Content

• Celebration of 5th Anniversary of Drug Information Centre (DIC) publishing special issue of Drug Information Bulletin on the auspicious occasion of World Health Day
• UK court finds SEROQUEL XR® formulation patent invalid
• FDA Adds New Side Effects to Finasteride Label
• Fast-track mode work for 264 backward districts’
• PhRMA Member Companies Invested $49.5 Billion in Research and Development in 2011
Celebration of 5th Anniversary of Drug Information Centre (DIC) publishing special issue of Drug Information Bulletin on the auspicious occasion of World Health Day

To commemorate 5th Anniversary of the Drug Information Centre (DIC) a compilation book of all issues published during last year was released in this programme. It has been reported that the DIC started 5 years back is providing services to the health care professionals, Patients and the general people with all information regarding Drugs and Medicines uninterruptedly till the date. Every year this Centre providing information on Indication, ADR, Incompatibility of any drug. It is also providing information on availability, price, generic version etc. to the people from India and abroad. We have a group of experts who are being consulted whenever necessary.

The Drug Information Bulletin was started 5 years back to update IPA, Bengal Branch Members now spread its wings throughout the globe. This publication earned reputation amongst the global health care community. Several Drug Information centers including some Govt. centers have taken permission to reproduce the same in their publication. All dignitaries and the members present appreciated this publication and requested to continue the same.

UK court finds SEROQUEL XR® formulation patent invalid

A High Court in the UK has just declared Astra Zeneca’s formulation patent on SEROQUEL XR® (quetiapine fumarate) prolonged-release tablets invalid. The judgment was given in response to a case filed by India’s Intas Pharmaceuticals Limited and others.

AZ had a patent on SEROQUEL expiring on 23 March 2012. On that expiry some companies wanted to introduce generic version of Serequel. But Astra Zeneca wanted to keep hold on the molecule on the pretext of the SEREQUEL XR formulation that will expire in May 2017.

FDA Adds New Side Effects to Finasteride Label

The Food and Drug Administration on Thursday expanded the warning label on the drug finasteride, which is used to treat enlarged prostate and male pattern baldness, saying some men who took the drug continued to have sexual side effects after they stopped taking it.

Finasteride is the main ingredient in Merck & Co.’s prostate drug Proscar and its baldness treatment Propecia, and in generic equivalents. The drug has been linked to other sexual side effects, but the FDA said it was making further changes to the warning label because some side effects have been noted to continue after patients were no longer taking the drug. The revised warning label for Propecia says some men who took the drug experienced libido disorders, ejaculation disorders, and orgasm disorders that persisted after they were no longer taking it. The label for Proscar now includes decreased libido, and the labels for both drugs were amended to include a description of reported cases of male infertility and poor semen quality that got better or normalized after patients stopped taking the drug.

Proscar was approved in 1992 for symptoms of enlarged prostate, and it is used to reduce the risk of urinary retention or need for surgery in those patients. Propecia was approved in 1997 for treatment of male pattern hair loss.

Finasteride has been shown to reduce the risk of prostate cancer, but in June 2011, the FDA updated the drug’s warning label to say that finasteride may increase the risk of a more serious type of prostate cancer.

Fast-track mode work for 264 backward districts

Work on districts lagging on various health parameters across the country will be fast
tracked in the year ahead, minister of state for health and family welfare Sudip Bandyopadhyay said here on Wednesday.

“The health ministry has identified 264 backward districts across the country which is lagging behind on health parameters. This includes parameters like maternal mortality rate, infant mortality rate, disease burden and effectiveness of policies,” Bandyopadhyay said at a consultation celebrating National Safe Motherhood Day.

“Emphasis is being given on community involvement under the national rural health mission (NRHM) for local health needs that affect these parameters,” the minister added.

The two-day consultation, organised by ministry of health, government of Rajasthan, White Ribbon Alliance and USAID (United States Agency for International Development), saw participation from health workers and officials from all across the country.

While the districts cover states of Jharkhand, Bihar, Orissa and Uttar Pradesh among others, the ministry has also added an additional workforce of 13,000 health managers at the district level. The medical workers will work in assistance with ASHA (Accredited Social Health Activist) and ANM (Auxiliary Nurse and Midwife) workers who are the pulse of the NRHM, said the ministry officials.

“We have added around 13,000 health managers at the local level under NRHM. There has also been an addition to the workforce of specialized doctors, medical officers and Ayush (Ayurveda, Yoga, Unani, Siddha and Homeopathy) doctors,” said Anuradha Gupta, mission director for NRHM, ministry of health.

“Improvement has been there, but we are yet to translate this addition to better statistics. The year ahead for NRHM is very crucial as the centre and states will have to work together on policies,” Gupta added.

The ministry and Rajasthan government also flagged off ‘Hamari Beti Express’ to reach out to rural and urban population over the year and disseminate messages on girl child and sex determination.

[Source: IANS]

**PhRMA Member Companies Invested $49.5 Billion in Research and Development in 2011**

Investment in research and development by members of the Pharmaceutical Research and Manufacturers of America remained strong at $49.5 billion in 2011, as the sector adapts to meet the challenges of evolving science, a changing marketplace and a difficult economic environment.

Biopharmaceutical research companies are continuing to explore the possibilities associated with more targeted therapies and personalized medicines, and are building on the benefits associated with partnerships among experts throughout the research ecosystem.

These efforts are reflected in PhRMA’s new 2012 Industry Profile as well as an updated version of its informational chart pack resource, “Biopharmaceuticals in Perspective,” both released today. Both sets of materials are available for public use and are intended to provide timely, relevant information about the biopharmaceutical research sector, which includes both pharmaceutical and biotechnology companies.

The 2011 R&D investment figures reflect the biopharmaceutical sector’s standing as America’s most research-intensive industry. According to a recent report by the National Science Board of the National Science Foundation, the U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business R&D, representing nearly 20 percent of all domestic R&D funded by U.S. businesses. In the U.S., R&D expenditures among
PhRMA members represented a remarkable 21.1 percent of domestic sales.

"Despite facing market, scientific and regulatory challenges, the U.S. biopharmaceutical sector - led by our member companies - has remained a major contributor to American innovation," said John J. Castellani, PhRMA president and CEO. "Our member companies' investment represents a boost to America's economy, with 78 percent of those dollars invested on our shores. But more importantly, it shows a continued commitment to medical progress that will continue to bring new solutions to America's patients."

In fact, last year alone, 35 new molecular entities received Food and Drug Administration (FDA) approval - one of the highest totals in the last decade. These include medicines that address significant unmet medical need, including two personalized medicines for cancer, 11 new medicines for patients with rare diseases, the first new medicine for lupus since 1955, and two medicines that are the first in a new class to treat Hepatitis C.

These remarkable breakthroughs are a testament to our greater understanding of the molecular and genetic basis of disease. As our knowledge and research capabilities grow, PhRMA member companies are able to use those advances to develop more targeted and effective therapies, a new generation of treatments for the most costly and challenging diseases. According to a survey conducted by the Tufts University Center for the Study of Drug Development, 94 percent of surveyed companies are currently investing in the field of personalized medicine.

"Beyond the impressive numbers reported by our member companies is the unfolding story of how companies are adapting to a changing research paradigm," added Castellani. "Part of that story is our shift to a more agile sector, which increasingly involves collaborative, constructive partnerships with both public and private experts."

The growing complexity of science requires access to broader expertise. These partnerships - which can involve experts from across the healthcare spectrum, including academia, government-funded research, and of course other biopharmaceutical companies - help companies build upon a larger reservoir of knowledge.

Other steps that companies are taking include identifying efficiencies and reorganizing research structures throughout the R&D process and improving productivity and achieving other efficiencies through incorporation of new technologies.

By continuing to explore enhancements to their R&D and manufacturing approaches, PhRMA member companies are striving to turn compounds in their ever-growing pipelines into medical breakthroughs for the good of patients across the world. Today, there are more than 3,200 medicines in clinical trials or undergoing FDA review in the U.S., up from 2,400 in 2005.

The 2011 R&D numbers reflect investment made by PhRMA's 28 full members; the list of current full members is available here. The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members invested an estimated $49.5 billion in 2011 in discovering and developing new medicines.

Source: PharmaLive.com