News Updates: December 10, 2013

PhRMA

Publication: Authint Mail
Edition: Online
Date: December 9, 2013
Headline: Stricter US patents may hamper access to affordable drugs for poor

Synopsis: Access to affordable drugs for the world's poor will be hampered if a US plan to impose stricter pharmaceutical patents is adopted at talks on a Pacific trade pact, activists say. President Barack Obama has portrayed the TPP as the economic centrepiece of renewed US engagement in Asia, which also involves a shift in its defence posture in favour of the Pacific theatre. The World Health Organization says about one-third of the developing world's people do not have access to essential medicines on a regular basis. Generic drugs manufactured by local firms in developing countries have become popular alternatives to branded pharmaceuticals from the West. International charity Oxfam said developing countries negotiating the TPP, or joining it in the future, will be the most affected. "The US is putting the interests of the drug industry above those of public health," said Rohit Malpani, Oxfam policy advisor on access to medicines in a statement this year. He urged the US to "reconsider this approach because it undermines the sustainability of public health-care programmes and discredits trade itself as a tool for poverty reduction". Global advocacy group Avaaz said a poll it commissioned showed 62 percent of Americans, 63 percent of Australians, 70 percent of New Zealanders, and of 75 percent Chileans opposed limiting access to generic medicines through the patent proposal But the lobby group Pharmaceutical Research and Manufacturers of America (PhRMA) said it was necessary for companies to recover investments and conduct further research into new cures. It also said data protection should start from the time the new medicine is approved by regulators for release into the market. Jay Taylor, PhRMA vice president of international affairs, told AFP it takes an average of 10-13 years and more than $1.0 billion in investments to develop a new cure, but not all research projects are successful and some could lead to financial losses. "We do not view intellectual property (IP) as a barrier to access," Taylor said. "IP is a necessary catalyst for the development of new medicines."

FDA / Drug Regulatory / DCGI / Pharma Policy

Publication: The Economic Times
Edition: National
Date: December 10, 2013
Journalist: Kiran Kabtta Somvanshi
Headline: Jubilant Life Sciences: USFDA regulatory rap hits near-term prospects

Synopsis: Drug maker Jubilant Life Sciences has been a laggard in the pharma sector because of a subdued performance in recent quarters. The company's performance in the last quarter was encouraging as it reported a sequential improvement in operations over the preceding quarter - with improvement in margins for its key segments. However, with a recent rap on its knuckles from the drug regulator US FDA for its second manufacturing facility, hopes of a recovery in the company's fortunes and its stock price have been dashed for now.

Publication: The Economic Times
Edition: National
Journalist: Soma Das
Date: December 10, 2013
Headline: Fallout of new US labelling norms: Lawsuits from across Atlantic loom

Synopsis: Indian pharmaceutical companies may have to brace themselves for a possible surge in lawsuits from patients and consumer groups in the United States if the regulator there goes ahead with its plan to grant

generic drugmakers the freedom to update "newly acquired" safety warnings on their product labels. The US Food & Drug Administration (USFDA) is currently inviting public comments on a proposal to allow generic drugmakers to independently update safety warnings on product labels.

Publication: The Economic Times
Edition: National
Date: December 10, 2013
Journalist: Anumeha Chaturvedi
Headline: Management accountants, data scientists, app developers and marketing managers to get big pay hikes this year

Synopsis: Consulting firm Mercer estimates that roles like that of experienced marketing analyst and sales representatives in sectors like automobiles, consumer durables and pharmaceuticals will continue to be on companies' priority list. Jobs in regulatory affairs in the pharma and medical devices sector are in demand and can expect hikes in the range of 11% to 20%, according to Kelly Services. "This is mainly because a lot of Indian companies have been wanting to sell in the US for which they require FDA approval and expertise in FDA filing," says Kamal Karanth, managing director, Kelly Services.

Publication: Business Standard
Edition: National
Date: December 9, 2013
Headline: Gujrat drug inspectors to help USFDA officials

Synopsis: In the backdrop of several pharmaceutical manufacturing facilities that export drugs to the US have coming under the drug regulator's scanner recently, the US Food and Drug Administration (USFDA) has now decided to take help from local drug inspectors when visiting pharma facilities. According to H G Koshia, commissioner of the Food and Drug Control Administration (FDCA) of Gujarat, the government of India has recently initiated a process together with the US drug regulator, whereby local drug inspectors would accompany USFDA officials during their plant visits. "As such at the FDCA we do conduct regular checks on pharma manufacturing facilities whenever there is any compliance issue. However, when one has to export drugs to the US, the manufacturer has to comply with USFDA norms."

Publication: Business Standard
Edition: National
Date: December 9, 2013
Headline: Glenmark Pharma gains after unit launches skin infections cream in US

Synopsis: Glenmark Pharmaceuticals rose 0.68% to Rs 528.65 at 10:07 IST on BSE after the company said its US-based subsidiary announced an exclusive launch of Hydrocortisone Butyrate cream in the United States. Glenmark Generics Inc. (GGI), USA, the subsidiary of Glenmark Generics, announced the exclusive launch of Hydrocortisone Butyrate cream USP, 0.1% in the United States. The company received approval from the United States Food and Drug Administration (US FDA) for Abbreviated New Drug Application (ANDA) for its generic version of Locoid Lipocream on 27 September 2013, Glenmark Pharmaceuticals said in a statement.

Publication: BusinessWorld
Edition: Online
Date: December 10, 2013
Headline: A Gem Of A Drug

Synopsis: Pankaj Patel, chairman and managing director of Zydus Cadila (Cadila Healthcare), announced that his company had developed a drug for treating diabetic dyslipidemia, which combines lipid- and glucose-lowering capabilities in a single molecule. Named Lipaglyn, it will be the first glitazar class of drug to be approved in the world and is the first NCE discovered and developed indigenously by an Indian company. Patel said the Drug Controller General of India (DCGI) had approved the drug for marketing in India. Lipaglyn

was launched in the Indian market in mid-September.

Publication: Press Information Bureau
Edition: Online
Date: December 9, 2013
Headline: Manufacturing and Marketing of Banned/ Unapproved Drugs

Synopsis: Certain cases of manufacturing and marketing of banned/ unapproved drugs have been reported in the country. The Government has taken action against the offenders. The Central Drugs Standard Control Organization (CDSCO) had conducted raids in 2011 in and around Delhi and in Mumbai to check the withdrawal of the drugs Gatifloxacin, Tegaserod and Rosiglitazone after these were prohibited by the Central Government under the provisions of the Drugs & Cosmetics Act, 1940 by notification in the Gazette of India. In 29 shops, banned drugs were found. Action was initiated in those cases as per the provision of the Drugs and Cosmetics Act, 1940. Twenty three cases of new Fixed Dose Combinations (FDCs), considered as new drugs were also found to be licenced by State Licensing Authorities (SLAs) without approval of the Drugs Controller General (India) [DCG(I)]

Publication: Press Information Bureau
Edition: Online
Date: December 9, 2013
Headline: Steps by Government to Strengthen Aefi Monitoring

Synopsis: AEFI surveillance (Adverse Events Following Immunization Surveillance) is a mechanism to track all kinds of adverse events including deaths that may occur following vaccination whether related or unrelated. There is an established system of AEFI surveillance which signals zero tolerance on the part of Government for missing out even single vaccine related adverse event. All these AEFI cases have been examined by the AEFI committee.

Publication: Pharmabiz
Edition: Online
Date: December 10, 2013
Headline: Regulatory officials in Gurgaon seize habit forming drugs worth Rs.one lakh from an unlicensed godown

Synopsis: Regulatory officials from the Gurgaon zone of the FDA, Haryana raided four chemist shops in Gurgaon city and recovered habit forming drugs worth Rs.1 lakh after a long search in an unlicensed godown of a chemist, on Friday last. The seized drugs include codeine syrups and spasmo proxy von capsules besides other type of habit-forming drugs, said Lalith Kumar Goel, senior drug control officer and licensing authority, Gurgaon zone.

Publication: Pharmabiz
Edition: Online
Date: December 9, 2013
Headline: IPC's NCC starts dedicated website for PvPI & organises awareness workshop at NIN Hyderabad from Dec 9-10

Synopsis: Indian Pharmacopoeia Commission (IPC), National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) has now announced the launch of its dedicated website. In order to be familiar with the link: www.ipc.gov.in/PvPI/pv_home.html, the Commission is holding a two-day national workshop from December 9 - 10, 2013 at National Institute of Nutrition (NIN), Hyderabad. While launching the website and toolkit to the nation, Dr Surinder Singh, director, National Institute of Biologicals and former DCGI highlighted the importance of the website and toolkit for the stakeholders. The NIB Chief also provided a snap shot of the initiatives taken by NCC-PvPI under Dr G N Singh, secretary-cum-scientific director, IPC & DCGI to promote patient safety. He lauded the efforts of Dr Thota Prasad, scientific assistant, PvPI, coordinators of AMCs, and technical support from WHO-country office.

Publication: Equity Bulls
Edition: Online
Date: December 9, 2013
Headline: Lupin launches Generic Trilipix Delayed-Release Capsules 45 mg & 135 mg in the US

Synopsis: Pharma Major Lupin Limited (Lupin) announced today that its US subsidiary, Lupin Pharmaceuticals, Inc. (LPI) has launched its generic Fenofibric Acid Delayed-Release Capsules 45 mg and 135 mg. Lupin had earlier received final approval from the US FDA for the same. Lupin's Fenofibric Acid Delayed-Release Capsules 45 mg and 135 mg are the generic equivalent of AbbVie Inc.'s Trilipix® Delayed-Release Capsules 45 mg & 135 mg strengths are indicated as co-administration therapy with statins for the treatment of mixed dyslipidemia, treatment of severe hypertriglyceridemia and primary hypercholesterolemia or mixed dyslipidemia.

Patents / Intellectual Property Rights / Compulsory Drug Licensing

Publication: The Hindu Business Line
Edition: National
Date: December 9, 2013
Headline: Venus Remedies inks pact with Austell Lab for marketing antibacterial drug

Synopsis: Venus Remedies Limited has signed a memorandum of understanding with South African pharmaceutical firm Austell Laboratories to exclusively out license its flagship product Elores in South Africa. The antibiotic adjuvant entity effectively counters serious hospital-acquired infections caused by multidrug-resistant extended-spectrum beta-lactamase (ESBL) and metallo-beta-lactamise (MBl)-producing gram negative bacteria, the company said in a filing to the BSE.

Publication: Pharmabiz
Edition: Online
Date: December 10, 2013
Headline: Baring India sees geographical diversification driven by patent expires, rise in R&D spend as 2 emerging trends

Synopsis: Baring India, a leading private equity fund, signals that Indian pharmaceutical sector seems to suggest two clear emerging trends. One is the greater interest in geographical diversification of the business especially in favour of other emerging markets. The other is the increasing focus and allocation of Indian companies in research & development. The commentary across firms in the industry is giving the impression on the interest their focus is the emerging markets or rest of the world (ROW) markets as these are referred to. The number of patent expiries will peak in 2016 which will restrict the incremental market opportunity in the regulated markets. ROW markets have similar growth drivers like India in terms of higher healthcare spend and medicine consumption supported by improving affordability in turn led by increasing GDP levels.

Publication: SiliconIndia
Edition: Online
Date: December 9, 2013
Headline: Thomson Reuters Releases 2013 State Of Innovation India Report

Synopsis: The Intellectual Property & Science business of Thomson Reuters, the world's leading source of information for businesses and professionals, unveiled the results of its analysis of patent activity for inventions originating in India in a 2013 State of Innovation India report. This information was made publicly available at the recent Innovation Awards 2013 ceremony the company held acknowledging India’s top innovators. Using data from the Thomson Reuters proprietary Derwent World Patents Index, the world’s most trusted, authoritative source of patent information for 50 years, analysts uncovered that the largest sectors of innovation activity by Indian companies are Pharmaceuticals and Transportation. Computing & Control and Communications, which ranked second and third following Pharmaceuticals and before Transportation in total volume, respectively, have a mix of domestic and foreign (non-Indian) patent owners.

Drug Pricing

Publication: Business Standard
Edition: National
Date: December 10, 2013
Headline: Drug retailing: SC upholds 15-day deadline for price-control rollout

Synopsis: The Supreme Court ruled on Monday that manufacturers and importers of pharmaceutical products must implement the Drugs (Prices Control) Order within 15 days from the date of notification or receipt of the order. During these 15 days, they cannot manufacture or clear the bulk drug or formulation at the pre-notification price. “The provisions of the DPC Order are clear, that prices should be revised within 15 days even in regard to formulations manufactured prior to the date of notification or those manufactured within 15 days from the date of notification,” went the verdict by a bench headed by R M Lodha. The court thus dismissed the appeals of the manufacturers, upholding the government stand.

Publication: The Financial Express
Edition: National
Date: December 10, 2013
Journalist: Jayati Ghose , Indu Bhan
Headline: No reprieve for drug cos in new DPCO prices

Synopsis: Reducing the leeway for drug firms to sell older stocks of price-regulated medicines in the market at previously notified — rather than new — prices, the Supreme Court on Monday held that the firms are liable to replace these stocks within the grace period provided by the National Pharmaceuticals Pricing Authority (NPPA). While the ruling was in respect to a dispute involving the now repealed Drug Price Control Orders (DPCOs) 1995 and 1987, which gave 15 days for the old stocks to be replaced, it will have major implications for the pharma industry that has been opposing the 45-days time period given to them for replacing existing stocks under the new DPCO 2013. For the consumer, this means that once the regulator reduces the price of a drug, it will soon be made available at that price, rather than the old (higher) price. The pharma industry, including multinationals like Abbott and Novartis India, have challenged the new drug price fixing orders that were to be implemented from July 29. Even two major industry bodies — the Indian Drug Manufacturers Association and the Confederation of Indian Pharmaceutical Industry — have approached the Delhi High Court, challenging the DPCO 2013 that had asked them to replace stocks in the market with those carrying reduced prices within 45 days of new price notification.

Publication: The Indian Express
Edition: National
Date: December 10, 2013
Headline: Sell drugs at govt rates, not higher prices mentioned on box, says SC

Synopsis: The Supreme Court on Monday ruled that drug manufacturers and retailers cannot sell medicines at higher prices mentioned on the label of the boxes if the government notifies a lower rate. They must implement the price fixed under the Drugs (Prices Control) Order (DPCO) within 15 days from the date of notification. The bench of Justices R M Lodha and Kurian Joseph rejected the argument that the revised prices should not impact the existing stocks.

Clinical Trials

Publication: Mumbai Mirror
Edition: Mumbai
Date: December 10, 2013
Headline: I feel like a college girl

Synopsis: An accounts professor gambled with stem cell therapy to battle diabetes. But experts say it's too soon to sing halleluiah. Jaggi, who admits, "I was so desperate to get well, I didn't bother checking on results with

other patients who'd tried it," isn't alone. And that's odd since stem cell therapy is still in the clinical trial stage in India, with an estimated 4,000 trials currently underway. Dr Pravin Mahajan, a general surgeon researching regenerative medicine for five years, who treated Jaggi among 40 others suffering from arthritis, hair fall, facial scars, acne, muscular dystrophy and cerebral palsy, agrees that not all patients respond to the same degree. "The response depends on the state and immunity of the patient. But all my diabetes patients are now either off insulin or on reduced dosage," he says. All others can be only conducted as clinical trials only after approval from the Drug Controller General of India (DGCI), and for free after the patient signs a consent form. "What is going on across the country is simply not acceptable," says Dr Jotwani.

Publication: Press Information Bureau
Edition: Online
Date: December 9, 2013
Headline: Steps by Government to Strengthen the Approval Procedure for Clinical Trials

Synopsis: The Government of India has taken a number of steps to strengthen the approval procedure for clinical trials, monitoring mechanism and payment of compensation to ensure that safety, rights and well-being of clinical trial subjects are protected. These are as follows:

1. Twelve New Drug Advisory Committees (NDAC) consisting of leading experts from the Government medical colleges, institutes from all over the country have been constituted to advise CDSCO in matters related to approval of clinical trials and new drugs.
2. Applications of Investigational New Drugs (IND), i.e. new drug Substances which have never earlier been used in human beings, are evaluated by the IND committee, chaired by the Director General, Indian Council of Medical Research.
3. Registration of clinical trial in ICMR registry at www.ctri.in has been made mandatory.
4. Guidelines for conducting inspection of Clinical Trial sites and sponsor/Clinical Research Organizations (CROs) have been prepared and posted on CDSCO website.

General Industry

Publication: The Economic Times *(Reproduced from IANS)*
Edition: National
Date: December 9, 2013
Headline: Government identifies exports to Africa with growth potential

Synopsis: Aiming to increase bilateral trade with Africa, the government has identified certain sectors of India's exports to African countries that are presently quite low, the commerce ministry said Monday. Minister of State for Commerce Sudarsana Natchiappan informed parliament that "the sectors identified as having considerable potential for growth in exports from India to Africa are, namely, pharmaceutical products, machinery, plastic and linoleum products, among others

Publication: Business Standard
Edition: National
Date: December 10, 2013
Headline: Health care majors look towards Punjab

Synopsis: Punjab is all set to emerge as the new pharmaceutical hub, with major health sector players such as Biocon, Ranbaxy, Max, Merck eying state for their major investment plans in the next three years. Taking part in the Progressive Punjab Investors' Summit, organised by the state government held here on Monday, the multintional companies said they saw Punjab as the most preferred destination for investment as the state offered the best incentives in the health care sector. The upcoming Medicity in New Chandigarh was the centre of attraction with maximum queries coming for it.

Publication: Mint
Edition: National
Date: December 10, 2013

Headline: Dubai's DM Healthcare plans to invest Rs.4,000 crore in India

Synopsis: Dubai-based healthcare group DM Healthcare Llc is planning to invest at least Rs.4,000 crore in four years in the fast-growing Indian healthcare market, a top executive said. The Dubai group's expansion plans in the Indian healthcare space come at a time when the country's leading hospital service providers Fortis, Apollo and Manipal Group are adopting diverse strategies as they ready themselves to tap the expanding healthcare services market in India and other emerging economies.

Publication: Financial Chronicle
Edition: National
Date: December 9, 2013
Headline: Celon Labs-Aurobindo tieup to develop oncology products

Synopsis: Market for cancer drugs pegged by 2018 at $100 billion
Sequoia Capital-backed Celon Labs has joined hands with pharma major Aurobindo to make and sell innovative and niche hormonal and oncology products, it said on Monday. These generic formulations will be marketed in the US and Europe under a special purpose vehicle named 'Eugia Pharma Specialities'. Aurobindo Pharma owns 60 per cent in the SPV and the rest is with Celon

Innovation

Publication: The Economic Times
Edition: National
Date: December 10, 2013
Author: P Chidambaram
Headline: Future of India depends on inclusive growth and reforms driven by game changing ideas, institutions

Synopsis: "We face issues such as unbalanced, uncoordinated, unsustainable development. There is no strong capability in technological innovation. There is a gap between urban and rural development. Many problems and issues affect interest of the masses such as education, employment, social security, healthcare, housing, environment, food and drug safety, workplace safety, social order, law enforcement, and judicial issues. There is too much formalism and bureaucratism. The anti-corruption situation is still grim. The crucial thing in resolving these issues is to deepen reforms."

Publication: Financial Chronicle *(Op-Ed)*
Edition: National
Author: Arun Kumar Jain, Professor of strategy and corporate governance, IIM-Lucknow
Date: December 9, 2013
Headline: Gearing up the country's universities

Synopsis: Universities are the best arrangement for conducting and communicating new evidence-based research findings for bringing forth new ideas, and pushing the frontiers of knowledge. First, the university system, as it has evolved in our country, is highly risk-averse. The second reason is lack of interdisciplinary approach in innovative research. Faculty members are usually trapped in their own so-called specialisations beyond which it is difficult for them to see. The universities can learn much from the field of medicine which has remarkably blended technology with the traditional and has adapted to the requirements of multiple-specialisation by becoming interdisciplinary. This field banks on real-time results of X-ray or ECG tests, pathology reports can be accessed online by the doctors and patients simultaneously, and consultants can advise from remote locations. The practice has thrived on an excellent partnership between various players in the ecosystem such as medical equipment manufacturers, hospitals and doctors with different specialisations, pathologists and drug producers, among others.

Publication: Press Information Bureau
Edition: Online
Date: December 9, 2013

Headline: **Promotion of Indigenous Technology**

Synopsis: The Government has taken a number of steps for promotion of indigenous technologies. Important among them are given below: National Innovation Foundation (NIF), Ahmedabad conducts biennial national competitions for grass-root level, promote green technologies developed by farmers, mechanics, artisans and validate these innovations and help to protect their Intellectual Property. Technology Development Board (TDB) extends soft loans for promoting inventions of commercially viable technologies. Technology Information, Forecasting and Assessment Council (TIFAC) in collaboration with Small Industries Development Bank of India (SIDBI) facilitates promotion of indigenous technologies. In addition, TIFAC also provides support for promotion of innovative technology/ products through its Technology Refinement and Marketing Programme (TREMAP).

Access and Affordability

Publication: Pharmabiz
Edition: Online
Date: December 9, 2013
Headline: **GE unveils its first lifesciences solution 'AKTA start' developed in India to automate protein purification**

Synopsis: GE Healthcare Life Sciences has launched 'AKTA start', a compact, affordable and easy-to-use preparative chromatography system for laboratory-scale protein purification. It is the latest addition to the company's new generation of ÄKTA systems and the first product designed and developed by the company's research and development centre in India, for the world.