council of India/concerned State Pharmacy Council would hold an enquiry and give opportunity to the registered pharmacist to be heard in person or by pleader. If the registered pharmacist is found to be guilty of committing professional misconduct, the Pharmacy Council of India/concerned State Pharmacy Council may award such punishment as deemed necessary or may direct the removal altogether or for a specified period, from the register of the name of the delinquent registered practitioner. Deletion from the Register shall be widely publicized in local press as well as in the publications of different Pharmacy Associations/ Societies/Bodies.

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New Drug: Mirabegron Prolonged Release Tablet 25 mg /50 mg

It was approved by USFDA in the year of 2012 with a brand name "MYRBETRIQTM"

HIGHLIGHTS OF PRESCRIBING INFORMATION as per USFDA:

INDICATIONS AND USAGE: Myrbetriq is a beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency (1)

DOSAGE AND ADMINISTRATION: • Recommended starting dose is 25 mg once daily, with or without food (2.1) 25 mg is effective within 8 weeks. Based on individual efficacy and• tolerability, may increase dose to 50 mg once daily (2.1, 14) Swallow whole with water, do not chew, divide or crush (2.1) • Patients with Severe Renal Impairment or Patients with Moderate Hepatic Impairment: Maximum dose is 25 mg once daily (2.2, 8.6, 8.7, 12.3) • Patients with End Stage Renal Disease (ESRD) or Patients with Severe Hepatic Impairment: Not recommended (2.2, 8.6, 8.7, 12.3)

DOSAGE FORMS AND STRENGTHS: Extended-release tablets: 25 mg and 50 mg (3)

CONTRAINDICATIONS: None (4)

WARNINGS AND PRECAUTIONS: • Increases in Blood Pressure: Myrbetriq can increase blood pressure. Periodic blood pressure determinations are recommended, especially in hypertensive patients. Myrbetriq is not recommended for use in severe uncontrolled hypertensive patients (5.1). • Urinary Retention in Patients With Bladder Outlet Obstruction and in Patients Taking Antimuscarinic Drugs for Overactive Bladder: Administer with caution in these patients because of risk of urinary retention (5.2). • Patients Taking Drugs Metabolized by CYP2D6: Myrbetriq is a moderate inhibitor of CYP2D6. Appropriate monitoring is recommended and dose adjustment may be necessary for narrow therapeutic index CYP2D6 substrates (5.3, 7.1, 12.3)

ADVERSE REACTIONS: Most commonly reported adverse reactions (> 2% and > placebo) were hypertension, nasopharyngitis, urinary tract infection and headache (6.1) To report SUSPECTED ADVERSE REACTIONS, contact Astellas Pharma US, Inc. at 1-800-727-7003 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch -

DRUG INTERACTIONS: • Drugs Metabolized by CYP2D6 (e.g. Metoprolol and Desipramine): Mirabegron is CYP2D6 inhibitor and when used concomitantly with drugs metabolized by CYP2D6, especially narrow therapeutic index drugs, appropriate monitoring and possible dose adjustment of those drugs may be necessary (5.3, 7.1, 12.3). • Digoxin: When initiating a combination of Myrbetriq and digoxin, prescribe the lowest dose of digoxin; monitor serum digoxin concentrations to titrate digoxin dose to desired clinical effect (7.2, 12.3).

USE IN SPECIFIC POPULATIONS: Pregnancy: Use only if the benefit to the mother outweighs the potential• risk to the fetus (8.1) Nursing mothers: Myrbetriq is predicted to be excreted in human milk• and is not recommended for use by nursing mothers (8.3) Pediatric use: The safety and effectiveness of Myrbetriq in pediatric• patients have not been established (8.4) Geriatric use: No dose adjustment is recommended for elderly patients• (8.5)

For details:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202611s000lbl.pdf

Status in India: Mirabegron Prolonged Release Tablet 25 mg /50 mg & Bulk approved by the CDSCO for Symptomatic treatment of urgency, increased micturition frequency and / or urgency incontinence as may occur in patients with over active bladder (OAB) Syndrome on 18.08.2017.

Antibiotic-resistant superbug threatens Vietnam's malaria eradication efforts

An artemisinin-resistant superbug was reported in five provinces of Vietnam and poses a serious health threat to the Vietnamese people, according to a letter from Thailand researchers published in the journal Lancet Infectious Diseases. The superbug also threatens to undermine Vietnam's malaria control and eradication efforts aimed at stamping out malaria in the country by 2030.

Ref. The Washington Times/The Associated Press

Pharmacovigilance Programme (PvPI) released Pharmacovigilance Guidance documents for MAH

Recently PvPI along with CDSCO published Pharmacovigilance Guidance Document for Marketing Authorization Holders of Pharmaceutical Products which was released by the Health Secretary, Govt. of India, which will be effective from 01.01.2018. This will help the MAH to comply Post Marketing Survilance, which was made mandatory vide GSR 22(E) dtd. 08.03.2016.
For details:
http://www.ipc.gov.in/PvPI/pub/Guidance%20Document%20for%20Marketing%20Authorization%20Holders.pdf
Ref. Indian Pharmacopoeia

Secretary, Dept. of Health & Family Welfare, Govt. of India releasing several documents including Pharmacovigilance Guidance documents for MAH

Indian Pharmacopoeia Commission (IPC) released a catalogue of Reference Substances

Recently IPC released a catalogue including 600 reference standards, 100 impurity standards and 23 Phytochemical Reference Standards. IPC is the authorized source of reference standard of India. For procurement of the same contact-
Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Govt. of India, Reference Standard Division, Sector-23, Rajnagar, Gaziabad-201002, Fax: 91(0120) 2783311, E Mail: ipcalab@vsnl.net

USFDA advises on orphan drug submissions

The challenges of orphan drug development require different clinical trial approaches, such as crossover studies and randomized withdrawal studies, officials of the FDA's Center for Drug Evaluation and Research said. They also stressed the importance of natural history studies and other preclinical preparation.
Ref. Regulatory Focus

Mylan's generic MS drug gains USFDA nod

The FDA approved Mylan's generic multiple sclerosis drug Glatiramer acetate in two doses: 40 mg/mL for 3-times-a-week injection; and 20 mg/mL for once-daily injection. The generic of Teva's Copaxone is intended for relapsing forms of the condition.
Ref. Reuters

Guidance documents for medical device makers released by USFDA

Seven new or updated documents were released by the FDA to provide medical device makers with guidance on its user fee programs and how the performance goals set by MDUFA IV are affected by FDA and industry actions. A guidance on the presubmission program for medical devices was also updated by the agency to include changes in meeting scheduling and timing of providing feedback to companies.
Ref. Regulatory Focus

USFDA unveils drug-safety database

The FDA's new Adverse Event Reporting System portal enables searches of the web-based database and allows users to categorize information by drug, patient age, nature of adverse event and other criteria. The FDA hopes that increased transparency will encourage more thorough data submissions from health care professionals and other stakeholders.
Ref. Rare Disease Report

USFDA issues combination-product guidance

The FDA on Tuesday issued its final guidance on the classification of combination products including drugs, biologics and medical devices. It includes a revised definition of chemical action in the definition of a medical device, a new question-and-answer section and examples of products that do or do not achieve their intended result through chemical action.
REF. Regulatory Focus

EU docs' panel rejects use of bioresorbable stents

Last month, the National Pharmaceutical Pricing Authority in India had allowed the immediate withdrawal of Absorb, the bioresorbable stent being sold by Abbott, taking note of the safety concerns. In July, Boston Scientific terminated its Renuvia bioresorbable stent program.

Bioresorbable cardiac stents, which many top cardiologists in India lobbied to keep out of price capping in the name of technological advance, have been ruled out for clinical use by a task force of European cardiologists. They have warned against the use of such stents in place of drug eluting stents as long as concerns remain about the increased risk of heart attack and stent-linked blockage seen with bioresorbable stents. Last month, the National Pharmaceutical Pricing Authority in India had allowed the immediate withdrawal of Absorb, the bioresorbable stent being sold by Abbott, taking note of the safety concerns.

Ref.

https://health.economictimes.indiatimes.com

Loperamide (high dose) Risk of serious cardiac adverse events

The National Pharmaceutical Regulatory Agency (NPRA) has updated the package inserts for all products containing loperamide with warnings and safety information related to the risk of serious cardiac adverse events with high doses. Loperamide is an antidiarrhoeal medicine. Between 2000 to December 2016, the NPRA has received 14 reports containing a total of 29 adverse events suspected to be related to loperamide use in Malaysia. More than half the adverse events (15 events, 52%) were related to skin disorders such as rash and pruritus. Other adverse events reported were anaphylaxis, shortness of breath, dizziness, dysaesthesia, face and mouth oedema, nausea, oculogyric crisriskis, stomatitis, and throat tightness. To date, the NPRA has not received any reports of cardiac adverse events related to loperamide use. A search of the WHO global database of Individual Case Safety Reports (ICSRs), VigiBase, identified 7 431 individual case safety reports involving loperamide since year 1977. A total of 328 reports involved cardiac disorders such as ventricular tachycardia (60 reports), cardiac arrest (50), and torsades de pointes (46). The NPRA has issued advice to health-care professionals, alerting them to potential risks of cardiac events, susceptible individuals, drug interactions, and management of suspected cardiotoxicity with loperamide use.

Reference: Reaksi Drug Safety News, NPRA, No. 35, July 2017 (See WHO Pharmaceuticals Newsletter No.4, 2016: Serious heart problems with high doses in the US)

Inauguration of Guahati Local Branch & IPASF Chapter of Assam on 13.10.2017