



News Updates: August 20, 2014

OPPI- UCPMP

Publication: The Economic Times

Edition: Online

Date: August 19, 2014

Headline: [OPPI asks Department of Pharmaceuticals to make Uniform Code of Pharmaceutical Marketing Practices a statutory code](#) (flashed by PTI)

Synopsis: Organisation of Pharmaceutical Producers of India (OPPI) has urged the Department of Pharmaceuticals (DoP) to make its Uniform Code of Pharmaceutical Marketing Practices (UCPMP) a statutory code in the best interests of patients and the industry. This would lead to increased levels of transparency and accountability across the healthcare industry and remove ambiguity on all aspects of pharmaceutical marketing, OPPI Director General Ranjana Smetacek said here today.

Similar report in-

Business Standard- [OPPI asks Department of Pharma to make UCPMP a statutory code](#)

Drug pricing/ NPPA

Website: Pharmabiz

Edition: Online

Date: August 20, 2014

Headline: [DoP asks NPPA to revalidate data on Famotidine tabs of Abbott Healthcare, rejects review petition of Fresenius](#)

Synopsis: The Department of Pharmaceuticals (DoP) has directed the National Pharmaceutical Pricing Authority (NPPA) to revalidate data on Famotidine tablet 20mg on a review application filed by Abbott Healthcare Pvt. Ltd. against fixation of ceiling prices of Famotidine tablet 20mg. The NPPA vide its price fixation Order S.O. No.1016(E) dated 2.4.2014 had fixed the ceiling price of scheduled medicine Famotidine tablet 20mg under Drugs Prices Control Order, 2013 (DPCO, 2013). Aggrieved by the NPPA notification, Abbott Healthcare had represented to the reviewing authority, DoP, against the price fixation. After personal hearing on 18.7.2014, the DoP decided, "NPPA is directed to revalidate the data of the Petitioner as empowered under para 9 of DPCO, 2013. Whether Gelatin coated tablets are technologically different and deserve a different ceiling price the matter may be referred to Standing Technical Committee for advice. The Petitioner in the meantime is directed to maintain the ceiling price already notified by NPPA".

Patents/ Compulsory licensing/ Intellectual Property Rights/ Access

Website: NDTV

Edition: Online

Date: August 20, 2014

Headline: [Generic Opportunities to Drive Indian Pharma Sector Growth: Icra](#)

Synopsis: With many drugs going off patent in the US, Indian pharma companies would continue to experience strong growth in American market, credit rating agency Icra has said. Indian pharma companies would continue to experience strong growth in the US over the medium-term. This would be driven by the sizable generic opportunity (drugs with brand value of \$25-30 billion are expected to face generic competition) over the next 2-3 years, the investment information and credit rating agency said in a statement. The other factor that would drive growth will be "strong product pipeline of pending ANDAs with high increasing proportion of complex generics that compares favourably with generic majors such as Teva, Mylan and Actavis", it added.

Website: Pharmabiz

Edition: Online

Date: August 20, 2014

Headline: [Granting CL for Dasatinib](#) (editorial)

Synopsis: The Department of Industrial Policy and Promotion (DIPP) last week once again approached the health ministry with the request to grant a compulsory license (CL) for the cancer drug, Dasatinib, on the ground that it is unaffordable to several thousands of cancer patients in the country. DIPP had already rejected the health ministry's request to grant CL for Dasatinib, a patented drug of US based Bristol Myers Squibb, in March last on technical grounds. The health ministry wanted the government to issue a CL under Section 92 of the Indian Patents Act which allows issue of licences in a situation of national emergency or for a public non-commercial use. DIPP's stand is that if the health ministry wanted a CL to be issued for a drug on the affordability ground, application should be made under Section 84 of the Patent Act and generic drug firms have to first seek a compulsory licence for the same. The government then starts a process of calling for applications from these companies. But the generic companies have not yet applied for a CL for the manufacture of generic versions of this cancer drug from DIPP. India's first CL was granted in 2012 under Section 84 to Hyderabad-based Natco Pharma to manufacture a generic version of another cancer drug, Nexavar, belonging to German multinational, Bayer.

Blog: SpicyIP

Edition: Online

Date: August 19, 2014

Headline: [Access to Medicines for Hepatitis C: Evaluating the Arsenal – Part II](#)

Synopsis: Gilead's 300\$ a bottle (900\$/12 weeks) announcement for blockbuster anti Hepatitis C drug 'Sovaldi' comes at a time when Gilead is under tremendous pressure internationally from both governments and civil society organisations to decrease their exorbitant pricing (see here, here and here). In Part I of this post I described developments in India in relation to the drug. In this post I look at the larger picture and situate Gilead's pricing decisions in the context of targeted advocacy as well as the existence of and willingness to utilise TRIPS flexibilities that promote public health. Gilead's announcement and the advocacy surrounding it give us a unique chance to evaluate the tools available to safeguard public health interests in the face of abuse of patent monopolies.

MCI/ Medical corruption

Publication: The Asian Age

Edition: National

Date: August 20, 2014

Headline: [Taking gifts can now get Doctors in trouble](#)

Synopsis: The code of ethics for doctors restricts them from accepting gifts from pharmaceutical companies and health sector firms. Doctors accepting gifts/commissions from the pharmaceutical companies, beware. For the first time ever Medical Council of India (MCI) has suspended two doctors after they were found to be accepting commissions from pharmaceutical companies. The code of ethics for doctors restricts them from accepting gifts from the pharmaceutical companies and health sector firms. "While it was notified long back, this is for the first time that such a stringent action has been taken against the doctors," said a senior official in the health ministry.

Health ministry

Publication: The Economic Times

Edition: Online

Date: August 19, 2014

Headline: [Politics will not interfere with health policy: Harsh Vardhan](#)

Synopsis: Politics should in no way affect the health programme and policies of the country, Union Health Minister Harsh Vardhan today emphasised even as he stressed on "improving health" of the

various government departments. "For the health of the nation, the health of government departments needs to be improved. I will not let politics to interfere in the health of the country," said Vardhan as he launched a music video on child health and immunisation created by Global Health Strategies in collaboration with the Ministry of Health and Family Welfare.

Similar report in-

The New Indian Express- ['Government Aims to Immunise Every Child Against Fatal Diseases'](#)

Website: IANS

Edition: Online

Date: August 20, 2014

Headline: [Indian health portal is 'match maker' for doctors abroad](#)

Synopsis: A newly launched Indian health portal www.swaasthIndia.gov.in serves as a "match maker" between public & private medical institutions in India and from around the globe. Launched under the leadership of American Association of Physicians of Indian Origin (AAPI), the portal provides a platform to connect Government of India's health related requirements with medical expertise of physicians of Indian origin globally. It is also intended to ensure a seamless and easy online interaction for users of SwaasthIndia, ensuring a comfortable, efficient and productive experience, according to a media release from one of the largest ethnic organisation representing 100,000 Indian-American doctors.

Modi government/ WTO/ Indo- US ties

Website: IBN Live

Edition: Online

Date: August 19, 2014

Headline: [Modi government mulling raising age limit for tobacco consumption from 18 to 25 years: sources](#)

Synopsis: There is more bad news for cigarette smokers as there could soon be an age limit for smokers. Three months into being in power, the Narendra Modi government is working on curbing the consumption of tobacco products. After raising taxes on cigarettes and calling for a countrywide ban on sale of tobacco products, sources have told CNN-IBN that the Centre is considering banning branding on cigarette packets, raising the age limit on tobacco consumption to 25 years from the present 18 years and substantively increasing penalties for smoking in public. Health Minister Harsh Vardhan had constituted a committee of experts last month to suggest changes to the Cigarettes and Other Tobacco Products Act 2003. The report is expected by the end of this month.

Publication: The Economic Times

Edition: National

Date: August 20, 2014

Headline: [G20 countries expected to cite food security to make India take a relook at its WTO stance](#)

Synopsis: G20 countries are expected to impress upon India the benefits of easier trade facilitation for global food security, when Prime Minister Narendra Modi attends the G20 leaders' summit in Brisbane this November, where India's vetoing of the WTO Bali trade deal would be high on the agenda. A coalition of G20 countries' business communities, working together as B20, has pointed out that 30% of the world's food is wasted due to trade barriers so the WTO pact is important for food security reasons as well.

Similar reports in-

The Hindu- [India confident of solution to food security issue at WTO](#)

The Financial Express- [Govt concerned over WTO 'attempt to push developed world's agenda'](#)

Website: Firtspost

Edition: Online

Date: August 19, 2014

Headline: [India Inc's loo-natic rush for toilets, post Modi's I-Day speech, is a win-win for all](#)

Synopsis: Narendra Modi's passion for toilet-building, mentioned before but given a new impetus in his Independence Day speech, has opened the flood gates to focused corporate spending in the area. In quick succession, many profitable companies and corporate trusts, from Tata Consultancy Services to Bharti Foundation, Hindustan Unilever, Aditya Birla Group, ITC and Adani Group, among others, have announced plans to focus their corporate social responsibility (CSR) spending in toilet building, especially for girls. Most of them have pledged substantial sums (Rs 100 crore or thereabouts) and are talking about building thousands of toilets – not the odd one or two in one village or two.

FDA/ Drug quality

Website: Pharmabiz

Edition: Online

Date: August 20, 2014

Headline: [State FDA scrutinises 23 cases of violation by wholesalers for non-compliance to D&C Rules](#)

Synopsis: As a part of its drive to ensure compliance to the conditions of wholesale licence, the Maharashtra Food and Drug Administration (FDA) is in the process of scrutinising 23 wholesalers from Mumbai and Thane with reference to violations of conditions of licence as stipulated in Rule 65 of Drugs and Cosmetics Rules, 1945. As per officials, show cause notices can also be served to the wholesalers for their explanations. Cases of violation under scrutiny are 13 from Thane Division and 10 from Mumbai. The FDA started the drive to inspect licences of around 18,000 drug wholesalers in the state from July, 2014 onwards to detect malpractices related to violations of conditions of license. The state as of today has 18000 wholesalers including those who export and import. Out of this, there are around 4000 stockists who supply to the retail trade.

Publication: Daily News & Analysis

Edition: Mumbai, Pune

Date: August 20, 2014

Headline: Too many drug reaction caste worry govt (*link unavailable, scan attached*)

Synopsis: Strange but true. Consuming medicines may land you in hospital! Medicines are known to have side effects that range from mild to severe. Some adverse drug reaction (ADR) can even lead to death. ADR refers to an Injury caused by a drug taken in normal or high dosages. It may also be caused if a drug is of sub-standard quality or has been used past its expiry date. On Monday; 28 women developed suspected ADR after being administered antibiotics Ceftriaxone and Cefotaxime at Kurla Bhabha Hospital. Of the 28,47-year-old Suraiya Shaikh is critical and is being treated at KEM Hospital.

Innovation

Website: Vox

Edition: Online

Date: August 19, 2014

Headline: [New study shows exactly how patent trolls destroy innovation](#)

Synopsis: Everyone agrees that there's been an explosion of patent litigation in recent years, and that lawsuits from non-practicing entities (NPEs) — known to critics as patent trolls — are a major factor. But there's a big debate about whether trolls are creating a drag on innovation — and if so, how big the problem is. A new study by researchers at Harvard and the University of Texas provides some insight on this question. Drawing from data on litigation, R&D spending, and patent citations, the researchers find that firms that are forced to pay NPEs (either because they lost a lawsuit or settled out of court) dramatically reduce R&D spending: losing firms spent \$211 million

less on R&D, on average, than firms that won a lawsuit against a troll. "After losing to NPEs, firms significantly reduce R&D spending — both projects inside the firm and acquiring innovative R&D outside the firm," the authors write. "Our evidence suggests that it really is the NPE litigation event that causes this decrease in innovation.

FDI- Insurance

Publication: Mint

Edition: Online

Date: August 19, 2014

Headline: [Government, RSS-backed trade unions set for face-off](#)

Synopsis: A tussle is brewing between the nearly three-month-old Narendra Modi government and the Rashtriya Swayamsevak Sangh (RSS)-affiliated trade unions that are preparing to launch a nationwide stir against the government's recent decision to open up the railways to foreign direct investment (FDI) and raise the cap on FDI in insurance and defence. These organizations are also annoyed that the government has delayed taking a final decision on demands to ban field trials of genetically modified crops.

General Industry

Publication: Business World

Edition: Online

Date: August 20, 2014

Headline: [Too big to ignore](#)

Synopsis: The proposed Sun-Ranbaxy deal, where Mumbai-based pharmaceutical major Sun Pharma has agreed to pay \$ 3.2 billion to acquire Ranbaxy Laboratories from its majority shareholder Daiichi Sankyo of Japan, is a fit case for scrutiny by the Competition Commission of India (CCI) for two reasons. First of all, India's competition law makes it mandatory for companies engaged in such activities to seek the CCI approval before the conclusion of the deal if the M&A activity results in the creation of combined assets worth Rs 1,500 crore or a sales turnover of Rs 4,500 crore and above. With a combined revenue estimate of over Rs 25,000 crore, Sun-Ranbaxy clearly is above the initial threshold. Secondly, approval of the CCI is needed if products from the combined entity have a market share of over 15 per cent. Here again, industry estimates indicate that there are at least two dozen medicines where the market share of Sun-Ranbaxy is significantly higher than the threshold limit. Thus, it is only natural that the CCI, whose key responsibilities include monitoring M&As to ensure that the combined entity does not cause appreciable adverse impact on competition, should scrutinise the Sun-Ranbaxy deal.

Publication: The Financial Chronicle

Edition: National

Date: August 20, 2014

Headline: **Generic drug prospects to fuel pharma sector in India** (*link unavailable, scan attached*)

Synopsis: With many drugs going off patent in the US, Indian pharma companies to experience strong growth in American market, a credit rating agency has said. Indian pharma companies would continue to experience strong growth in the US over the medium term.

Publication: The Asian Age

Edition: National

Date: August 20, 2014

Headline: [Drug firms try merger and acquisition route](#)

Synopsis: Leading Indian pharmaceutical companies are expected to opt for the merger and acquisition (M&A) strategy to scale up their businesses in emerging markets as they are looking to diversify beyond their traditional markets seeking steady and sustainable growth. Emerging markets now account for just about 10-15 per cent of India's total pharma exports while the US accounts for

around 40 per cent of the total pharma exports. Of the 22 pharma companies that ICRA spoke to, some of the leading players are looking at acquisition for geographical expansion, while others are trying to fill their portfolio gap and scale up their technological capabilities.

Publication: The Indian Express

Edition: National

Date: August 20, 2014

Opinion piece: Poonam Khetrpal Singh, regional director, WHO Southeast Asia

Headline: [An emergency called Ebola](#)

Synopsis: The World Health Organisation has declared the current outbreak of the Ebola virus disease in some countries in West Africa as a public health emergency of international concern. The aim of this declaration is to contain existing outbreaks and prevent the further spread of Ebola through an internationally coordinated response. The declaration also serves as an international alert, so that countries can prepare for possible cases. It will help mobilise foreign aid and action to fight Ebola in affected countries. As of today, there are no cases of Ebola in the 11 countries of the WHO's Southeast Asia region. This is the time to step up preparedness. A successful public health response will need strong health systems with sensitive surveillance, infection control and community mobilisation.

Publication: Deccan Herald

Edition: National

Date: August 20, 2014

Headline: [WHO to focus on safe withdrawal of oral vaccine in polio-free India](#)

Synopsis: Nearly five months after declaring India free of polio, the World Health Organisation (WHO) is now focussing on implementing a risk-free withdrawal of the oral polio vaccine. At the regional consultation meeting on polio eradication and immunisation here on Tuesday, Dr Poonam Khetrpal Singh, regional director of WHO South-East Asia, said that member-states of the region were working on implementing the final and most critical strategy for polio eradication: the Polio Endgame Strategy. The first phase of this strategy involves a global switch from the trivalent oral polio vaccine to the bivalent oral polio vaccine in the immunisation programme and the introduction of Inactivated Polio Vaccine (IPV) in the entire country prior to this switch.

Website: Moneycontrol

Edition: Online

Date: August 19, 2014

Headline: [Drug makers set for 40% capex jump to Rs 50000 cr: CRISIL](#)

Synopsis: According to CRISIL, India's top 20 pharmaceutical companies are set to crank up capital expenditure (capex) by around 40% to over Rs.50,000 crore by fiscal 2018, in order to take advantage of greater opportunities from patent expiries and rising use of generics in the regulated markets, especially the US. That translates into an average capex of Rs.12,500 crore annually, compared with around Rs.9,000 crore seen in each of the last four fiscals. Yet the credit-risk profiles of these 20 drug makers - of which CRISIL rates a dozen -- are not expected to be impacted significantly because of steady cash flows from operations. Besides, leverage will remain moderate-to-comfortable as cash surpluses accrued in the last few years will be supportive.

Publication: The Economic Times

Edition: Online

Date: August 20, 2014

Headline: [More exits from Ranbaxy Laboratories' top management team](#)

Synopsis: Ranbaxy Laboratories' global HR head Sandeep Girotra has stepped down while its president of global pharma business, Rajiv Gulati, plans to leave soon, continuing the shake-up in senior management at the drugmaker that began a few months ago. Both Girotra and Gulati have

been part of the executive management council, the 10-member apex body that provides functional leadership to the company, people familiar with matter told ET, confirming the development.

Publication: Business Standard (B2B Connect)

Edition: Online

Date: August 19, 2014

Interview: Veena Singh, Regional Commercial Manager, Dow Pharma & Food Solutions, Dow India

Headline: ["Novel drug delivery system is driving the demand for innovative excipients"](#)

Synopsis: Recently, Dow Chemical International Pvt Ltd, the Indian arm of the US-based chemical major Dow Chemical Company, announced the establishment of a Pharma Task Force to collaborate with the industry for discovering the un-met needs of the sector. Task force aims to bring together allied Dow businesses to deliver well rounded, innovative solutions that will pave way for the growth of the pharmaceutical sector. In conversation with Rakesh Rao, Veena Singh, Regional Commercial Manager, Dow Pharma & Food Solutions, Dow India, elaborates more on this task force and the excipients market in India.