



# MEDICINE INFORMATION NEWSLETTER

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## Editors' Desk

*With great satisfaction, we would like to thank our readers for their goodwill and encouragement. We have just completed three years of our publication and this is the first issue of the fourth year.*

*The recent two disturbing news have shaken the faith of the common man: one related to the clinical trial deaths and the other is overcharging by a corporate hospital. The news revealed that 24, 117 cases of deaths and serious adverse events occurred between January 2005 and September 2016 during clinical trials. The report continues "only in 160 cases compensation is given out of 4534 deaths occurred". The clinical trials are mandatory requirements in the development of new drugs or therapy. In order to protect the interest of the clinical trial participants, the law is revised and new ethical guidelines are laid down. The law enforcement authority should be vigilant enough to protect the safety and interest of the patients while allowing clinical trials in our population. Clinical trial is risky and provision of compensation needs to be enforced rigidly.*

*A corporate hospital of Delhi is reported to have charged up to 1700% margin on medical items given to the admitted child, though the child died. Even the margin for scheduled drugs (for which Drug Price Control Order is applicable) is above 300%. This is gross violation of our regulations. The government should come out with price fixation for different procedures or therapy based on categories of hospital. If this is not done, the patients continue to be the victims in the hands of private health institutions. About 40% of our population depends on private facilities for their healthcare need.*

*The pharmaceutical companies, private health facilities and the regulators should take patients into confidence failing which the distrust will continue to grow further.*

*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.*

*Wishing you all happy, healthy and prosperous 2018.*

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## Quote

*If you look over a list of medicinal recipe in vogue in the last century, how foolish and useless they are seem to be! And yet we use equally absurd ones with faith today.*

*Henry David Thoreau, 1860*

# Courses

**Distance Education on Pharmacovigilance:** A free on-line training programme is offered by Uppsala Monitoring Centre. It offers training on signal detection and causality analysis. More details can be accessed at <https://courses.who-umc.org/registration/sdca>

**Online courses to people preparing to work in epidemics, pandemics and health emergencies:** The WHO's new OpenWHO platform offers the online courses for people who have interest on epidemics, pandemics and health emergencies. The platform is managed by WHO's Department for Infectious Hazards Management, in Geneva, Switzerland. The more details can be seen at <https://openwho.org/> and e. mail contact is [outbreak.training@who.int](mailto:outbreak.training@who.int).

**Free London School of Hygiene & Tropical Medicine Course: Control and Elimination of Visceral Leishmaniasis:** More details are

available at: <https://www.futurelearn.com/courses/visceral-leishmaniasis>

**Free online course from nature:** A free online course on 'peer review' is available from nature. The details are available at: <https://masterclasses.nature.com/users/4925-claire-hodge/posts/20006-free-online-course-on-peer-review>

**Master of Science in Global Urban Health (MSc GUH):** This modular course of one academic year begins in September 2018 at the University of Freiburg, Germany. The course includes cross-disciplinary approaches with inputs from several faculties of Freiburg University and external lecturers, organized by the "Centre for Medicine and Society" on behalf of the Humanities Faculty. There will be excursions to Geneva, Basel, Strasbourg and other places of interest. More details are available at: <https://www.zmg.uni-freiburg.de/training/mscglobalhealth/master>

# Conferences

**The Clinical Pharmacy Congress 2018:** The clinical pharmacy Congress is scheduled during April 27-28, 2018, at London. The abstract submission details can be seen at: <https://www.pharmacycongress.co.uk/poster-zone>

**ISPOR 8th Asia - Pacific Conference:** The Conference is scheduled during 8-11th September 2018 at Tokyo, Japan. Conference Theme: Moving Into Action: Informing Policy and Strengthening Healthcare Systems in Asia-Pacific. The last date for submission of abstract is 14th March 2018. More details are available at: <https://www.ispor.org/conferences/2018Tokyo/ISPOR-Tokyo-CFA-postcard.pdf>

**Fifth Global Symposium on Health Systems Research (HSR2018):** The event is scheduled from 8 - 12 October, 2018 in Liverpool, UK. More details can be obtained from: <http://healthsystemsresearch.org/hsr2018/>

**78th World Congress of Pharmacy and Pharmaceutical Science:** The 2018 FIP congress is scheduled in Glasgow, Scotland, during 2-6 September 2018. More details can be accessed at <https://www.fip.org/glasgow2018/>

NEW YEAR GREETINGS!!!

Dear Readers  
WISHING YOU ALL  
A HAPPY,  
HEALTHY  
PROSPEROUS NEW  
YEAR!

## Focus

**Delamanid - New anti-TB Drug:** The government of India has recently approved this drug for the treatment of multi-drug resistant tuberculosis. The World Health Organization currently recommends that the drug may be added to the WHO recommended regimen in adults with Pulmonary MDR-TB with five conditions: proper patient inclusion, adherence to the principle of designing a WHO recommended MDR-TB regimen, close treatment monitoring, active pharmacovigilance and proper management of adverse drug reactions, and informed patient consent. Later, its use is also recommended for children and adolescents (6 years - 17 years) with multi-drug or rifampicin resistant TB (MDR/RR-TB) who are not eligible for the shorter MDR-TB with similar conditions as specified for adults.

**Dose:**

Category	Dose	Duration
Patients aged 6-11 years	50 mg twice a day	6 months
Patients aged 12-17 years	100 mg twice a day	6 months
Adult patients	100 mg twice a day	6 months

The medicine is to be taken after food.

**Adverse Effects:**

The common side effects are: nausea, vomiting and dizziness. Other important side effects include anxiety, "pins and needles", and shaking. It may cause serious side effect: QT prolongation.

In view of these side effects, the patients need to be closely monitored.



# Alert

**Long Term Use of Proton Pump Inhibitors (PPIs):** PPIs are perhaps one of the most widely used medicines intended for treatment gastroesophageal reflux disease and for prevention of upper gastrointestinal adverse effects caused by NSAIDs. Long term use of them are reported to be associated with increased risk of fracture (may be due to interference of calcium absorption), hypomagnesemia and QT prolongation (may be due to interference in magnesium absorption), increased risk of chronic kidney disease (mechanism not known), increased deficiency of vitamin B12 (release of vitamin B12 from dietary protein is dependent on gastric acidity), increased risk of iron deficiency (maybe due to interference in iron absorption), small increase in risk of community acquired pneumonia (reduced gastric acidity may promote bacterial colonization in upper gastrointestinal tract), increased dementia (reduction in vitamin B12 level is associated with cognitive decline) and increased risk of "all cause mortality".

**Insulin degludec in combination with liraglutide:** The fixed-dose combination in an injection pen of insulin degludec, a long-acting insulin, and liraglutide, a GLP-1 analogue has been in use for the treatment of type 2 diabetes.

It is reported that Insulin degludec has no proven benefits over other

insulins. Like the other GLP-1 analogues, liraglutide mainly exposes patients to nausea, renal failure, and more rarely to pancreatitis including cancer of pancreas and thyroid. The combination of insulin degludec and liraglutide in a single pen does not allow the dosage of each substance to be adjusted independently, in particular at the start of treatment or in the case of an adverse effect. It is preferable to rule out this combination.

**Sodium valproate has risk of birth defects:** Sodium valproate, an anti-epilepsy medicine, is reported to have risk of 10 per cent chance of causing physical abnormalities in children born to mothers who take it during pregnancy. Babies exposed to it also have a 40 per cent risk of developmental problems, including autism, low IQ and learning disabilities. The European Medicine Agency has urged to improve patient information on this risks.

**Removal of Modified Release Paracetamol:** The European Medicine Agency's Pharmacovigilance Risk Assessment Committee has recommended for suspension of modified or prolonged-release release Paracetamol. The decision was taken in view of the difficulties of managing overdose in patients.

[EMA News, 1 September 2017]

## Did You Know?

**America did not have the problem of thalidomide disaster**

The whole world suffered from Thalidomide disaster with the exception of US. One US FDA officer, Dr. Frances Kathleen Oldham Kelsey, prevented its entry by not approving the drug. In 1962, she was awarded with President's award for Distinguished Federal Civilian Service from President John F. Kennedy. In 2010 the FDA honoured Kelsey by naming one of their annual awards after her and she was the first recipient.

## Website of Interest



**TechNet Resource Library (TRL):** It is an on-line repository of more than 1500 resources in all areas of immunization. It has journal articles, documents, tools, videos, websites, and other immunisation resources. The website can be accessed at: <https://www.technet-21.org/en/library>

### Healthy Life Style for High Blood Pressure Management

1. Lose weight – Avoid over weight or Obesity;
2. Reduce your salt intake – Reduce your intake of processed and salty foods;
3. Increase your dietary potassium intake – Potassium rich foods include: fresh vegetables and fruits. Ratio of sodium and potassium in diet is important.
4. Restrict Alcohol – If possible should be completely avoided. Beer contain 5% and wine 8-10% of alcohol, while brandy, rum and whisky contain much higher concentrations (30-40%);
5. Do Exercise – Exercise regularly to be physically active to maintain ideal body weight. Adults over the age of 20 years should undertake a minimum of 30-45 minutes of physical activity of moderate intensity (such as brisk walking 5-6 km/hr) 5-6 days of the week. Greater health benefits can be obtained by engaging in physical activity of longer duration or more vigorous intensity such as jogging, running, cycling and swimming.
6. Decrease your fat intake – Butter, ghee, and edible oils are contributors for fat. Minimize the use of processed foods. red meat, eggs, organ meats are responsible for contributing cholesterol; and
7. Take fibre rich diets - Dietary fibre delays and retards the absorption of carbohydrates and fats. They also reduce glucose and lipids in bloods; and increase the bulk of stools. Fruits, vegetables, whole grain cereals and pulses are good source of fibre.

# NEWS

**First Gene Therapy:** The first approved gene therapy, Tisagenlecleucel, is aimed for treatment of children and young adults up to 25 years of age with B-cell precursor acute lymphoblastic leukaemia (ALL) that is refractory or in second or later relapse. Approved Benefits: Remission rate of 83% within three months in a clinical trial. Safety information: The product carries a boxed warning about the risk of cytokine release syndrome (CRS), which causes high fever and flu-like symptoms, and the risk of neurological events. Both these events can be life-threatening. Other severe side effects of Kymriah include serious infections, hypotension, acute kidney injury, fever, and hypoxia. Most

symptoms appear within one to 22 days following infusion. [US FDA Press release, 30 August 2017]

**Daily Dosage Regimen for TB:** The Revised National TB Control Programme has adopted new treatment strategy to introduce daily dosing of anti-TB medicines. The new dosing therapy was already started first in five states: Bihar, Himachal Pradesh, Kerala, Maharashtra and Sikkim. Now it extends to rest of India. The important features of new therapy: Fixed Dose Combination; and Dose is based on individual body weight. This is expected to increase adherence and improve effectiveness.

## Resources

**Standard Treatment Guidelines:** The Government of India has developed a series of guidelines for the treatment of various ailments. They are free and can be accessed at <http://clinicaestablishments.nic.in/En/1068-standard-treatment-guidelines.aspx>

**Resource Guide for Disaster Medicine and Public Health:** This is a database of links to disaster medicine and public health documents available on the Internet at no cost. Documents include expert guidelines, research reports, conference proceedings, training classes, fact sheets, websites, databases, and similar materials selected from over 700 organizations for a professional audience. The resource can be accessed at: <https://disasterlit.nlm.nih.gov/>

**Managing complications in pregnancy and childbirth:** a guide for midwives and doctors – 2nd Edition is released and is available at: [ed.http://apps.who.int/iris/bitstream/10665/255760/1/9789241565493-eng.pdf](http://apps.who.int/iris/bitstream/10665/255760/1/9789241565493-eng.pdf)

## Updated Guideline on Hypertension Treatment

A new guideline for prevention, detection, evaluation and management of High Blood Pressure in adults is recently released by American College of Cardiology and American Heart Association. The new definition of hypertension: Systolic BP measurement of 130 mm Hg or higher; or Diastolic BP measurement of 80 mm Hg or higher.

BP Category	Systolic BP		Diastolic BP	Treatment or Followup
Normal	<120 mm Hg	And	<80 mm Hg	Evaluate yearly; encourage healthy life style changes.
Elevated	120-129 mm Hg	And	<80 mm Hg	Recommend healthy life style changes and reassess in 3-6 months
Hypertension Stage - 1	130-139 mm Hg	Or	80-89 mm Hg	Assess the 10year risk of heart disease and stroke: <ul style="list-style-type: none"> <li>• If risk is less than 10%, start with healthy life style recommendations and reassess in 3-6 months;</li> <li>• If the risk is greater than 10% or the patient has known clinical cardiovascular disease, diabetes mellitus, or chronic kidney disease, recommend life style changes and BP lowering medication (1 medication); reassess in in 1 month for effectiveness of medication therapy:               <ul style="list-style-type: none"> <li>• If goal is met after 1 month, reassess in 3-6 months;</li> <li>• If goal is not met after 1 month, consider different medications or titration;</li> <li>• Continue monthly follow-up until control is achieved.</li> </ul> </li> </ul>
Hypertension Stage - 2	≥140 mm Hg	Or	≥90 mm Hg	Recommend healthy life style changes and BP lowering medication (2 medications of different classes); reassess in 1 month for effectiveness <ul style="list-style-type: none"> <li>• If goal is met after 1 month, reassess in 3-6 months</li> <li>• If goal is not met after 1 month, consider different medications or titration</li> <li>• Continue monthly follow – up until control is achieved</li> </ul>



PharmD students are in Dengue Awareness Campaign. The school children were addressed on Dengue Prevention and Treatment. The children were sensitized to look at the stagnant water in and around their house; and remove these water.



Professor Guru Prasad Mohanta is with the other international experts in a meeting on Pharmacovigilance Education at the Netherlands pharmacovigilance centre lareb. The meeting was held during 22-24 November 2017. The Netherlands pharmacovigilance centre lareb is the WHO collaborating centre on pharmacovigilance education.



Mr. C. Karuppusamy, Quality Lead of GSK Consumer Healthcare Limited, addressing pharmacy students on Good Manufacturing Practices and Quality Management System in pharmaceutical industries on 28<sup>th</sup> December 2017.

**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.