News Updates: September 12, 2014

NPPA/ DPCO/ Drug Pricing

Website: Pharmabiz Edition: Online

Date: September 12, 2014

Headline: Cipla, Pfizer, Sanofi cut prices of diabetic, cardiac drugs as per NPPA order on July 10

Synopsis: Cipla, Pfizer and Sanofi have started supplying drugs capped in the anti-diabetic and cardio-vascular segments as per the July 10 NPPA notification which has brought in as many as 108 anti-diabetic formulation and cardiovascular formulation packs under price control. Few other pharma companies have however approached the Courts against the NPPA order. National Pharmaceutical Pricing Authority (NPPA) had fixed the prices of 108 formulation packs of 50 non scheduled drugs in antidiabetic and cardiovascular segments effective from July 10, 2014 in the wider public interest.

Website: Pharmabiz Edition: Online

Date: September 12, 2014

Headline: NPPA warns of penal action against cos failing to maintain production level of essential drugs

Synopsis: Concerned over the scarcity of certain essential medicines like anti-malarial combination of sulfadoxine + pyrimethamine tablets, rabies vaccine, anti-snake venom, etc in the country, the National Pharmaceutical Pricing Authority (NPPA) has warned the concerned manufacturers and importers of penal action under the relevant provisions of Essential Commodities Act, 1955 if they fail to resolve the issue of shortage of these drugs in the country immediately. The NPPA has also directed them to maintain the production level and adequate supply of these medicines and also ensure submission of the information in Form- III of the Schedule -II of the DPCO, 2013 quarterly. Besides, the NPPA has directed them to comply with the requirements contained in para 21(1) and provide the month-wise production and sale figures for these drugs for the last 12 months under para 29 of DPCO, 2013.

OPPI HR Summit

Publication: Express Pharma

Edition: Online

Date: September 11, 2014

Headline: OPPI organises HR Summit

Synopsis: The Organisation of Pharmaceutical Producers of India (OPPI) recently organised its annual HR Summit on 'Attracting, Developing and Retaining Talent'. The event witnessed participation of business leaders, academia and HR professionals from the pharma and allied industry. At the event, distinguished speakers discussed the HR challenges of the pharma industry and drew upon experiences from other industries to provide likely solutions to these challenges. In his inaugural address, Dr Shailesh Ayyangar, President, OPPI and Managing Director, India and Vice President, South Asia, Sanofi said, "Each business leader needs to be a good HR manager. It is important that the pharma industry is cognisant of the current HR challenges. Innovative talent development programmes alongwith competency and skill development workshops are the need of the hour to harness young talent."

Patents/ IPR/ Compulsory licensing

Publication: The Financial Express

Edition: National

Date: September 12, 2014

Headline: Fresh, detailed norms for drug patent filing examiners

Synopsis: Fresh and detailed guidelines are being put in place for examiners of drug patent filings in the wake of a spate of litigations involving pharmaceutical players in the country. In a bid to provide a thorough patent approval process, the country's intellectual property office — the office of the controller general of patents, designs and trademarks — is now taking steps to ensure that the process of drug patent examinations is being done consistently and in uniform format on all the patent filings.

Publication: Business World

Edition: Online

Date: September 11, 2014

Headline: US Patent Expiries To Benefit India Drugmakers

Synopsis: Expiry of drug patents in the US is great news for not only consumers but also the domestic pharmaceutical industry, where generics account for about 75 per cent of total sales, CARE Ratings said in its report released on Wednesday. Indian pharmaceutical companies have an opportunity to capitalise on the patent cliff and gain a greater share of the growing generics market. At present, India accounts for nearly 40 per cent of generic drugs, over-the-counter products and 10 per cent of finished dosages used in the US.

Similar report in-

Moneycontrol- Drug patent expiry in US- Opportunity for Indian pharma cos

Website: NCPA blog Edition: Online

Date: September 10, 2014

Headline: Indian Patients Suffer from India's Weak Pharmaceutical Patents

Synopsis: India's recently elected Prime Minister, Narendra Modi, will visit the United States later this month. One of the sticking points in the U.S.-India relationship is weakness in India's laws governing intellectual property (IP). The Global Intellectual Property Center of the U.S. Chamber of Commerce ranks 25 countries in its Global IP Index, and India comes in last place. Indian growth will continue to lag as long as this persists, as researchers have demonstrated the positive relationship between IP protection and a country's prosperity. One of India's weak spots is patent protection for new prescription drugs. New research also shows, counterintuitively, that this limits patients' access to new medicines. Professors Ernst R. Berndt and Ian M. Cockburn analyzed the 184 new medicines approved by the U.S. Food and Drug Administration between 2000 and 2009. Shockingly, it took more than five years for half of those drugs to become available in India.

Clinical trials/ Vaccine

Publication: The Hindu Business Line

Edition: National

Date: September 12, 2014

Headline: Clinical trials: pharma firms, labs told to justify benefits for India

Synopsis: Pharmaceutical companies, research labs and others looking to conduct clinical trials will now have to justify the research. India is seen as a cheap destination for clinical trials and companies often test products meant for overseas markets here. A new order issued by the Central Drugs Standard Control Organisation makes it compulsory for these entities to prove why the research needs to be conducted in India.

Website: Health Impact News Daily

Edition: Online

Date: September 11, 2014

Headline: Bill & Melinda Gates Foundation Vaccine Empire on Trial in India

Synopsis: While fraud and corruption are revealed on almost a daily basis now in the vaccine industry, the U.S. mainstream media continues to largely ignore such stories. Outside the U.S., however, the vaccine empires are beginning to crumble, and English versions of the news in mainstream media outlets are available via the Internet. One such country is India, where the Bill & Melinda Gates Foundation and their vaccine empire are under fire, including a pending lawsuit currently being investigated by the India Supreme Court. Narayana Kumar of The Economic Times of India has just written a scathing report of fraud and scandals surrounding the Gates vaccine empire: Controversial vaccine studies: Why is Bill & Melinda Gates Foundation under fire from critics in India?

Cancer

Publication: The Economic Times

Edition: National

Date: September 12, 2014

Headline: New drug approves immunotherapy for Cancer treatment

Synopsis: Many current chemotherapy drugs are expensive too, but most of them offer no cure. Immunotherapy may change this situation a bit. Some clear thinking and action by the government now might ease the pain later for patients. It could think of ways of funding the purchase of drugs for the poor, or take the controversial route of compulsory licensing. In the end, there is no substitute to building India's own research base and developing drugs in the country itself. Aurigene's drugs will be cheap in India if they make it to the market. But the country needs the strength of numbers, and a large number of companies working in this exciting field.

Health Ministry

Website: Pharmabiz Edition: Online

Date: September 12, 2014

Headline: Professional bodies of doctors demand formation of Union of Healthcare Commission of India

Synopsis: The professional bodies of allopathic doctors from all over the country are contemplating on a new idea to put up before the Union government by demanding to form a Union Healthcare Commission for India (UHCI) to bring all the healthcare governance under the control of doctors. With this demand the leaders of the associations, including those of specialties, will soon meet the Union health minister, Dr Harsh Vardhan, it is learnt.

Publication: Mint Edition: Online

Date: September 11, 2014

Headline: AMU scientist urges health ministry to identify occurrence of NDM-4

Synopsis: A scientist at Aligarh Muslim University (AMU) has urged the Union health ministry to launch a nationwide multi-centered joint project to identify the percentage of occurrence of NDM-4, a deadly bacteria variant which was found by researchers in Aligarh recently. Dr Asad Ullah Khan, chief coordinator of the Interdisciplinary Biotechnology Lab, AMU headed the team along with other researchers which found the deadly bacteria also called the "super bug" from a hospital's sewage.

Publication: The Financial Express

Edition: Online

Date: September 12, 2014

Headline: Expert panel likely to recommend raising minimum age for smoking to 25

Synopsis: An expert committee set up by the Health Ministry for recommending amendments to the

Tobacco Regulation Act is likely to recommend that the minimum age for smoking be increased to 25 years from the current 18 years. The committee is also in favour of raising fines for tobacco related offences, including smoking in public, but has decided that the increase should be at a reasonable level. However, the final report on amendments to the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act (COTPA), 2003, is yet to be prepared. Former Delhi health secretary Ramesh Chandra, who heads the committee, said the report will be ready early next week.

Similar report in-

Outlook- Neither Cigarette Nor A Cure

Publication: Deccan Chronicle

Edition: National

Date: September 12, 2014

Headline: Corruption likely in faculty postings of six new AIIMS

Synopsis: Even before premier medical institute — All India Institute of Medical Sciences (AIIMS) — could start functioning in six other cities in the country, large scale irregularities in the appointment of faculty members of these institutes have come to light. The Union ministry of health and family welfare has sought CBI probe into the alleged irregularities committed in the appointment of faculty members in the 'ophthalmology' department in these medical institutes which are being set-up in Patna, Jodhpur, Bhopal, Bhubaneshwar, Rishikesh and Raipur.

Modi government

Publication: The Times of India

Edition: Online

Date: September 12, 2014

Headline: Food security tops agenda of FAO director general's meeting with Prime Minister Modi

Synopsis: Prime Minister Narendra Modi and Food and Agriculture Organization director general Jose Graziano da Silva have agreed on how to strengthen efforts to promote India's food security and sustainable agricultural development during talks held in New Delhi, stated an official statement. Tuesday's meeting was Modi's first with the FAO director general since he took office as Prime Minister in May 2014. During the discussions, the Indian leader expressed his concern on the impact that international trade agreements could have on national efforts to fight hunger and defended the setting up of strategic food stocks. Prime Minister Modi urged FAO to defend the concerns of the poor and farmers in developing countries.

Publication: Deccan Chronicle

Edition: Online

Date: September 12, 2014

Headline: US, Indian biz community pitch for PM Modi's visit to US

Synopsis: The US and Indian businessmen have high hopes over Prime Minister Narendra Modi's visit to the US as they believe that it has the potential to unlock huge trade opportunities between the two countries. The US business community is expected to take up the issue of the ease of doing of business in India while the Indian businessmen are expecting the Prime Minister to take up the issue of visa restrictions and social security with the US authorities.

FDA

Publication: The Economic Times

Edition: National

Date: September 12, 2014

Headline: Sun Pharmaceutical's woes deepen as US arm Taro recalls Warfarin from markets

Synopsis: Sun Pharma's recall worries continue with its American subsidiary Taro recalling its leading blood clot drug from the market after the USFDA found that the product did not meet its quality norms. Taro has recalled Warfarin Sodium after the USFDA faulted its poor quality.

Similar reports in-

Mint- Sun Pharma falls 6% on FDA inspection report

Business Standard- Sun Pharma, Ranbaxy extends fall on US FDA's surprise plant inspection

Daily News & Analysis- Sun tanks 6% as Halol unit comes under cloud

The Hindu- Sun Pharma stock price reacts on news of US FDA's surprise plant inspection

Website: Pharmabiz Edition: Online

Date: September 12, 2014

Headline: Mumbai FDA lab report says drugs with ADRs in patients are of standard quality

Synopsis: Maharashtra Food & Drug Administration's (FDA) Mumbai testing lab, in its recent report, says the concoction of drugs ceftriaxone and cefotaxime which led to adverse reactions in patients at three state run government hospitals a fortnight ago in Mumbai are of standard quality. Maharashtra FDA is also in the process of directing stockists and hospitals to allow use of ceftriaxone and cefotaxime. Maharashtra FDA had started a probe a fortnight ago into three other cases of adverse drug reactions at the state-run Indira Gandhi Memorial Hospital (IGM) in Bhiwandi and later at BMC-run K B Bhabha and Rajawadi hospitals in Ghatkopar. In the case of the Bhiwandi and Ghatkopar hospitals, all patients went home after some days, but the drug reaction at Bhabha Hospital claimed the life of a 47 year old lady.

FDI Insurance

Publication: Business Standard

Edition: Online

Date: September 11, 2014

Headline: GIC to meet select panel on insurance tomorrow

Synopsis: The General Insurance Council (GIC), comprising private sector players and state-owned general insurers, will meet the select committee of Parliament on the controversial Insurance Bill to put across its views and suggestions on the bill in New Delhi tomorrow. The bill, which proposes to hike the FDI limit in the insurance sector to 49 per cent, has been caught in a logjam with the Congress-led opposition insisting that it be referred to a select committee.

Public health

Publication: Business Standard

Edition: Online

Date: September 11, 2014

Headline: Oral health a major threat to public health: Mukherjee

Synopsis: Underlining that oral diseases pose a major threat to public health, President Pranab Mukherjee today said they have become leading health problems resulting from tobacco use, alcohol and changing life style. Inaugurating the FDI Annual World Dental Congress hosted by the Indian Dental Association at Greater Noida, Mukherjee said most people are ignorant of the significance of oral health and its impact on general health.

Publication: The Hindu Edition: Thiruvananthapuram Date: September 12, 2014

Headline: State records good show in DLHS 4

Synopsis: Kerala has emerged as one of the well-performing States in the District-Level Family Health Survey 4 (DLHS 4) (2012-13) undertaken by the Ministry of Health and Family Welfare. There have been significant improvements in immunisation coverage and ante-natal care for women. The survey covered all 14 districts in the State. The data was collected between April 2013 and February 2014.

CSR

Publication: Mint Edition: National

Date: September 12, 2014

Opinion piece: Sudeep Chakravarti

Headline: Toilets: Bare necessities for CSR

Synopsis: There appears to be a flurry of breathless activity in the space of corporate social responsibility (CSR). But there is this matter of earning brownie points. It can even make some efforts seem transactional. You know: toilet equals transgression. The Prime Minister's Independence Day speech focused, among other matters, on the need for sanitation appears to have hit home. IndiaCSR.in, a web site that showcases chief executive officers and CSR professionals, has announced the India Sanitation Summit 2014 for mid-December in New Delhi. Billed as India's first summit and award, Sanitation for All—Toilet First, it hopes to showcase "the agenda of priority for our visionary Prime Minister Shri Narendra Modi".

Publication: The Hindu Business Line

Edition: National

Date: September 12, 2014

Headline: Toilet revolution through CSR: Companies, varsity pitch in with mega plans

Synopsis: Responding to the Independence Day appeal by Prime Minister Narendra Modi, leading corporate houses and a university have come up with big ticket projects to set up around 30,000 new toilets in schools, with funds to the tune of hundreds of crores of rupees. While Larsen and Toubro plans to construct some 5,000 toilets, the Vedanta Group's Hindustan Zinc would construct 10,000 and the Jaipur-based Indian Institute of Health Management Research (IIHMR) University has plans to add 13,000 toilets in 6,500 schools.

General Industry

Publication: The Hindu Business Line

Edition: National

Date: September 12, 2014

Headline: For new entrepreneurs, pharma sector 'formidable' to crack

Synopsis: Even as contract manufacturing of pharmaceutical products provides ample opportunity for small and medium enterprises to grow, the sector remains a distant dream for new entrepreneurs. Costly machinery, stringent regulatory norms and price controls are seen as major deterrents for new entrepreneurs from venturing into the pharmaceuticals business, even in contract manufacturing, which contributes about 50 per cent to the country's ₹77,000-crore domestic drug business. According to industry insiders, contract manufacturing in the country is growing at the rate of 20 per cent per annum.

Publication: Business Standard

Edition: Online

Date: September 11, 2014

Headline: Unnecessary antibiotic use ups avoidable healthcare costs

Synopsis: Widespread use of unnecessary and duplicative antibiotics in US hospitals could have led to an estimated USD 163 million in potentially avoidable healthcare costs, scientists, including one of Indianorigin, have found. The inappropriate use of antibiotics can increase risk to patient safety, reduce the efficacy of these drugs and drive up avoidable healthcare costs, researchers said. "The overuse of

antibiotics is an industry-wide public health issue that is occurring across all care settings," said Leslie Schultz, the lead author of the study and director of the Premier Safety Institute, Premier, Inc.

Publication: Mint Edition: National

Date: September 12, 2014

Headline: India's drug industry to touch \$48 billion by 2018

Synopsis: India's drugs and pharmaceuticals industry is likely to post total sales of Rs.2.91 trillion (\$47.88 billion) by 2018, with an average yearly growth of at least 14%, aided by a rapidly growing domestic market and the newly emerging export opportunity as patents of at least a dozen blockbuster drugs in the US expire in the next three years. "During 2014-2016, about \$92 billion worth patented drugs are expected to go off patent in the US as compared with \$65 billion during 2010-12," says an industry analysis report released on Wednesday by Care Ratings, India's second largest credit rating agency. The domestic drugs industry, which is valued at Rs.1.6 trillion at present, according to Care Ratings, is also expected to grow in the local market with aggressive rural penetration by drug makers, increased government spending on health and growing health awareness among people.

Publication: Forbes Edition: Online

Date: September 11, 2014

Blog: Vijay Ramnath Jayaraman, writes about the business of healthcare in India and the U.S.

Headline: 5 Things to know about India's Healthcare System

Synopsis: Now that the 2014 general elections are in the rear view mirror, Prime Minister Narendra Modi and his ministers face the challenge of expectations set by the media and all his supporters. One of the key challenges his team will be facing is: Healthcare. With the World Health Organization's 2000 World Health Report ranking India's healthcare system at 112 out of 190 countries, some key questions in his mind should be: How should the country transform its healthcare system? What are its current pain points? What could be achieved during his tenure? For those living in urban areas, healthcare is merely a political issue. They argue that the country faces bigger challenges such as economic development, infrastructure, jobs, and border disputes with Pakistan. I believe that the 2014 elections have presented India with a unique opportunity to take a fresh look at its healthcare landscape. I was happy to browse through the PM's campaign website which had a section on his achievements in this sector.

Publication: Business Standard

Edition: Online

Date: September 11, 2014

Headline: Pharma contract manufacturers seek WHO-GMP compliance

Synopsis: As the share of multinational firms (MNCs) in pharmaceuticals contract manufacturing rises, more and more companies are looking at upgrading their facilities as per the World Health Organisation-Good Manufacturing Practices (WHO-GMP) norms to meet quality standards. What's more according to the Indian Drug Manufacturers' Association (IDMA) the Centre is likely to incentivise the upgradation of Schedule M facilities to WHO-GMP compliant units through scheme of soft loans.

Publication: Mint Edition: National

Date: September 12, 2014

Headline: Hormone drug combination therapy gives new hope to tackle diabetes

Synopsis: New findings from clinical studies on thousands of type-2 diabetics in the US and Canada may open up a new treatment to counter the world's most prevalent disease. The systematic review and meta-analysis study, led by a doctor of Indian origin and published in the latest edition of The Lancet, finds that a combined treatment with a drug that mimics the action of a gut hormone and basal insulin is much more

effective in improving blood sugar control than all existing anti-diabetic treatments. The new approach also reduces the risk of hypoglycemia, or low blood sugar, and weight gain associated with the existing treatment regime.

Publication: The Wall Street Journal

Edition: National

Date: September 11, 2014
Blog: Ed Silversman (Pharmalot)

Headline: Generic Drugs Saved Americans How Much Money?

Synopsis: The prices for some generic drugs may have risen precipitously in recent months, but a new report from the trade group representing generic drug makers boasts that these medicines saved Americans nearly \$239 billion last year, a 14% increase from the year before. And much of those savings came from new generics – about \$140 billion – while older copycat drugs helped U.S. consumers pocket \$98 billion in savings. A new generic refers to a drug that recently became available after a brand-name drug lost patent protection.

Publication: The Times of India

Edition: Online

Date: September 12, 2014

Headline: Nitish seeks official record on drug purchase scam

Synopsis: In his first reaction to medicine and equipment scam, former CM Nitish Kumar on Thursday shot a letter to the chief secretary, asking to provide him all the details of the purchase of the medicine by the State Health Society (SHS) and Bihar Medical Services Infrastructure Corporation Limited (BMSICL). The former CM also sent a letter in this regard to his former deputy and BJP leader Sushil Kumar Modi who has hurled frequent charges against him.