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

10th Year

Volume: 10 ***Number: 09*** ***31st July 2016***

Content

Editorial

Practice in Pharmacy is existing in India since long back, with a different name and structure and it has got a regulated structure since implementation of Pharmacy Act 1948. Engagement of Pharmacist in serving the prescription of a registered practitioner has been made mandatory by an amendment of sec 42 of Pharmacy Act 1940, in the year of 1984 and it was further bolstered by the amendment of Rule 65 of Drugs and Cosmetics Rules 1945 in the same year. Publication of "The Role of the Pharmacist in the Health Care System" by World Health Organization in the year of 1990 has given a solid platform to create more conducive environment for growing Pharmacy Practice in India. Dispensing by pharmacists is mandatory worldwide for better health care services. Framing and notification of Pharmacy Practice Regulation 2015 in the month of January 2015 is a landmark event in the history of Pharmaceutical Profession in India, which will certainly help in giving proper shape to the unorganized state of Pharmacy Practice in India. In the present regulation the Pharmacy Practice is well defined and the same has set up certain regulation to regulate the same. The document is available at http://www.pci.nic.in/Circulars/Pharmacy%20Practice%20Regulations.pdf.

In the mean time a few states like Kerala have implemented the same through notification by the state Government. In the last Indian Pharmaceutical Congress a resolution has been passed for implementation of the same and IPCA is pursuing the same. Hope all professional organizations will take up the issue with the concerned authorities, so that all state governments implement the act immediately for improving the health care outcome.

Dr. Subhash C. Mandal
Editor
E mail: subhash.mandaldr@gmail.com
Mob. 9830136291

Drug price regulation saved Rs 4,988cr in 2 yrs

Various drug price regulatory measures by the government helped consumers save Rs 4,988 crore over the last two years, Rajya Sabha was told on 28th July.

Following approval of the pharmaceutical pricing policy in 2012, the government has capped prices of essential medicines at least three times since 2013, when the policy was first implemented by the National Pharmaceutical Pricing Authority through the Drugs Price Control Order (DPCO), 2013.

According to chemicals and fertilizers minister Ananth Kumar, the drug price regulator NPPA had initially brought 530 essential medicines under price control, giving consumers a benefit of Rs 2,422 crore.

Thereafter, the government revised the National List of Essential Medicines to include 404 more drugs, which saved consumers another Rs 2,216 crore. Apart from this, the NPPA also fixed prices of 106 other drugs under public interest provision which saved consumers Rs 350 crore in a span of last two years.

Kumar also said the government planned to make compulsory the existing voluntary uniform code for pharma marketing practices as well as open 3,000 Jan Aushadhi outlets across the country to ensure people got cheap generic drugs instead of costly branded ones.

Admitting that the voluntary code introduced last year had not proven effective in curbing unethical practices, with doctors continuing to prescribe branded instead of generic medicines, Kumar said his ministry had asked the health ministry to ensure it was made compulsory.

Ref. The Times of India

USFDA advises restricting fluoroquinolone antibiotic use for certain uncomplicated infections; warns about disabling side effects that can occur together

The U.S. Food and Drug Administration is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.

An FDA safety review has shown that fluoroquinolones when used systemically (i.e. tablets, capsules, and injectable) are associated with disabling and potentially permanent serious side effects that can occur together. These side effects can involve the tendons, muscles, joints, nerves, and central nervous system.

As a result, we are requiring the drug labels and Medication Guides for all fluoroquinolone antibacterial drugs to be updated to reflect this new safety information. We are continuing to investigate safety issues with fluoroquinolones and will update the public with additional information if it becomes available.

Patients should contact your health care professional immediately if you experience any serious side effects while taking your fluoroquinolone medicine. Some signs and symptoms of serious side effects include tendon, joint and muscle pain, a "pins and needles" tingling or pricking sensation, confusion, and hallucinations. Patients should talk with your health care professional if you have any questions or concerns.

Health care professionals should stop systemic fluoroquinolone treatment immediately if a patient reports serious side effects, and switch to a non-fluoroquinolone antibacterial drug to complete the patient's treatment course.

Fluoroquinolone drugs work by killing or stopping the growth of bacteria that can cause illness (see List of Currently Available FDA-approved Fluoroquinolones for Systemic Use).

We previously communicated safety information associated with systemic fluoroquinolone antibacterial drugs in August 2013 and July 2008. The safety issues described in this Drug Safety Communication were also discussed at an FDA Advisory Committee meeting in November 2015.

We urge patients and health care professionals to report side effects involving fluoroquinolone antibacterial drugs and other drugs to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Source: USFDA

MHRA Drops Pharmacovigilance Compliance Reporting Requirements

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) says it no longer wants drug makers to submit regular drug safety surveillance compliance reports, unless they are specifically requested by the agency. Previously, MHRA used the reports as a factor in its risk-based inspection scheme, at times basing pharmacovigilance inspections on companies' responses to the report questionnaire. While the compliance reports were not mandatory, MHRA said that companies who did not submit them would be given a high-risk rating for the purposes of inspection scheduling."We have used the data provided in these reports to support our inspection scheduling and planning activities. In addition, we have used the reports to enhance the information that we maintain on our inspection universe by understanding the number of pharmacovigilance systems in operation in the UK," MHRA writes. The agency made the announcement in an update to the good pharmacovigilance practice (GPvP) page on its website on Monday, saying, "As of 2016, we no longer require routine compliance reports to be submitted as we now have access to a variety of information sources that can support our scheduling and planning activities."Going forward, MHRA says it will contact companies directly if it requires information about their authorized products and pharmacovigilance systems.However, other aspects of pharmacovigilance practice and reporting will not be affected by the move to halt routine compliance reporting, as MHRA plans to continue its risk-based inspections program using other data to inform scheduling priority.According to MHRA's most recent Pharmacovigilance Inspection Metrics Report, which covers inspections between April 2014 and March 2015, the agency carried out a total of 48 pharmacovigilance inspections. The bulk of which were routine re-inspections (21) or routine first time inspections (15), while only 10 were inspections triggered by a specific issue. - See more at: http://www.raps.org/Regulatory-Focus/News/2016/07/26/25395/MHRA-Drops-Pharmacovigilance-Compliance-Reporting-Requirements/#sthash.mc48vApD.dpuf

Cloud tech aids HIV drug resistance testing

Scientists from Johannesburg have developed a technological innovation, underpinned by cloud computing, which will assist in testing for HIV drug resistance in SA.

Professor Simon Travers and his team of researchers based at the South African National Bioinformatics Institute (SANBI) at the University of the Western Cape (UWC) have launched the Exatype platform, which runs on Amazon Web Services (AWS).

Exatype will improve clinicians' ability to diagnose HIV drug resistance in patients and provide them with a correct course of treatment, by analysing data from

multiple patients securely and simultaneously.

A blood sample is taken from a patient by their doctor or nurse and is sent to a centralised pathology lab. The lab extracts the virus and obtains the DNA sequence of the virus using sequencing machines. The output is then uploaded to the Exatype Web site to be analysed and a report is sent back to the pathology lab or doctor.

"The long-term hope is that these sequencing machines will become so portable that the clinician will be able to easily produce the sequence data at the point of care and receive a drug resistance report immediately," says Travers.

He says this is the first time an analysis platform has been developed that is capable of analysing the data directly from the sequencing machine.

"One other tool is available but requires end-users to do some analysis on the data prior to uploading. It is substantially more expensive and has a much lower accuracy rate than Exatype."

Reference:
http://www.itweb.co.za/index.php?option=com_content&view=article&id=154531

Complaints against 33 'misleading ad' of Patanjali Ayurved

The Information and Broadcasting Ministry on Friday said that complaints against as many as 33 advertisements of Baba Ramdev's Patanjali Ayurved have been received during April 2015-July 2016. These complaints were made against the company's advertisements appearing on TV, print as well as product packaging communications.

Replying to a query in the Lok Sabha, Minister of State for Information & Broadcasting Rajyavardhan Rathore said, "The Department of Consumer Affairs has informed that 17 advertisements out of 21 advertisements complained against were considered to be in violation of the Advertising Standards Council of India (ASCI) Code for Self Regulation of advertising content as per the findings of Consumers Complaints Council (CCC) of ASCI."

The Ministry also said that six product packaging communications (out of eight complained against) and complaints against two TV ads (out of four) were also considered in violation of the ASCI code.

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The Department of Consumer Affairs had earlier launched a portal to look into the grievances against misleading ads by consumers and ASCI has been assigned to process these complaints. In cases, where advertisers do not comply with ASCI directions, such complaints are then referred to the concerned Ministry or regulator to take appropriate actions.

Ref. Hindu Business line

News: IPA, Bengal Branch received best branch Award-2015