Drug Information Bulletin

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Content

Editorial

Scientific studies show, that an estimated 4.8 million people suffering from moderate to severe cancer pain do not receive treatment. Similarly, about 1.4 million people suffering from moderate to severe pain at terminal stages of HIV annually, remain untreated. In India, a million people with cancer and an unknown number of people with other incurable and disabling diseases like HIV/AIDS, need opioids for pain relief and only a minute fraction (0.4%) of the population in need of opioids have access to the drugs. Major barriers to gain access to opioids are complicated regulations and problems related to attitude and knowledge among health professionals, regulators, administrators and the public regarding pain relief and opioids. As a result of collaborative efforts among the WHO, certain Palliative Care Organizations and Pain & Palliative care activists, the Government of India has taken some steps like - asking all state governments to modify the narcotic rules & regulations following a model, extended schedule K exemption to Morphine Tablets. Currently, more than 15 states and union territory in India have simplified regulations, but opioid availability for medical use has improved only in a minority of these states. Establishment of simple standard operating procedures to implement the simplified regulations, advocacy, and aggressive and improved education of professionals are essential for further improvement of the situation.

In the mean time Govt. of India has published a Gazette Notification of NDPS Act 1985 to improve access to opoids for medical purpose. It is expected that the same will be effective to improve palliative care of millions of patients suffering from pain.

Dr. Subhash C. Mandal
Editor

India to let market forces decide medtech prices

India wants to let market forces dictate medtech prices, even as it pursues expanded regulation of drugs, Department of Pharmaceuticals Secretary V.K. Subburaj said. However, the government would like medtech firms to charge reasonable prices and avoid overly high margins, he said. Although the Department of Pharmaceuticals was recently made the nodal body for medical devices in India, other ministries will deal with regulatory and import-export issues.
Ref. Business Standard (India)

Japan launches public-private genome project to combat cancer

The National Cancer Center of Japan is leading a research project with 13 private pharmaceutical firms to gather genomic information from thousands of cancer patients to develop individualized cancer treatments. The project will focus on approximately 150 genes linked to the disease, said Koichi Goto of the National Cancer Center.
Ref. BioSpectrum Asia

FDA task force seeks coordinated registries for medical devices

An FDA task force report summarized in the Journal of the American Medical Association has suggested the creation of a coordinated registries network to monitor the post-marketing performance of medical devices. The report outlines how the platform should be designed to give providers and patients access to near-real-time data. The task force recommended that the program should be capable of providing constant updates on benefits, risks and safety, should be developed through pilot programs that build momentum for the centralized database, and should offer customized analysis for stakeholders and regulators.
Ref. Healthcare Informatics online

ICRIER advocates dynamic and responsive regulation to handle drug quality, safety issues

The Indian Council for Research on International Economic Relations (ICRIER) is now focusing on the drug regulatory reforms in India as the country is at the cusp of a pharmaceutical and medical device regulation reformation phase.

The Council went on to highlight two key focus areas needed to transform the drug regulatory landscape. One was to view the administrative structure and functions of drug regulatory authorities in India and the other was to have an in-depth comprehension of the current drug quality and safety issues in India.

According to Dr Nupur Chowdhury, consultant, ICRIER, the key objective of drug regulation is to ensure patients access to safe, good quality and efficacious drugs. A drug regulatory administration is needed to facilitate the achievement of this objective. For this, it is critical to put in place a dynamic and responsive regulation.

For the conception of a regulatory system, a primary need is to ensure stakeholders are sensitive to regulations. We will need to map the functioning of Central Drugs Standard Control Organisation (CDSCO) and State Drug Regulatory Authorities (SDRAs) to examine the nature and scale of challenges confronting the regulatory authorities, said Dr. Choudhury who was liberating at the ICRIER seminar held recently at New Delhi. Further it is vital to explore lessons drawn from experiences

from global jurisdictions like the USFDA and EMA to ensure that regulations help evolve a set of actionable policy recommendations which are current to cover the new developments in drug research, he added.

Deliberating on final dissemination seminar on 'Drug Regulatory Reforms in India', Dr. Choudhury focused on the 'Administrative Structure and Functions of Drug Regulatory Authorities' in the country. The recent reform efforts began with the Mashelkar Committee Report 2003 which was quite comprehensive covering recommendations on spurious drugs and indicating a ratio of personnel including inspectors to pharma plants in the regulatory departments. Another transformation on the regulatory landscape in India came in with the Ranjit Roy Chaudhary Committee Report 2013 which mandated stringent norms for clinical trials and new drug approvals. The recent Drugs & Cosmetics Amendment Bill 2015 called for central licensing of 17 categories of drugs, he said.

Recommending the need for major policy changes, Dr. Chowdhury said there was need to expand the legislative mandate of Drug Consultative Committee (DCC), ensure public outreach and transparency by building public confidence besides strengthen the risk-based inspections.

Discussing on the drug quality safety issues in the country was Maulik Chokshi, consultant, ICRIER who said that the need of the hour was to undertake drug sampling not just from production plants but also pharmacy outlets in rural areas to make certain efficacy of medicines and wellbeing of the patients.

Dr. BR Jagashetty, former national advisor, (drugs control) to ministry of health & family welfare, and former Karnataka drugs controller who was a participant at the seminar insisted on the creation of a cadre 'Indian Drug Administrative Service (IDAS) on similar lines that of the Indian Administrative Service (IAS) to ensure uniformity in the functioning of the regulatory departments at all states.

Ref. Pharmabiz

Teva to acquire Rimsa for $2.3 billion

Teva announced recently that it has entered into definitive agreements to acquire Mexican firm Representaciones e Investigaciones Médicas SA, also known as Rimsa, in addition to other assets in a transaction valued at $2.3 billion. Teva CEO Erez Vigodman remarked "this acquisition delivers on our strategy of increasing our presence in key emerging markets in order to position Teva for long-term growth in these markets." The Israeli drug maker noted that the transaction is expected to be completed in the first quarter of next year.

The drugmaker said that the acquisition of Rimsa, which generated $227 million in sales last year, will add to earning beginning in 2017. Siggi Olafsson, CEO of Teva Global Generic Medicines, commented "we will build on their brand reputation, successful sales force model, well-established commercial footprint and loyal customer base to introduce additional specialty and generic Teva medicines to patients in Mexico and across the region."

Teva indicated that it would finance the transaction using a combination of cash on hand and lines of credit. The company noted that the deal specifically includes a "portfolio of products and companies, intellectual property, assets and pharmaceutical patents in Latin America and Europe." Earlier this year, Teva reached an agreement to acquire Allergan's global generic business for $40.5 billion, withdrawing its offer to purchase Mylan for $82 per share, or around $40.1 billion.

Ref: Globes, Bloomberg, Fidelity, Street Insider, Business Wire, Market Watch)

NEWS: Forty three posts of Pharmacist cum store keeper created for Blood Banks

Department of Health & Family Welfare, Government of West Bengal recently created 43 Posts of Pharmacist cum Store keeper for Blood Banks (located at District Hospitals & Sub Divisional Hospitals) vide notification No. HF/O/MA/2266/4C-08/2015 dtd. 24th September 2015.

This development materialized due to continuous persuasion of Dr. C.M.Ghosh, Director, Directorate of Drugs Control, Govt. of West Bengal.

Photos from FIP Congress, Dusseldorf, Germany

Dr. Rao Vadlamudi, President, IPA with Ms.Caramen Pena. President.FIP

Dr. Rao Vadlamudi, President, IPA with other participants

Forthcoming Events:

National workshop on "Combating Antimicrobial Resistance"

Call for abstract for Poster presentation:

Abstracts are invited for poster presentation concurrently with National seminar on "Combating Antimicrobial Resistance" scheduled to be held on 22nd November 2015 at H.L.Roy Building, Jadavpur University, Kolkata. The abstracts can be submitted in the following subjects-

Pharmaceutics and Pharmaceutical Technology, Pharmaceutical Chemistry, Pharmacology & Toxicology, Pharmacognosy and Phytochemistry, Regulatory Affairs, Pharmacoepidemiology and Pharmacoeconomics.

Eligibility:

Presentation of the scientific paper is restricted to author who has registered for attending "National seminar on Combating Antimicrobial Resistance" scheduled to be held on 22nd November 2015 at H.L.Roy Building, Jadavpur University, Kolkata.

The presenting author should be final year student of Bachelor of Pharmacy, final year student of Diploma in Pharmacy & M. Pharmacy or having above/ equivalent qualification to Bachelor of Pharmacy. The abstracts will be selected after review by experts.

Abstracts should be sent to-

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