



MEDICINE INFORMATION NEWSLETTER

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Editors' Desk

The Government of India (GOI) has recently released the draft of "Charter of Patients' Rights" inviting suggestions and feedback. It is a welcome move intended for empowering the patients. The draft has a missing point: it does not have provision for Right to Know about Medicines. Knowledge about medicines helps the patients to improve adherence, promote safe and effective use of medicines besides keeping them properly at home. The medicines are the most important component of healthcare delivery system after the trained health care professionals. The GOI should consider incorporating this provision in item 16 of the draft notification "Right to Patient Education".

In another good move, the GOI has banned 328 Fixed Dose Combinations, though temporarily the marketing companies are permitted to sell the products till the stock is exhausted. Our regulation treats FDCs as new drugs and the company needs to show evidence of safety and add efficacy of new combinations besides showing the rationality of combination. Unfortunately, the companies are retaining the brand name but with different molecules. This is going to cause serious confusion among the doctors, pharmacists and the patients. The regulators should look into this issue to avoid confusion and prevent medication errors. When the combinations are banned because of irrationality, then the retention brand name with different molecules is

perhaps most irrational.

The World Patient Safety Day falls on this quarter. In the second global summit of Health Ministers on patient safety in Bonn, Germany, on March 29, 2017, the director General of World Health Organization (WHO) said that the 'Medication Without Harm' is third global patient safety challenge. Utilization of pharmacists' service in community and hospital sector has been proved beneficial reducing medication related harms. Hence, we have included 10 facts about patient safety in the present issue just to sensitize the healthcare professionals.

This year's Pharmacists Day is celebrated on 25th September with the theme: "Pharmacists: Your Medicine Experts". The pharmacists by education and training have the expertise to offer medicine related information to both healthcare professionals and the public. The public and health professionals should utilize the services of the pharmacists to promote appropriate use of medicines at their level.

The current issue has all our regular features and hope you would find them interesting read. We shall be glad to have your feedback to improve the quality and contents of the newsletter.

With Durga Puja and Deepavali Greetings!

-Editors

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Quote

"The art of medicine consists of amusing the patient while nature cures the disease."

-Voltaire

Courses

Alerts

WHO Online Course: Cholera – Introduction: This course provides a general introduction to cholera and is intended for personnel responding to outbreaks in complex emergencies or in settings where the basic environmental infrastructures have been damaged or destroyed. The details can be accessed at: <https://openwho.org/courses/cholera-introduction-en>

E-learning Course: ‘Global Health and Disability’ - The London School of Hygiene & Tropical Medicine is offering a free online course that aims to raise awareness about the importance of health and well-being of people with disabilities in the context of the global development agenda: Leaving no one behind. This course is designed for anyone with a professional or personal interest in disability as it relates to health, rehabilitation, international development and humanitarian assistance. The details can be accessed at: <https://www.futurelearn.com/courses/global-disability>

Fluoroquinolone Antibiotics associated with low blood sugar levels and mental health side effects: Fluoroquinolone antibiotics (Ciprofloxacin, Norfloxacin like drugs) have been in use for more than 30 years treating certain serious bacterial infections. They are known to cause blood sugar disturbances (high blood sugar / low blood sugar) and a range of mental health conditions. The USFDA, the drug regulatory authority has revised the label changes requirements for these antibiotics. It requires that the following information be included: “Low blood sugar levels, also known as hypoglycaemia, can lead to coma.” The mental health side effects: disturbances in attention, disorientation, agitation, nervousness, memory impairment, serious disturbances in mental abilities (delirium) should be included in the label. [https://www.drugs.com/fda/fluoroquinolone-antibiotics-fda-requires-labeling-changes-due-low-blood-sugar-levels-mental-health-14177.html?utm_source=ddc&utm_medium=email&utm_campaign=FDA+Alert+-+Fluoroquinolone]

+Antibiotics%3A+FDA+Requires+Labeling+Changes+Due+to+Low+Blood+Sugar+Levels+and+Mental+Health+Side+Effects, July 10, 2018]

Azithromycin associated with increased risk of cancer relapse with long term use after donor stem cell transplant: USFDA recommends that healthcare professionals should not prescribe long term azithromycin for prophylaxis of bronchiolitis obliterans syndrome to patients who undergo donor stem cell transplants because of the increased potential for cancer relapse and death. [https://www.drugs.com/fda/zithromax-zmax-azithromycin-fda-warning-increased-risk-cancer-relapse-long-term-after-donor-stem-14179.html?utm_source=ddc&utm_medium=email&utm_campaign=FDA+Alert+-+FDA+Warning%3A+Zithromax%2C+Zmax+%28azithromycin%29+-+Increased+Risk+of+Cancer+Relapse+With+Long-Term+Use+After+Donor+Stem+Cell+Transplant]

Focus: Tafenoquine

Tafenoquine: Single Dose radical cure of *Plasmodium vivax* Malaria: The USFDA has recently approved this simple one-dose oral treatment to prevent relapse of malaria. A brief description of this new drug is given here to promote its safe and effective use. Tafenoquine is an improved primaquine analogue.

Indications: Radical cure (prevention of relapse) of *Plasmodium vivax* malaria in patients of 16 years or older who are receiving appropriate antimalarial therapy for acute *P. vivax* malaria. This is NOT indicated for the treatment of acute *P. vivax* malaria.

Dose and Dosage: Single dose 300 mg (two tablets of 150 mg strength) with food. It is to be taken on the first or second day of an appropriate anti-malarial therapy.

Contraindications: G6PD deficiency or unknown G6PD status; Pregnancy; Breastfeeding by a lactating woman when the infant is found to be G6PD deficient or if G6PD status is unknown; Known hypersensitivity reactions to tafenoquine and other 8-aminoquinolines, or any component of the product.

Common Adverse Effects: dizziness, nausea, vomiting, headache, and decreased haemoglobin.

Warning and Precautions:

- G6PD testing must be performed before prescribing due to the risk of haemolytic anaemia. Monitor patients for clinical signs or symptoms of haemolysis;
- Check infant's G6PD status before breastfeeding begins;
- Initiate appropriate therapy if signs or symptoms of methemoglobinemia occur;
- The benefit of treatment must be weighed against the potential risk for psychiatric adverse reactions in patients with a history of psychiatric illness;
- Serious hypersensitivity reactions may occur. Initiate treatment immediately;
- Psychiatric effects and hypersensitivity reactions may be delayed in onset and/or duration.

Patient Counselling Points: Patients need to be advised on G6PD testing and haemolytic anaemia; risks involved and appropriate use. They may be advised to swallow the tablets whole (without breaking) and with food.

Important Health Days

October	Breast Cancer Awareness Month
October 1	International Day of Elderly World Vegetarian day
October 2	National Anti-Drug Addiction Day
First Wednesday of October	World Cerebral Palsy Day
October 9	World Sight Day
October 10	World Mental Health Day
October 12	World Arthritis Day
October 15	Global Hand Washing Day
October 16	World Food Day
October 17	World Trauma Day
October 20	World Osteoporosis Day
October 21	World Iodine Deficiency Day
October 24	World Polio Day
October 26	World Obesity Day
October 29	World Stroke Day
October 30	World Thrift Day
November 10	World Immunization Day
November 12	World Pneumonia Day
November 14	World Diabetes Day
November 17	World Epilepsy Day
November 19	World COPD Day World Toilet day
November 16-22	World Antibiotic Awareness Week
December 1	World AIDS Day
December 2	National Pollution Prevention Day
December 3	International Day of Persons with Disabilities
December 9	World Patient Safety Day
December 12	Universal Health Coverage Day

Patient Safety

Patient Safety (10 Facts): Patient safety is a serious global public health concern. There is a 1 in a million chance of a person being harmed while travelling by plane. In comparison, there is a 1 in 300 chance of a patient being harmed during health care. Industries with a perceived higher risk such as the aviation and nuclear industries have a much better safety record than health care.

1. Patient harm is the 14th leading cause of global disease burden, comparable to diseases such as tuberculosis and Malaria;
2. While in hospital, 1 in every 10 patients is harmed;
3. Unsafe use of medication harms millions and costs billions of dollars annually;
4. 15% of health spending is wasted dealing with all aspects of adverse events;
5. Investments in reducing patient safety incidents can lead to significant financial savings;
6. Hospital infection affects 14 out of every 100 patients;
7. More than one million patients die annually from surgical complications;
8. Inaccurate or delayed diagnoses affect all settings of care and harm an unacceptable number of patients;
9. While the use of radiation has improved healthcare, overall medical exposure to radiation is a public health and safety concern; and
10. Administrative errors account up to half of the all medical errors in primary care.

[http://www.who.int/features/factfiles/patient_safety/en/]

Did You Know?

World Health Organization at 70:

The WHO has just completed 70 years of its existence and working for better health for everyone, everywhere. Currently the WHO has 194 member states with more than 150 offices. 7th April, founding day, is celebrated as World Health Day. It was established in 1948 following the approval by the UN Conference in San Francisco, USA, in 1945.

Websites of Interest

Pharm-Ed: Pharm-Ed is an Educational and collaborative platform for efficient, safe and rational management of medicines in hospitals is created by the pharmacy department of the Hôpitaux Universitaires de Genève. This resourceful website can be accessed at: <http://pharmacie.g2hp.net/>.

Design for Health: Through improvements in current practices and the development of innovative solutions, it is possible to build upon today's momentum and accelerate progress in the future. The use of design in global health can lead to improvements in current practices and foster the development of innovative solutions.

To accelerate the use of design in addressing global health challenges, the Bill & Melinda Gates Foundation and USAID's Center for Innovation and Impact (CII) have partnered to develop resources to support the understanding, appropriate use, and effectiveness of design in global health. The website has series of resources, which are accessible free, which provide guidance around when, why, and how design can be used in global health, as well as a strategic roadmap outlining priority activities that can advance the appropriate application of design in global health. The website can be accessed at: www.designforhealth.org

NEWS

First Drug for the Treatment of Small Pox: The first drug therapy 'tecovirimat (TPOXX)' is recently approved in USA for the treatment of small pox. Small pox, once a deadly viral disease, was declared eradicated from the world in 1980. This eradication was possible due to successful immunization. There has been concern whether small pox virus will be used as biological weapon. The USFDA granted approval of TPOXX to SIGA Technologies Inc. TPOXX was developed in conjunction with the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA). The drug is available in the form of capsule and dosage is one capsule twice daily for 14 days. .

International Classification of Diseases (ICD – 11):

ICD is the foundation for the identification of health trends and statistics globally, and the international standard for reporting diseases and health conditions. It is the diagnostic classification standard for all clinical and research purposes. ICD defines the universe of diseases, disorders, injuries and other related health conditions, listed in a comprehensive, hierarchical fashion that allows for:

- easy storage, retrieval and analysis of health information for evidenced-based decision-making;
- sharing and comparing health information between hospitals, regions, settings and countries; and
- data comparisons in the same location across different time periods.

This can be accessed at: <http://www.who.int/classifications/icd/en/>

Oxytocin available in Private Pharmacy: The prohibition of the sale through pharmacy is revoked. With current regulation, the import of oxytocin is banned and will only be manufactured by the government owned 'Karnataka Antibiotics & Pharmaceuticals Limited. The government has announced that the drug is available for sale in retail

pharmacy.

Medical Insurance applicable for treatment of mental illness: The new Mental Healthcare Act, made effective from 29th May 2018, mandates 'medical insurance for treatment of mental illness on the line of insurance coverage for the treatment of physical illness.' The Insurance Regulatory and Development Authority of India has issued circular directing the insurance companies to cover mental illness too in medical insurance.

New WHO guideline on Bedaquiline for MDR-TB: The World Health Organization revised the MDR-TB treatment guideline introducing the oral bedaquiline in 'Group A' along with levofloxacin / moxifloxacin. Earlier, bedaquiline was in 'Group C' indicating that it is to be used when Group A and Group B regimens cannot be used. Bedaquiline is recommended in India for patients with extensively drug resistant TB (XDR-TB), TB resistant to isoniazid and rifampicin plus any fluoroquinolone and at least one of three injectable second line drugs. Johnson & Johnson, the patent holder of the drug, proposes the substantial price reduction which would make the treatment further affordable.

HIV and AIDS Act implemented: The implementation of the Act is just notified ensuring equal rights to people affected by HIV and AIDS in getting treatment, admission in educational institutions and jobs. The Act prohibits discrimination against such people in accessing health care, getting jobs, renting accommodation, and in admission to public and private institutions. Violation of the Act by publishing information of these affected people or advocating hatred against them invites punishment ranging from three months to two years imprisonment or a maximum fine of one lakh rupees or both.

Resources

Pharma Resource Centre: Ecumenical Pharmaceutical Network (EPN) manages a resource centre with useful documents and information sources. It has documents related to formularies, pharmacovigilance, treatment guidelines, pharmacy practice, standard operating procedures etc. They can be accessed at: http://www.epnetwork.org/index.php/en/pharma-center?utm_source=Netlink+Recipients+English&utm_campaign=e7bc14d97a-EMAIL_CAMPAIGN_2018_04_04&utm_medium=email&utm_term=0_6405cefcfbf-e7bc14d97a-195551237

OpenBoxes: This is an open source supply chain management system that has been under development since 2010 and is designed to meet the needs of organizations delivering health care in resource-scarce settings, but has also been used for inventory management in the private sector. The OpenBoxes community is continually optimizing existing features and developing new features to innovatively meet users' needs. More details are available at: <https://openboxes.com/>

Standard Treatment Guidelines and Essential Medicine List for South Africa: The National Department of Health, South Africa has updated the Paediatric Care STG. The fourth edition (2017) is available at: <http://www.health.gov.za/index.php/standard-treatment-guidelinesand-essential-medicines-list>



Vice Chancellor, Prof. V. Murugesan, interacting with students on Pharmacist Day



Vice Chancellor, Prof. V. Murugesan, giving prize to debate competition winner



Professor Guru Prasad Mohanta in MyDispense Symposium 2018 at Monash University's Prato Centre, Italy



Executive Members of ISPOR Student Chapter - Annamalai University



Inaugural Function of ISPOR Student Chapter - Annamalai University



ORS Day Activities by Pharmacy Students of Annamalai University

DISCLAIMER:

The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the University shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.