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
&
Regulatory Affairs Division (RAD), IPA

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Editorial

Undiscovered Pharmaceutical Scientist won Nobel Prize in Medicine 2015 for discovering Artemisinin

You You Tu is a Chinese scientist and phytochemist known for her isolation and study of the antimalarial substance *qinghaosu*, later known as Artemisinin, which is one of the world's most-effective antimalarials, specially for drug resistant malaria. For her discoveries, Tu received the 2015 Nobel Prize for Physiology or Medicine (shared with Irish-born American parasitologist William Campbell and Japanese microbiologist Ōmura Satoshi).

Tu studied at the department of Pharmaceutics of Beijing Medical College. After graduating in 1955, she was joined the Institute of Materia Medica at the Academy of Traditional Chinese Medicine (later the China Academy of Chinese Medical Sciences). From 1959 to 1962, she participated in a full-time training course in the use of traditional Chinese medicine that was to be integrated with theories of Western medicine. The course provided a foundation for her later application of traditional Chinese medical knowledge to modern drug discovery. Tu started working on developing antimalarials in 1967 and she initially was prohibited from publishing her team's findings, because of Chinese Govt's restrictions on the publication of scientific information. The work finally reached international audiences, to receive wide acclaim, in the 1980s. In the early 2000s, the World Health Organization recommended the use of Artemisinin-based combination drug therapies as first-line treatment for malaria. She continued to investigate artemisinin and developed a second antimalarial compound, Dihydroartemisinin (a bioactive Artemisinin metabolite). In 2011 she received the Lasker-DeBakey Clinical Medical Research Award for her contributions to the discovery of artemisinin.

Congratulations Ms. You You TU !!!

Dr. Subhash C. Mandal, *Editor*

FDA revises label of diabetes drug canagliflozin (Invokana, Invokamet) to include updates on bone fracture risk and new information on decreased bone mineral density

The U.S. Food and Drug Administration (FDA) has strengthened the warning for the type 2 diabetes medicine canagliflozin (Invokana, Invokamet) related to the increased risk of bone fractures and added new information about decreased bone mineral density. Bone mineral density relates to the strength of a person's bones. To address these safety concerns, we added a new *Warning and Precaution* and revised the *Adverse Reactions* section of the Invokana and Invokamet drug labels.

For details:
http://www.fda.gov/Drugs/DrugSafety/ucm461449.htm

FDA strengthens warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) can cause heart attacks or strokes

The U.S. Food and Drug Administration (FDA) is strengthening an existing label warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) increase the chance of a heart attack or stroke. Based on our comprehensive review of new safety information, we are requiring updates to the drug labels of all prescription NSAIDs. As is the case with current prescription NSAID labels, the Drug Facts labels of over-the-counter (OTC) non-aspirin NSAIDs already contain information on heart attack and stroke risk. We will also request updates to the OTC non-aspirin NSAID Drug Facts labels.

For Details:
http://www.fda.gov/Drugs/DrugSafety/ucm451800.htm

Industry groups, MSF criticize Pacific trade agreement

Both the Biotechnology Industry Organization and Pharmaceutical Research and Manufacturers of America criticized the Trans-Pacific Partnership agreement, which sets exclusivity periods for biologic drugs at five to eight years. "The Congress set 12 years as the appropriate period to both foster innovation and provides access to biosimilars in a reasonable timeframe. ... [W]e believe the failure of our Asian-Pacific partners to agree to a similar length of protection is remarkably short-sighted," BIO President and CEO Jim Greenwood said. Medecins Sans Frontieres, or Doctors Without Borders, said the agreement would raise prices and delay cost-saving generics while serving as a "dangerous blueprint" for other international agreements.

Ref. Regulatory Focus

Novel Drug First to Treat Negative Symptoms in Schizophrenia

A novel antipsychotic that treats predominant persistent negative symptoms in schizophrenia and improves overall function is significantly more effective than standard antipsychotic therapy and is well tolerated, new phase 3 trial results indicate.

"What's important is that cariprazine was significantly more effective than risperidone [*Risperdal*, Janssen Pharmaceuticals, Inc] at not only improving symptoms but also the functionality of patients," George Nemeth, MD, PhD, chief medical officer, Gedeon Richter, Budapest, Hungary, told *Medscape Medical News.*

"And together, these two things could have a high impact on the patient's quality of life."

The study was presented here during the 28th European College of Neuropsychopharmacology (ECNP) Congress.

For details:
http://www.medscape.com/viewarticle/850701?src=confwrap&uac=174558MX

Drug makers hike prices for numerous drugs

Pfizer, Merck, Bristol-Myers Squibb and

other drugmakers raised prices on dozens of brand-name products this year, some by more than 10%, according to UBS. "Some companies have made greater use of price increase than others, and those are typically companies that are trying to paper over financially an absence of innovation that they've not been able to generate internally," said John Schroer of Allianz Global Investors.

For details:
http://www.bloomberg.com/news/articles/2015-10-02/pfizer-raised-prices-on-133-drugs-this-year-and-it-s-not-alone

Brazil halts sales of silicone implants

Anvisa, the Brazilian health regulatory agency, has suspended the production and sale of silicone breast and other implants by the firm Silimed after an inspection by a German entity found manufacturing surfaces contaminated with particles. Silimed, largest maker of silicone implants in South America, said the sterile particles do not pose a health risk.

Ref. Reuters

CDSCO to meet state DCs to review compliance of WHO-GMP norms by drug units

A meeting of all state drug controllers has been called by CDSCO in Delhi on October 16 in the wake of repeated adverse reports of manufacturing facilities of Indian pharmaceutical companies by international regulatory agencies. Such reports are causing doubts about standards followed by Indian companies in the international market. CDSCO, therefore, is in the process of examining this issue as a part of India's commitment towards compliance with global WHO-GMP norms.

This comes close on the heels of around 10 such cases of global scrutiny done on Indian drug makers by international regulators this year. "Our aim is to supply safe and efficacious medicines to other countries for the sake of patient safety. Process of adopting and learning WHO-GMP standards is a dynamic process and learnings from global regulatory counterparts on continuing good manufacturing practices will help manufacturers in adopting global practices followed in other countries where our medicines are consumed," explained Drug Controller General of India Dr G N Singh.

CDSCO had conducted 17 training programmes to train drug inspectors on carrying out GMP inspections in the year 2013-14 to ensure quality of drugs supplied to over 200 countries from India. Several Indian drug makers have come under the scanner of the US Food and Drug Administration (FDA) in recent years over a range of issues, including production quality, sanitation standards and alleged data manipulation. Ranbaxy was one of the companies that came under US regulatory heat as it had products from the company's facilities in Toansa, Paonta Sahib, Dewas and Mohali in India barred. Generic giant Sun Pharma also came under fire after a US FDA ban on its plant at Karkhadi in Gujarat.

US and European Union sanctions have hurt India's image as an inexpensive and reliable supplier of generic drugs in international markets. India's pharmaceutical exports totalled about $15.3 billion in 2014-15, marginally up from the previous year's $14.84 billion.

As per the WHO website, GMPs includes factors such as sanitation and hygiene, qualification and validation, self-inspection, quality audits, suppliers' audits, prevention of cross-contamination and bacterial contamination during production, training employees and personal hygiene.

Aimed at strengthening the regulatory mechanism, health ministry has also concluded a survey recently to test 43,000 drug samples from across the country, a process that started in April this year. The idea is to get more clarity

on the percentage of spurious or low-quality drugs circulated in India.
Ref. Pharmabiz

Advocacy done by IPA in last three months:

17.08.2015: Suggestions on Public Notice about prescribing drugs by generic name.

22.09.2015: Comments / Suggestions for the inclusion of B. Pharm. Graduates as a qualification for recruitment as a Food Safety Officer & Food Safety Analyst under Food Safety and Standards Rules2011

08.10.2015: Request for consideration for inclusion of Pharmacy / Pharmaceutical Sciences as an optional subject in Civil Services Examinations like, IAS, IPS and IFS (Preliminary and Main) conducted by UPSC

Pharmacists Day Celebrated

Pharmacists Day Celebration-2015
by
IPA, Bengal Branch
Date: 25.09.2015

- *Pharmacist's badges worn by the Pharmacists in all sectors at their work place throughout the state.*
- *Get well soon cards were distributed amongst the patients in Hospitals (Govt. & Private), clinics & community pharmacies throughout the state.*

Seminars organized:

- **IPA Auditorium, Kolkata:**
  Seminar on "Impact of Pharmacy Practice Regulation-2015"
  Speaker: Dr. V. Ravichandiran, Director, National Institute of Pharmaceutical Education &Research (NIPER), Kolkata
  Time: 6.00 pm
- **Institute of Pharmacy, Kalyani:**
  "Impact of Pharmacy Practice Regulation-2015"
  Time: 1.30 pm
- **Coochbehar Municipality Hall (Jointly with PAWB):**
  Seminar on "Impact of Pharmacy Practice Regulation-2015"

Forthcoming Event

National workshop on "Combating Antimicrobial Resistance"

Date: 22.11.2015

Venue: Dr. H. L. Roy Auditorium, Indian Institute of Chemical Engineers, Jadavpur University Campus.

:Time:

10.00: Registration

10.30: Inauguration

11.15: Tea

11.30: How vulnerable our health system to the onslaught of AMR: **Dr. Nirmal Gurbani**, Professor, Institute of Health Management, Jaipur

12.15: Strategy against Drug resistance to Tuberculosis-A reemerging disease: **Mrs. Manjiri Gharat,** Vice President & Chairperson, Community Pharmacy Division, IPA, Mumbai

1.00: Lunch

2.00: Regulatory measures to prevent Antimicrobial resistance: TBD

2.45: Nosocomial infection & Antimicrobial resistance: **Dr. Shantanu Tripathy,** Head, Dept. of Clinical Pharmacology, STM & Coordinator, AMC, STM

3.30: Pharmacovigilance of antibiotics & Role of Pharmacists: **Dr. Anjan Adhikary**, Associate Prof. R.G.Kar Medical College & Head, Coordinator, AMC, R.G.Kar Medical College

4.15: Panel discussion

4.45: Valedictory session