



News Updates: August 8, 2014

OPPI Access Summit

Publication: Tarun Bharat

Edition: Mumbai

Date: August 8, 2014

Headline: 'Healthcare Access Summit' organized in Mumbai (Scan Attached)

Synopsis: OPPI is organizing the third 'Healthcare Access Summit' in Mumbai.

Patents/ Compulsory licensing/ IPR

Publication: The Economic Times

Edition: Online

Date: August 7, 2014

Headline: [High Court issues notice on PIL over disclosure policy of Patents Act](#)

Synopsis: It has been eight years since Right to Information (RTI) Act came into being but the country's activists are clueless about what happens when India's most potent information weapon clashes with other information dispensation mechanisms coded in a host of other pre-existing laws--such as Patents Act and Companies Act. This has become the moot point of a public interest litigation, filed by Shamnad Basheer, a patent expert in the Delhi High Court, which argued on Wednesday that the government arms are misusing these grey areas to frustrate RTI seekers and conceal information, which they should be readily sharing under the transparency law. Basheer, under RTI had sought information on the level at which pharma companies are commercialising the patents they hold particularly in critical and chronic diseases such as cancer, AIDS, diabetes, Hepatitis and more. This sort of information all patent holders are mandated to file with the patent office annually in a prescribed format.

WTO/ Modi government

Publication: The Economic Times

Edition: National

Date: August 8, 2014

Headline: [India, US to talk ways to remove differences on trade](#)

Synopsis: After sparring for months, India and the US are finally getting down to negotiate ways to sort out their differences on trade and economy. A team of senior officials from the US Trade Representative's office will reach the Capital later this week to discuss issues ranging from India's patent regime to Washington's reluctance to have a liberal visa regime for local techies. The meeting — which comes days after talks at the World Trade Organization over easier customs rules collapsed — is a precursor to much awaited India-US Trade Policy Forum, the ministerial level consultations, scheduled for later this year.

Publication: The Economic Times

Edition: National

Date: August 8, 2014

Headline: [Government has done more work in 60 days than UPA did in 6 Parliament sessions: Nirmala Sitharaman](#)

Synopsis: An interview with the Minister of State for Commerce and Industry, Corporate Affairs and Finance on matters related to IPR, industry, FDI, WTO, the Union Budget and more.

Publication: Money Control

Edition: Online

Date: August 7, 2014

Headline: [Biocon committed to list Syngene amid boost in R&D spends](#)

Synopsis: The biotech firm is currently engaging with potential partners to out-license novel molecule Itolizumab, says Kiran Mazumdar Shaw, CMD, Biocon. The healthcare major remains committed to listing Syngene with an increase in Research and Development (R&D) spends, she says in an interview with CNBC-TV18's Latha Venkatesh and Sonia Shenoy.

Q: If I can start of by asking you about the NPPA stand-off, we had you speaking on the issue and the impact it would have on the pharmaceutical sector as a whole, what is the status currently on that and what kind of an impact would it have on the sector?

A: I have been overseas until yesterday so I am not very updated on what is happening on that front but I haven't heard any progress on that front other than the fact that Indian Pharmaceutical Association (IPA) members did take this to the court and I know that the court has asked for a hearing later in September but there is no stay on the matter. The issue is about the formula used to arrive at a price ceiling because having a price ceiling per se is not a grave concern but how do you arrive at the price ceiling is something that will impact the industry as a whole. Therefore, I am not very clear on what progress has been made but I do hope that there is an engagement with the government to resolve this stand-off.

Q: I understand you had written an open letter to the PMO regarding the unilateral fixing of prices; did you get any response to that letter?

A: Unfortunately, not as yet. I have not yet heard from the PMO and I remain optimistic that some discussions and engagement will happen with industry because this is a very vital industry for the country, and this is one industry that has attained global leadership almost on its own because it has had very little support in terms of incentives from the government. This is a sector that is almost entirely self-funded and self perpetuated. Therefore, this sector needs investment, support and I hope government does not neglect this very important sector.

Health ministry

Publication: The Times of India

Edition: Online

Date: August 8, 2014

Headline: [33% of generic medicine stores non-functional](#)

Synopsis: Over one-third of generic drug stores or Jan Aushadhi Stores (JAS), which started during UPA rule, are lying defunct across states, including the maximum of 53 such stores in Rajasthan, opened during Ashok Gehlot's tenure. In a written reply in Lok Sabha, MoS (chemical & fertilizer) Nihal Chand submitted that till July, 166 JAS had been opened and 76 of them are non-functional. He submitted that stores are lying closed due to change in health policy of state governments and for administrative reasons. The states where more such stores are functional include Odisha, Punjab, Jharkhand and Jammu & Kashmir. While Odisha has a maximum of 22 such stores operational, Punjab has such 21. None of the stores in Andhra Pradesh, West Bengal and Uttarakhand is operational.

Publication: Business Standard

Edition: National

Date: August 8, 2014

Headline: [Allow pharmacists as medical practitioners in rural areas: IPA](#)

Synopsis: Soon pharmacists may don the role of a medical practitioner in rural areas if the proposal made by the Indian Pharmacist Association (IPA) to the Union Ministry of Health comes through. The IPA has suggested that pharmacists be allowed to double up as non-doctor medical cadre in the rural areas with some additional training as they already have knowledge of pharmacology. IPA has stated in its representation made to the Union Health minister Harsh Vardhan last month that, "Union Cabinet has approved BSc Community Health

course. The main objective of the course as stated is to create mid-level health professionals with necessary public health and ambulatory care competencies to serve the rural population. MBBS can't be substituted with any other cadre. The course is against the wishes of 'The Parliamentary Standing Committee on health'."

Publication: Hindustan Times

Edition: National

Date: August 8, 2014

Headline: CAG raps Assam govt on NRHM fund-misallocation (*scan attached*)

Synopsis: The recent report of the CAG which was tabled in the budget session of the Assam Assembly, highlighted gross misuse of funds provided under NRHM, the Union ministry of health and family welfare's flagship health scheme. "Mission Director, NRHM, Guwahati and Govt, of Assam made deviation in the revised estimate from the approved estimate without obtaining approval from Govt of India which result the expenditure of ^46.50 crore incurred on incomplete super-specialty hospital unfruitful", the report alleged.

Publication: The Hindu

Edition: Vijayawada

Date: August 8, 2014

Headline: [Health Minister releases 60-day progress report](#)

Synopsis: Getting the Medical Council of India approve 950 medical seats for the State has been listed as the first major achievement by Health Minister Kamineni Srinivas. In a report released on completing 60 days in office, the Minister said besides the 650 seats in government medical colleges, he was able to get the MCI approve another 300 seats in private medical colleges. The sanction of Rs 1,200 crore for the establishment of an AIIMS-like super-specialty hospital in Vijayawada, Rs. 120 crore for the re-opening of a cancer hospital at Chinakakani in Guntur district, sanction of Rs. 45 crore each for cancer units in Visakhapatnam, Nellore and Kurnool districts, sanctioning of a Nature Cure unit in Guntur General Hospital, basic equipment for SVIMS in Tirupati and VIMS in Visakhapatnam and Rs. 40 crore (Rs. 20 crore each) for development of maternity hospitals at Kakinada and Guntur are top on the Minister's progress report.

Website: Cliniindia.com

Edition: Online

Date: August 8, 2014

Headline: [Pharma Positive news - CDSCO STRENGTHENING REGULATORY SYSTEM "D5"](#)

Synopsis: Under the 12th five year Plan, a budgetary allocation of Rs.1750 crore is provided by the Union finance ministry for expanding the country's entire drug control machinery. Out of this, a sum of Rs. 900 crore is earmarked for the strengthening the Central Drugs Standard Control Organisation, country's apex drug regulatory body while the remaining Rs. 850 crore is expected to be spent for the development of the state regulatory bodies. The funds will be used to help the CDSCO and state drug control departments in their capacity building measures like construction of new drug testing laboratories, expansion of existing facilities and hiring of regulatory staff. Adequate regulatory infrastructure, qualified technical staff and proper coordination between the Centre and state governments are the key factors that determine the efficient functioning of a national drug control network. And that is what has been lacking in the country for several years despite India being a major producer and exporter of drugs and pharmaceuticals today.

Publication: Pharmabiz

Edition: Online

Date: August 8, 2014

Headline: [Centre's efforts to launch Pharm D course in govt colleges fails to take off, allocation of Rs.624 cr may lapse](#)

Synopsis: An amount of Rs.824 crore allocated by the Central government to introduce Pharm D course in government medical colleges may soon lapse as most of the government colleges are yet to start this

advanced pharmacy degree course. The Pharmacy Council of India (PCI) has given approval to several pharmacy colleges attached to government medical colleges in various parts of the country, but the principals of the institutions are not taking any follow up action to commence the course.

Innovation

Publication: Business Standard

Edition: National

Date: August 8, 2014

Headline: [R Gopalakrishnan: Innovation across borders](#)

Synopsis: Foreign direct investment can encourage a healthy flow of research & development in either direction.

Foreign direct investment (FDI) is vital to world economic growth as well as for India. Hence, I was delighted to speak at The World Forum for FDI 2014 in Philadelphia in June. My subject, however, seemed unusual: the connection between FDI and innovation. As I prepared, I learnt some not-so-top-of-mind nuances.

First, why FDI? For 14 years, A T Kearney has published its annual FDI Confidence Index. The 2014 report shows that global confidence in India was ranked seven, just behind Germany and just ahead of Australia and Singapore - does not seem bad. However, India was number two in 2012 and number five in 2013, so India has also been slipping. Knowing the political and economic events in the country, perhaps this is no surprise. There is a good prospect of a recovery in rankings in the near future. The report argued that a core group of developing economies (China, Brazil and India) continues to enjoy widespread confidence among business leaders. Eighty per cent of respondents showed optimism about the global economy, better than the 50 and 37 per cent in the two years before. Considering that the world FDI inflows are about \$1,500 billion a year, China is impressive at \$120 billion a year, but India is not so, with a much lower \$25 billion annually.

All of this is a statement of opportunity for an India, where confidence is currently on an upswing.

USFDA/FDA

Publication: The Economic Times

Edition: Online

Date: August 8, 2014

Headline: [Novo Nordisk says Food and Drug Administration approval for Tresiba could come end-2015](#)

Synopsis: Novo Nordisk could receive an approval from the US Food and Drug Administration for Tresiba by the end of next year, paving the way for its launch in the United States at the start of 2016, the company's chief executive said on Thursday. "Sometime in the first half (of 2015) we will be able to submit this additional data to the FDA, then the FDA has six months to review this. If we calculate the best possible scenario then we could see an approval by the end of the year meaning a launch into the beginning of 2016," Lars Rebien Sorensen told journalists on a call.

Publication: Business Standard

Edition: National

Date: August 8, 2014

Headline: [Zydus Cadila gets USFDA nod for kidney stone tablets](#)

Synopsis: Ahmedabad-based pharmaceutical major Zydus Cadila has received the final approval from the US drug regulator to market Potassium Citrate tablets that are used in the prevention of kidney stones. The company today said in a statement here that it has received the nod from the US Food and Drug Administration (USFDA) to market Potassium Citrate tablets in strengths of 5, 10 and 15 mEq. "The estimated sales in 2014 for Potassium Citrate ER Tablets is \$ 131.7 million, as per IMS," the statement said. The group now has 94 approvals and has so far filed 239 ANDAs since the commencement of the filing process in FY 2003-04.

Website: Moneycontrol.com

Edition: Online

Date: August 8, 2014

Headline: [Ipca tanks 10%; USFDA lists 6 serious violations at Ratlam](#)

Synopsis: Shares of Ipca Labs tanked over 10 percent intraday on Friday as US Food and Drug Administration (FDA) has raised more concerns over its quality. The drug regulator's Form 483 to IPCA Labs' Ratlam active pharmaceutical ingredients (APIs) facility lists six serious deviations from current good manufacturing practices (cGMP) on quality & training. The form details two severe data integrity issues in plant observed in the inspection done between July 14 and July 18 of the Ratlam API facility. Observations also point to senior staff involvement in data falsification. Lab analysts said they were "forced" to falsify the record by a direct supervisor. Quality system issues also date back to 2011 inspection that cited similar issues. There are issues overwriting previous raw data and falsifying batches being placed along with instances of manipulating integration parameters so as to achieve desirable results.

Website: Pharmabiz.com

Edition: Online

Date: August 8, 2014

Headline: [Overprescription of antibiotics, sedatives rampant despite Sch H1 norms](#)

Synopsis: Even when Maharashtra Food and Drug Administration (FDA) is trying to implement Schedule H1 Rules, city-based chemists rue that around 25 per cent of antibiotics, sedatives and pain-killer drugs are overprescribed by doctors and are purchased in bulk for drug addiction and substance abuse. Chemists say that dispensing these drugs comes with an added burden of maintaining detailed records and prescriptions albeit with a low margin. Medicines are not dispensed at times if the patients do not have valid prescriptions as in some cases doctors don't write clear prescriptions and with even longer validity ranging from over a year to six months. Says a city-based physician, "Chemists have stopped stocking sedatives and pain-killers which are covered under Schedule H1 as they are most often irrationally consumed."

General Industry

Publication: The Economic Times

Edition: National

Date: August 8, 2014

Headline: Sun-Ranbaxy Deal an Acid Test for CCI (scan attached)

Synopsis: The \$3.2-billion acquisition of Ranbaxy Laboratories by Sun Pharmaceutical Industries will be a test for the Industry Friendliness of the Competition Commission of India (CCI), which so far has cleared most merger and acquisition applications that have come before it.

Publication: Business Standard

Edition: National

Date: August 8, 2014

Headline: [Ranbaxy brands to stay alive](#)

Synopsis: Sun Pharmaceutical Industries has, in the wake of the acquisition of Ranbaxy Laboratories, prepared ambitious plans on research and development. A spokesman at Sun, largest pharma company in the country after the merger (and fifth largest speciality generics one in the world), said: "(We) intend to retain all of Ranbaxy's brands in, more or less, all markets. The brand itself has a rich heritage and value. Though no specific details have been worked out, Sun would like to preserve the Ranbaxy brand in geographies where it is an asset and has a perceived value." The exception might be America where the Ranbaxy brand has perhaps taken a beating. The company might consider phasing out the brand over time. Otherwise, the combined Sun-Ranbaxy entity will have operations in 65 countries, 47 manufacturing facilities across five continents, and a significant platform of speciality and generic products marketed globally, including 629 Abbreviated New Drug Applications.

Publication: The Economic Times

Edition: New Delhi

Date: August 8, 2014

Headline: [‘Ebola outbreak to get bigger before receding’](#)

Synopsis: Two cities, 10,000 km apart, have become the focus of attention in the ongoing Ebola epidemic that has taken 932 lives so far in Western Africa. One is Lagos in Nigeria, and the other Atlanta in US. Meanwhile, a top Ebola expert told TOI that the outbreak will get bigger before receding and that pharmaceutical companies had neglected vaccine development because Ebola affects some of the poorest countries. In Lagos, the first Nigerian casualty occurred on Wednesday. Lagos has a population of 21 million and is one of the densest and fastest growing cities in the world. If the deadly Ebola virus were to spread there, unimaginable havoc would ensue.

Publication: Hindustan Times

Edition: Kolkata

Date: August 8, 2014

Headline: R&D centers will help tame outbreak: Guv *(Scan Attached)*

Synopsis: Concerned over the outbreak of encephalitis in north Bengal and Uttar Pradesh’s Gorakhpur, West Bengal governor Keshri Nath Tripathi has requested the union health minister, Dr Harsh Vardhan, to set up research centres in the two states to find out the exact cause of the disease, Japanese Encephalitis (JE) and other similar viral diseases. After taking charge as the constitutional head of Bengal, Tripathi called on Prime Minister Narendra Modi in Delhi on Wednesday. He also briefed the Union health minister over phone about the encephalitis outbreak and requested him to take steps to prevent it from spreading further. “I have briefed the Union health minister (Harsha Vardhan) about the encephalitis outbreak in Bengal. He is very concerned. I have requested him to set up some research centres in Bengal and UP in order to find out the cause of the disease. The centres will help doctors cure the disease. He (Vardhan) has assured me he will look into my proposal,” Tripathi told HT over phone from Delhi.

Publication: The Financial Chronicle

Edition: Chennai

Date: August 8, 2014

Headline: [GSKCH evaluating Physiogel, NiQuitin products for India](#)

Synopsis: GlaxoSmithKline Consumer Healthcare plans to bring in more products being sold by the parent company globally to expand its portfolio of over-the-counter products in India. Skincare brand Physiogel and anti-smoking product NiQuitin are among the ones being evaluated for India launch. Physiogel is a skincare brand of Stiefel Laboratories with products like moisturisers, cleansers, lotions, shower creams and sunscreen lotion. Stiefel, the US-based pharmaceutical company that GSK acquired in 2009, is a leading name among dermatological product manufacturers and its products are available in 132 countries. Along with wellness and dental care, skincare is one of the main verticals for GSK globally.

Publication: The Hindu Business Line

Edition: National

Date: August 8, 2014

Headline: [A crisis of epidemic proportions *\(Op-Ed\)*](#)

Synopsis: Rising resistance to antibiotics could negate much of the advancements of modern medicine. At the peak of the discovery and use of antibiotics, a US Surgeon-General said: “The time has come to close the chapter of infectious diseases”. Sadly, this was not to be. Disease-causing microorganisms have effectively countered antibiotics by developing resistance to their action, called antimicrobial resistance (AMR). Several germs have accumulated resistance against almost all available antibiotics, making them “superbugs”. The world is at the brink of a disaster. Unless concerted global actions are initiated immediately, it is heading for the pre-antibiotic era with unstoppable progress of infectious diseases.

Publication: The Hindu

Edition: New Delhi

Date: August 8, 2014

Headline: CBI can't probe medical colleges under MCI, rules HC *(scan attached)*

Synopsis: In a landmark judgment, the Madras High Court has ruled that the Central Bureau of Investigation has no jurisdiction to investigate the affairs of any medical institution within the purview of the Medical Council of India (MCI). The MCI Act and regulations formed a complete code by themselves, providing for every contingency in the running of a medical institution, periodical inspection and action to be taken if the MCI did not do its work properly.

Publication: Deccan Chronicle

Edition: Chennai

Date: August 8, 2014

Headline: [Tamil Nadu healthcare role model for world: WHO](#)

Synopsis: World Health Organisation's (WHO) representative in India Dr Nata Menabde lauded the efforts of the Tamil Nadu government in providing quality healthcare to all its citizens. "Tamil Nadu is one of the top performing states by economic indicators, health indicators or by management and health system performance indicators. There are many things that TN has accomplished in terms of system improvements; so many things are possible to do," Dr Nata Menabde said while inaugurating the National Consultation on "Improving Access; Promoting Innovation" in the context of universal health coverage at IIT-Madras Research Park on Thursday.