Drug Information Bulletin

Drug Information Centre (DIC)
Indian Pharmaceutical Association
Bengal Branch
Tele fax: 033 24612776, E-mail: ipabengal.dic@gmail.com
Web Site: http://www.ipabengal.org
Contact: 09830136291

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Regulatory Affairs Division (RAD), IPA

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Content

Editorial

US FDA approved a fixed-dose combination tablet containing Sofosbuvir 400mg and Velpatasvir 100 mg and is the first to treat all six major forms of HCV on June 28, 2016. The first brand was approved is "Epclusa" of Gelead Sciences to treat adult patients with chronic hepatitis C virus (HCV) both with and without cirrhosis (advanced liver disease), for patients with moderate to severe cirrhosis (decompensated cirrhosis). Epclusa is approved for use in combination with the drug ribavirin.

The first generic version of this product developed by Beacon Pharma of Bangladesh named Sofosvel is already on the market.

Sofosbuvir 400 mg +Velpatasvir 100 mg Tablet & Bulk have been approved by CDSCO for the treatment of adult patients with -chronic Hepatitis C virus, Genotype 1,2,3,4,5 or 6 infection.-Without cirrhosis or with compensated cirrhosis-With decompensated with chronic for use in combination with Ribavirin on 04.05.2017. The first generic version of Epclusa was developed and launched in the market by Natco Pharma in the month of May 2017.

Normal dosage regimen of this drug is 12 weeks and the cost of innovator brand Epclusa is $74760 (RS. 4788378) whereas the cost of generic version developed by Natco Pharma **(**Velpanat) is Rs. 55500. The price of generic version is about 1 percent of the innovator brand. Apart from Natco Pharma 10 more Indian companies have got licence from Gelad Sciences for manufacturing the same drug. Hope price of this drug will be cheaper in future improving access to this drug

Dr. Subhash C. Mandal
Editor

Pharmacovigilance Division, Indian Pharmacopoeia Commission, MOH is now recognized as one of the six WHO Collaborating Centres round the globe

World Health Organization

WHO Collaborating Centres
Global database

Ref.No. [Initiator]
IND-145 [Headquarters]

Status
Active

Title of the centre:
WHO Collaborating Centre for Parmacovigilance in Public Health Programmes and Regulatory Services

Director / Head:
Dr GN Singh — dci@nic.in
Dr Vivekanandan Kalaiselvan — vivekarts@rediffmail.com

Institution:
Pharmacovigilance Division, Indian Pharmacopoeia Commission
Ministry of Health and Family Welfare

Address:
Sector 23, Raj Nagar
201 002
Uttar Pradesh

Town:	Country:	Region:
Ghaziabad	INDIA	SEARO
Phone:	**Fax:**	**Web Site:**
+91 120 6582849		http://www.ipc.gov.in/PvPI/pv_home.html
Date of Designation:	**Last Redesignation:**	**Expiry:**
18/Jul/2017	18/Jul/2017	18/Jul/2021

Terms of Reference:
1. Support WHO to develop relevant tools and guidelines for enhancing Pharmacovigilance (PV) practice in low and middle income countries (LMIC) in Asia and beyond.
2. Contribute to capacity building of WHO member states to establish high quality pharmacovigilance systems for medical products.
3. Scientific support to countries for pharmacovigilance in public health programmes (e.g. Tuberculosis, Neglected Tropical Diseases, Vector Borne Diseases, HIV-AIDS; Immunization Programme) and regulatory issues.
4. Work-sharing and joint activities in regulatory pharmacovigilance

Subjects:
1. Pharmaceuticals (including essential drugs and medicines)
2. Health systems research & development

Types of activity:
1. Training and education
2. Development and application of appropriate technology
3. Providing technical advise to WHO

WHO Outputs:
4.3.3 - Improved quality and safety of medicines and other health technologies through norms, standards and guidelines, strengthening of regulatory systems, and prequalification

Responsible Officer:	Phone:	Email:
PAL Shanthi Narayan	+41 22 791 1318	pals@who.int
Technical Counterpart:	**Phone:**	**Email:**
GUPTA Madhur	+911142595600	guptamadh@who.int

Access to annual progress reports and the current workplan (this is accessible to WHO Staff Members only):
Link to eWork

Drug Safety Alerts by PvPI during June 2017

Health care professionals, Patients/Consumers has been advised to closely monitor the possibility of the below mentioned adverse events associated with the use of the mentioned drugs. If such events are encountered they are requested to report to the NCC-PvPI either by filling of Suspected Adverse Drug

Reactions Reporting Form/ Medicines Side Effect Reporting Form for Consumer (http://www.ipc.gov.in) or by PvPI Helpline No. 1800-180-3024.

The preliminary analysis of ADRs from the PvPI database reveals that the following drugs are associated with the risks as given below.

Sl. No	Suspected Drugs	Indication	Adverse Reactions
1.	Paracetamol	Mild to moderate pain including dysmenorrhoeal pain, headache; pain relief in osteoarthritis and soft tissue lesions; pyrexia including postimmunisation pyrexia; acute migraine attack	Baboon Syndrome
2.	Lamivudine	HIV infection in combination with at least two other antiretroviral drugs	Hearing Loss
3.	Mebeverine	For Irritable Bowel Syndrome (IBS)	Retrosternal Pain

India grants Pfizer patent for blockbuster brand Prevenar 13

India has granted US drug giant Pfizer a patent for its blockbuster Prevenar 13, a vaccine that helps prevent cases of pneumonia, one of the leading causes of deaths of children under five years of age. The approval comes more than a decade after the company applied for the patent in the country. Global medical humanitarian organisation Médecins Sans Frontières (MSF) said it is a “major setback” to hopes for an affordable vaccine and is likely to legally challenge the patent approval. Prevenar 13 helps prevent pneumococcal pneumonia and infections caused by 13 strains of streptococcus pneumonia bacteria, according to Pfizer.

This vaccine and GlaxoSmithKline's Synflorix are the only two pneumococcal conjugate vaccines (PCV) available in the country.

In the private market, Prevenar 13 is priced at Rs 3,800 per dose, and Synflorix at Rs 1,800 per dose, industry insiders said. Three doses are required for each child, they said.

Read more at:
http://economictimes.indiatimes.com/articleshow/60174991.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

FDA panel to review pediatric cough medicine with opioids

The FDA's Pediatric Advisory Committee will evaluate the use of cough medications with opioids such as codeine and hydrocodone in children, including benefit-risk considerations and current treatment procedures, on Sept. 11 after an FDA meeting in which the American Academy of Pediatrics and other health care organizations opposed opioid use for pediatric cough treatment. "All of this work is essential to reducing preventable harm from opioid-containing medications and keeping children safe," said FDA Commissioner Scott Gottlieb.

Ref. STAT (tiered subscription model)

Johnson & Johnson and CSIR- IMTECH collaborate on tuberculosis treatment R&D

Johnson & Johnson and India's Institute of Microbial Technology, part of the Council of Scientific and Industrial Research, will collaborate on the research and development of new drug compounds for tuberculosis. The partnership will take advantage of J&J's research capabilities and CSIR-IMTECH's microbial technology competence.

Ref. Genetic Engineering & Biotechnology News

Study examines potential use of gold nanoparticles in cancer treatment

A UK animal study published in the journal Angewandte Chemie found that gold particles catalyzed a directed chemical reaction in zebrafish brains, in addition to activating lung cancer drugs in a petri dish, suggesting that the approach could be used to release drugs inside tumors. "We hope that a similar device in humans could one day be planted by surgeons to activate chemotherapy directly in tumors and reduce harmful effects in healthy organs," said author Asier Unciti-Broceta.

Ref.: Specialty Pharmacy Times

NPPA threatens legal action against 40 hospitals for not displaying knee implant prices

National drug pricing regulator NPPA has said 40 hospitals, including Medanta Medicity and Apollo Spectra in the national capital, will face action for not displaying prices of knee implants on their websites.

The National Pharmaceutical Pricing Authority (NPPA) on its Twitter handle released a list naming 40 hospitals across the country that will face action.

"40 hospitals not displaying knee implant prices on their websites to face action", the regulator said in a tweet.

NPPA, however, did not elaborate on the action it has envisaged.

Hospitals that have been named in the list include Rockland Hospital (Delhi), Moolchand Medcity (Delhi), Apex Multi Speciality Hospital (Varanasi & Mumbai), Vijaya Hospitals (Chennai) and Sahara Hospital (Lucknow).

Besides some hospitals located in cities like Noida, Patna, Bhopal, Ahmedabad and Kanpur have also been named in the list.

The authority in a memorandum on August 18 had asked all manufacturers /importers and marketers and hospitals to comply with the notified ceiling price of orthopaedic knee implant system.

The government on August 16 fixed a price range for knee implants from ▪ 54,000 to ▪ 1.14 lakh, nearly 70 per cent lower than their earlier cost.

"After cardiac stents, we have now decided to bring all kinds of knee implants under price control. In our country 1.5 to 2 crore people suffer from knee problems, who need health assistance," Chemicals and Fertilisers Minister Ananth Kumar had said in a news briefing.

The minister had also warned of stringent action against hospitals, importers, retailers if they charged in excess of the MRP saying that the government would recover excess profit from such knee implants with 18 per cent interest and may also cancel licences of hospitals.

The government had in February slashed the maximum price of life-saving heart stents implants by up to 85 per Earlier, the average maximum retail price (MRP) for BMS was ▪ 45,000 and for DES, it was ▪ 1.21 lakh. cent by capping them at ▪ 7,260 for bare metal ones and ▪ 29,600 for drug eluting variety.

Ref. ET Health

Forthcoming Events:

9th Indian Pharmaceutical Association (IPA)
Students Congress
September 2nd – 3rd, 2017
Venue: Vikash Institute of Pharmaceutical Sciences
Rajmundri, Andhra Pradesh
For Details:
http://www.ipapharma.org/events/IPASF%20B

Pharmacists Day 2017 celebration
Indian Pharmaceutical Association, Bengal Branch
Date: 25th September 2017
Theme:"From research to health care: Your pharmacist is at your service"

Congratulations !!!

Prof. B.Suresh, Past President, IPA has been conferred Fellowship of Commonwealth Pharmacists Association (CPA) for his significant contribution in uplifting the standards of pharmacy profession during the 13th Biennial CPA conference held during 28-30th July, 2017 at Sydney, Australia