Drug Information Bulletin

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Editorial

Greetings from Drug Information Bulletin!

In order to promote generic drugs and to improve access to medicines Govt. of India launched a programme- Pradhan Mantri Janaushadhi Pariyojana (PMBJP) since 2008. This programme is now quiet effective as 10,000 Jan Aushadhi Kendras across the country have led to savings of around Rs 7,416 crores for the citizens in the current financial year.

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. Now 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". Moreover 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" requires to be inserted in the Drugs and Cosmetic Act and Rules immediately.

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New Drug: Relugolix tablets for oral use

Initial U.S. Approval: 2020

INDICATIONS AND USAGE: Relugolix (ORGOVYX) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer

DOSAGE AND ADMINISTRATION: • Recommended Dosage: A loading dose of 360 mg on the first day of treatment followed by 120 mg taken orally once daily, at approximately the same time each day. • ORGOVYX can be taken with or without food. Instruct patients to swallow tablets whole and not to crush or chew tablets

DOSAGE FORMS AND STRENGTHS: • Tablets: 120 mg

CONTRAINDICATIONS: • None

WARNINGS AND PRECAUTIONS: • QT/QTc Interval Prolongation: Androgen deprivation therapy may prolong the QT interval. • Embryo-Fetal Toxicity: ORGOVYX can cause fetal harm. Advise males with female partners of reproductive potential to use effective contraception

ADVERSE REACTIONS: The most common adverse reactions (≥ 10%) and laboratory abnormalities (≥ 15%) were hot flush, glucose increased, triglycerides increased, musculoskeletal pain, hemoglobin decreased, alanine aminotransferase (ALT) increased, fatigue, aspartate aminotransferase (AST) increased, constipation, and diarrhea.

DRUG INTERACTIONS: P-gp Inhibitors: Avoid co-administration.

Ref. USFDA

Status in India: Relugolix Bulk Drug and Relugolix Tablet 120mg approved for the treatment of adult patients with advance prostate cancer on 16.10.2023. 30 Relugolix 120 mg tables are available at about Rs. 670.

Jan Aushadhi Scheme Led to Savings of Rs 7,416 Crore for Citizens This Fiscal year: Reported by Minister of State for Chemicals and Fertilizers

Recently the Minister of State for Chemicals and Fertilisers informed that over 10,000 Jan Aushadhi Kendras across the country have led to savings of around Rs 7,416 crore for the citizens this financial year. In a written reply in the Upper House he said an unprecedented 150 times growth in annual sales has been witnessed by the scheme in the last 9 years.

"During the financial year 2022-23, Pharmaceuticals & Medical Devices Bureau of India has sold Jan Aushadhi medicines worth Rs 1,236 crore, with approx 40% growth from the previous year and this has led to savings of approximately Rs 7,416 crore to the citizens," he noted. The projected sales target for 2023-24 is Rs 1,400 crore and the scheme is growing at a very fast pace garnering public trust and confidence, Khuba said. In all, during the past nine years, total savings have been estimated at more than Rs 23,000 crore for the citizens under this scheme, he stated.

On an average 10-12 lakh people visit Jan Aushadhi Kendras daily, the minister said. Khuba stated that as on November 30 this year, 10,006 Pradhan Mantri Bhartiya Janaushadhi Kendras have been opened covering 753 districts across the country. Replying to a separate question, Khuba said India's total import of active pharmaceutical ingredients for 2022-23 is worth Rs 36,229.15 crore and the quantity is 4,02,111.18 metric tonnes.

Source: PTI

Updated WHO Screening Guidelines Could Drastically Reduce Cervical Cancer Deaths in LIMCs

As per the findings of two new studies, cervical cancer death rates in low-to-middle-income countries (LIMCs) could be slashed by over 63% with the adoption of the updated World Health Organization (WHO) screening guidelines.

The findings published in two landmark papers in *Nature Medicine* focused on the efficacy of screening for human papillomavirus (HPV) in the general population across 78 countries and various screening scenarios for women with human immunodeficiency virus (HIV).

In 2021, the WHO recommended an HPV DNA-based test as the preferred method, replacing visual inspection with acetic acid (VIA) or cytology (commonly known as a Pap smear). HPV-DNA testing, which identifies high-risk strains of HPV, offers an objective diagnostic approach, eliminating the potential for result interpretation.

Dr. Kate Simms, lead author of the first study, emphasized the significance of the shift from Pap tests to HPV screening in LIMCs, where the majority of cervical cancer cases occur. The study revealed that primary HPV screening, when offered every five years, was the most clinically effective and cost-effective method, reducing mortality by an impressive 63-67%.

Dr. Michaelia Hall, lead author of the second study, highlighted the increased risk of cervical cancer among women with HIV, especially in low-to-middle-income countries. Focusing on Tanzania, where co-existing HIV and HPV infections are prevalent, the study modeled different scenarios. It found that primary HPV testing with triage, compared to no screening, could lead to a remarkable 71% reduction in cervical cancer mortality.
Source:
https://www.daijiworld.com/news/newsDisplay?newsID=1149299

Azithromycin Risk of fatal heart rhythms

The Medicines Control Authority of Zimbabwe (MCAZ) has alerted health-care professionals on the risk of fatal heart rhythms with azithromycin. Azithromycin is a macrolide antibiotic and is indicated for the treatment of various infectious diseases. The product information contains information on the risks of QT interval prolongation and torsades de pointes as well as the results of a clinical QT study which showed that azithromycin can prolong the QTc interval. Health-care professionals should consider the risk of fatal heart rhythms with azithromycin when considering treatment options for patients who are already at risk of cardiovascular events. Alternative medicines in the macrolide class, or nonmacrolides such as fluoroquinolones, also have the potential risks of QT prolongation or other significant adverse events that should be considered.

Reference: Medicine Information Bulletin, MCAZ, April 2023 (link to the source within www.mcaz.co.zw)

Febuxostat -Updated advice for treatment of patients with a history of major cardiovascular disease

The Medicines and Healthcare Products Regulatory Agency (MHRA) has updated the advice in the product information of febuxostat so that febuxostat is used cautiously in patients with pre-existing major cardiovascular diseases, particularly in those with evidence of high urate crystal and tophi burden or those initiating urate-lowering therapy. Prescribing clinicians should titrate febuxostat appropriately to minimize gout flares following initiation. Febuxostat is indicated for the treatment of chronic hyperuricaemia (gout) and the prevention and treatment of hyperuricaemia in patients undergoing chemotherapy. In 2019, the MHRA advised health-care professionals to avoid febuxostat treatment in chronic hyperuricaemia patients with pre-existing major cardiovascular diseases, unless no other therapy options were appropriate, based on the risk identified from the CARES study (Cardiovascular safety of febuxostat and allopurinol in participants with gout and cardiovascular comorbidities). Additionally, MHRA has reviewed the results from a further trial on the cardiovascular safety of febuxostat, the FAST study (Long-term cardiovascular safety of febuxostat compared with allopurinol in patients with gout), which concluded that febuxostat was non-inferior to allopurinol therapy with respect to the primary cardiovascular endpoint, and, unlike the CARES study results, that longterm use was not associated with an increased risk of death or cardiovascular death compared to allopurinol. Based on the review, the product information retains the warning for cardiovascular disorders and now advises that treatment of patients with preexisting major cardiovascular diseases with febuxostat should be exercised cautiously.
Reference: Drug Safety Update, MHRA, 25 May 2023 (link to the source within www.gov.uk/mhra) (See also WHO Pharmaceuticals Newsletter No.5, 2019: Febuxostat and Increased risk of cardiovascular death and all-cause mortality in Ireland)

Tramadol Risks of sleep-related breathing disorders, adrenal insufficiency and serotonin syndrome

The Health Products Regulatory Authority (HPRA) has announced that the product information for tramadol has been updated to include the risks of sleeprelated breathing disorders and adrenal insufficiency, as well as an update to the information on serotonin syndrome. Tramadol is a centrally acting synthetic opioid analgesic indicated for the treatment of moderate to severe pain. Following a review of available data, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommended updates to warnings and precautions as follows: • Tramadol can cause sleeprelated breathing disorders including central sleep apnoea (CSA) and sleeprelated hypoxemia. The risk of CSA increases in a dose- dependent fashion. • Tramadol may occasionally cause reversible adrenal insufficiency, requiring monitoring and glucocorticoid replacement therapy. • Serotonin syndrome has been reported in patients receiving tramadol alone or in combination with other serotonergic agents.

Reference: Drug Safety Newsletter, HPRA, 9 June 2023 (link to the source within www.hpra.ie)

Vaccination Training Programme during 4-8 Dec 2023 at Bangalore

55th Foundation Day Celebration of IPA, Bihar Branch at Patna on 10th Dec. 2023

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