Drug Information Bulletin

Drug Information Centre (DIC)

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Content

Editorial

Pharmaceutical Sciences & Technology is now considered as knowledge based frontier. A medicine which is deemed as life saving today may be banned tomorrow due to surfacing of serious adverse effects/toxic effects or it may be outdated due to introduction of a better alternative. Pharmaceutical technology which is considered latest today, gets outdated tomorrow due to development of newer, more sophisticated high-end, effective technology. Even frequent changes in regulation lead to altering of many dimensions in the field of Pharmacy. To cope with this situation, a pharmacist requires continuous updating of knowledge, and knowledge management. Though there are some isolated efforts to impart continuous education, but there is no structured system.

The following steps are being suggested for proper continuous education of the pharmacists:

1. *A comprehensive programme requires to be put into place after judging the present societal need from the pharmacists.*
2. *A well thought out pharmacy course curriculum, oriented towards good pharmacy practice requires to be implemented throughout the country uniformly.*
3. *Pharmacy council should impart training to pharmacists, or they must recognize training imparted by other organizations and allot credit points considering the effectiveness of the course curriculum/training module.*
4. *PCI should frame suitable legislation to make training mandatory for renewal of registration.*
5. *Pharmacy practice in our country is regulated by two major Acts, which are Drugs & Cosmetics Act and Pharmacy Act, but unfortunately there is no harmonization between these Acts, resulting in ineffective control over the pharmacy practice.*

Europe's tuberculosis bill is rising fast

German health economists say the costs associated with both typical and drug-resistant forms of tuberculosis throughout Europe already total more than $7 billion annually in lost productivity, as well as around $677 million in direct treatment costs. The lead author of the study, published in the European Respiratory Journal, called drug-resistant TB a "time bomb" and urged governments and drugmakers to invest in research to combat the disease. Reuters

Doctors overprescribe Broad-Spectrum Antibiotics

The Wall Street Journal reports that recent studies have found doctors are prescribing too many antibiotics and too often turning to broad-spectrum antibiotics when narrow-spectrum varieties will often be effective. The American Academy of Pediatrics and the Centers for Disease Control and Prevention both caution that overuse can lead to antibiotic-resistant infections and diminish the body's supply of good bacteria. A Journal of Antimicrobial Chemotherapy found that broad-spectrum antibiotics are chosen 60% of the time by doctors, and a pediatric study in the journal Pediatrics found broad-spectrum products chosen about half the time.

Over 15,000 dengue cases reported in India during 2013

India has recorded 15,893 dengue cases in 2013, a sharp increase from last year, health ministry figures show.

In a written reply in the Lok Sabha on Tuesday, Health and Family Welfare Minister Ghulam Nabi Azad said total dengue deaths across the country till July this year were 56 while it was 76 in 2012.

Dengue, a vector-borne disease, has affected major cities of the country. This year 15,893 cases have been reported, a sharp increase from 8,899 cases of last year.

The health minister said there is no single reason for the increase in cases. There could be various man-made and environmental factors, he said.

Azad said, “The unprecedented growth in population, unplanned rapid urbanisation and inadequate waste management are reasons behind the outbreak.”

Water supply mismanagement, gaps in public health infrastructure, increased mobility of population and poor infrastructure to monitor mosquito breeding were some other reasons cited by the health minister.

Kerala reported maximum 5,801 dengue cases followed by Karnataka (3,775), Tamil Nadu (3079) while 12 cases have come from Delhi till the end of July.

Toll has been highest in Kerala and Maharashtra, both reporting 19 deaths each. In Karnataka, 11 people have died while six have succumbed to the disease in Madhya Pradesh.

Dengue fever is a communicable disease and its symptoms include high fever for four to five days, usually accompanied by severe headache, pain in eyes, muscles and joints besides rashes. After the fever goes away, blood platelet count starts dipping. This is the most dangerous phase of the disease.

Obligatory licenses make sense for India, Cipla chairman says

The government of India should push for a compulsory drug licensing system to boost access to treatments, Cipla chairman Yusuf Hamied said during a stop in London. "I am in favour of obligatory licensing where we don't mind paying royalties to the patent holder but at least Indian companies should be able to manufacture and market essential drugs to make them more accessible in

the Third World," Hamied said. India should adopt Canada's system that lets any medicine be copied as long as the patent holder is paid 4% royalties, Hamied said. Business Standard (India)/Press Trust of India

Revival of pharma PSUs endorsed by parliamentary panel in India

India's Department Related Parliamentary Standing Committee on Commerce proposed the revival of drugmakers operating under public sector undertakings to increase the production of generic drugs. "They (pharma PSUs) need to be revived, re-strengthened and made dynamic and healthy so that generic medicines and vaccines are produced in larger quantities and made available to the masses at reasonable prices," the committee said in a report. The committee also proposed a government investigation into the poor performance of the PSUs. Pharmaceutical Business Review Online

Indian pharmas to be hit as US hikes fee

Many Indian drug makers will soon have to bear higher costs for sale of their products in American markets as the United States health regulator, Food and Drug Administration
(FDA) is hiking the fees for generic drug makers by up to 48 per cent from October.

According to the FDA, India is the second largest drug exporter to the US and Indian drug makers mostly specialise in manufacturing generic versions of innovative drugs at lesser cost after the expiry of their patent. Indian pharmas are estimated to command 10 per cent share in the $ 30-billion US generic drug market.

The US regulations require the companies to pay user fees to supplement the costs of reviewing generic drug applications and inspecting facilities.

The FDA's proposed hike in fees for generic drug makers is expected to push up the overall costs for companies from India and other countries, including the US itself.

The FDA said it is aware that the industry is adjusting to the new requirements and fees and it has minimised the hike in fees 'as much as possible'.

The increased fees have been published in the Federal Register, the official journal of the US government.

The proposed hike would be effective from October 1, 2013. The fees would be reviewed after a year.

The latest Abbreviated New Drug Application (ANDA) fee has been fixed at $63,860, which is around 24 per cent higher than the existing $ 51,520.
Ref. DECCAN HERALD

26 new drugs permitted for sale without trials in India

NEW DELHI: Notwithstanding strong warnings by the parliamentary standing committee on health, new drugs continue to be approved for marketing in the country without holding any clinical trials on Indian patients to test their safety and efficacy.
Sources in the Health Ministry admit that as many as 26 new drug molecules have been approved since 2010 without testing them through drug trials on local populations.
While eight new drug molecules of biologicals and non biologicals were

approved by the country's apex drug regulator, the Central Drugs Standard Control Organisation (CDSCO), last year, two have already been allowed for sale so far this year.

As many as 13 such new drugs were approved in 2010 and three more were approved in 2011.

Officials of the health ministry say that new drugs have been approved without clinical trials after taking adequate caution.

They said such drugs are the ones used in medical emergencies and where trials are not possible in the country due to less number of patients and in cases where diseases are rare.

They said that it is only after expert opinion that such drugs are being approved.

Importantly, the approval to 26 new drugs sans local trials comes within two years of the parliamentary panel exposing how 38 new drugs were approved without trials on Indians between January 2008 and October 2010.

The committee had while coming down heavily on the drug controller for allowing untested drugs to be used in India said that many such new drugs did not fall in the category of medicines meant for medical emergencies.

The report had focused nation's attention on the poor state of drug regulation in India and sought immediate corrective measures.

Following the report, the health ministry has introduced several new measures aimed at ensuring efficacy and safety of drugs.

The CDSCO has also written to states to prove within 18 months the safety and efficacy of all such fixed dose combination drugs which have been approved directly by states without seeking prior approval of the apex drug regulator.

The ministry is ready with a new Drugs and Cosmetics Act which deals with clinical trial regulation in a separate chapter.

Forthcoming Event

2nd Pharm. Tech IAPST

International Conference on "New insights into diseases and recent therapeutic approaches"

17th to 19th January 2014
Kolkata, India

Organizer:

Department of Pharmaceutical Technology, Jadavpur University, Kolkata along with the NSHM Knowledge Campus, Kolkata and Indian Association of Pharmaceutical Scientists and Technologists

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