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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Content

Editorial

Union Minister, Ministry of Chemicals & Fertilizers -Mr. Ananth Kumar has shown deep concern about Public Health & Pharmaceutical Industry of India during the Inauguration of 57th Indian Pharmaceutical Congress at Mysuru on 19th December 2015. He invited Pharmaceutical Manufacturers to spend more on Research & Development for discovering new molecules, as he felt that reverse engineering is no longer help pharma industry grow. He also expressed deep concern about lack of sufficient manufacturing facilities for Medical Devices in India and appealed entrepreneurs for investment in Medical Devices Industry to reduce dependency on import. Mr. Anant Kumar said that the Government has already framed separate set of legislations for Medical Devices and is going to implement it soon. He informed that his dept. is pushing for a separate Ministry of Pharmaceuticals & Medical Devices and is expecting it to materialize within one year. He also expressed that 106 more drugs will be included in DPCO. Recently a new version of NLEM has been published which contains 376 drugs. Seventy drugs , which are no longer in use or are sparingly used have been deleted and 106 more new drugs under the category of anticancer, cardiac, antidiabetics etc. have been included.

On the second day of the IPC, Mr. J.P.Nadda, Union Health Minister released "The Vision" document "expressing that Indian Pharmacists will realize the vision expressed in the caption by partnering with Government of India initiatives for developing a Healthy India (Swasth Bharat)".

Mr. J.P.Nadda has said that they are considering for extending greater role of pharmacists in health care system. He also expressed that his Govt. is seriously considering to allow pharmacists for prescribing a few drugs in the rural areas.

Pharmaceutical professionals are extremely happy about those decisions and are expecting proper implementation of the same.

Dr. Subhash C. Mandal
Editor

Government of India has notified the National List of Essential Medicines (NLEM), 2015 on 23rd December, 2015

The number of drugs included on the National List of Essential Medicines in India has increased from 348 to 376 after several treatments for hepatitis C, HIV/AIDS, cancer and other conditions were added. Updates were based on the 2015 list of essential drugs released by the World Health Organization, as well as on the views of nongovernmental organizations and drugmakers. Some industry stakeholders believe the prices of treatments on the list will be controlled, because that's what happened with drugs on the previous list.

CDSCO requested to take action as per Drugs & Cosmetics Act & Rules on sale of drugs over Internet contravening the provisions of Drugs and Cosmetics Rules, 1945

Dr. S. Eswara Reddy, Joint Drugs Controller (I) requested all State & UTs Drugs Controllers to take action as per Drugs & Cosmetics Act & Rules on sale of drugs over Internet contravening the provisions of Drugs and Cosmetics Rules, 1945 vide a circular No. 7-5/2015/Misc/(e-Governance)/091 dtd. 30.12.15.

Sitagliptin, saxagliptin, linagliptin, alogliptin: severe joint pain United States of America

The US Food and Drug Administration (FDA) has warned that the anti-diabetic medicines sitagliptin, saxagliptin, linagliptin and alogliptin may cause joint pain that can be severe and disabling. These medicines belong to the class of dipeptidyl peptidase-4 (DPP-4) inhibitors and are approved for treatment of type-2 diabetes. A new warning about this risk has been added to the product information of all FDA-approved products containing a DPP-4 inhibitor. Ref.: FDA Drug safety communication, 28 August

Diazoxide: pulmonary hypertension United States of America

The FDA has warned about a serious lung condition occurring in infants and newborns treated with diazoxide (Proglycem®) for low blood sugar. In all cases, the pulmonary hypertension resolved or improved after diazoxide was stopped. The FDA is investigating this safety issue and will determine whether changes are needed in the product information. Diazoxide is usually given in the hospital. Health care professionals should closely monitor infants receiving it, especially those with risk factors for pulmonary hypertension, and treatment should be stopped if the condition is identified. Parents and caregivers should be instructed to alert a health professional immediately if they notice signs of difficult breathing in their child.
Ref.: FDA Drug Safety Communication, 16 July 2015.

NSAIDs: heart attack or stroke United States of America

The FDA has strengthened its warning that nonaspirin nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, naproxen, diclofenac and celecoxib, can cause heart attacks or strokes. These events can occur from the first weeks of using an NSAID, and can occur in patients without heart disease or cardiovascular risk factors. The risk may increase with longer use and appears to be greater at higher doses. Patients and health care professionals should remain alert for heart-related side effects for the entire time that NSAIDs are being taken. The FDA is requiring updates to the product information of all prescription NSAIDs, and will also request updates to the over-thecounter non-aspirin NSAID Drug Facts labels. (1) New Zealand – Medsafe has

concluded its consultation on the proposed addition of warning statements on labels of overthe-counter oral and topical diclofenac medicines. The updated statements for oral formulations include warnings about their cardiovascular risks. (2)
Ref.: (1) FDA Drug Safety Communication, 9 July 2015. (2) Medsafe News, 19 August 2015.

TGA implements eCTD submissions Australia

Pharmaceutical companies can now submit applications for registration of medicines on the Australian Register of Therapeutic Goods to the TGA in the electronic Common Technical Document (eCTD) format. Paper dossiers are no longer required to accompany eCTD formatted submissions. Paper dossiers are also not required to accompany Non-eCTD electronic Submissions (NeeS). Guidance documents are being updated to reflect the changes. The eCTD format enables a faster, safer and more consistent exchange of information as well as the conduct of electronic review processes for quality, safety and efficacy of medicines. The change to electronic-only submissions follows the successful implementation of a pilot programme in the first six months of 2015.
Ref.: TGA News, 3 July 2015.

FDA regulation on use of antibiotics in food-producing animals United States

The FDA has announced the Veterinary Feed Directive (VFD) final rule, an important piece of the agency's overall strategy to promote the judicious use of antimicrobials in food-producing animals. VFD drugs are veterinary drugs intended for use in or on animal feed that require the supervision of a licensed veterinarian. This strategy will bring the use of VFD drugs under veterinary supervision so that they are used only when necessary for assuring animal health. The VFD final rule is the third of three core FDA policy documents related to the judicious use of medically important antimicrobial drugs in food-producing animals. It outlines the requirements associated with veterinary authorization, distribution and use of VFD drugs in animal feed. The VFD final rule will become effective on 1 October 2015.
Ref.: FDA News release, 2 June 2015.

Chinese drug maker receives USFDA OK to test herbal drug

The USFDA has allowed China-based Yiling Pharmaceutical to launch clinical tests for its Lianhuaqingwen capsule, an herbal treatment for patients with flu and common cold. The safety and effectiveness of the drug was tested when it was used by nine hospitals in China that joined the international effort to find clinical treatments for the influenza type A H1N1 virus epidemic in 2009. The World Health Organization has recognized the records of the treatment's performance from those hospitals.
Ref.: Xinhuanet.com (China)

Specialty overtakes traditional meds in FDA approvals

Specialty medications accounted for more FDA approvals in the past five years than did traditional treatments, even though less than 1% of US patients need them, Aimee Tharaldson, senior clinical consultant at Express Scripts, told a meeting of the Academy of Managed Care Pharmacy. The FDA specialty approval pipeline includes targeted and immunotherapies for cancer, as well as medications for inflammatory conditions, multiple sclerosis, hepatitis C, HIV -- including the first HIV vaccine -- asthma and allergies, bleeding disorders and Duchenne muscular dystrophy. Specialty Pharmacy Continuum

Pics of 57th Indian Pharmaceutical Congress

Mr. Anant Kumar, Union Minister, Ministry of Chemicals & Fertilizers in the Inaugural ceremony of 57th IPC

Mr. J.P. Nadda, Union Minister, Ministry of Health in 57th IPC at Mysuru

Release of handbook on responsible use of medicines-a guide for the layman, published by IPA & PCI

Forthcoming Events

Health Camp at Ganga Sagar Mela
10 – 16th January 2016

Services to be offered:

- **Free Medicines**
- **First AID**
- **Dissimination of Health Awareness information**

Annual Get Together of IPA, Bengal Branch
17th January 2016

Venue: Chanakyapuri Resort (A Unit of Country Club India Ltd.), Ramnagar-2, Canning Road, Baruipur, South 24 Pgs.

Contact Persons:
Mr. P.K.Banerjee, 9433559974
Mr. Joydeep Sanyal, 9477464789
Mr. Dibya Das, 9475678608