News Updates: August 23-25, 2014

Drug pricing/ NPPA

Publication: The Hindu Business Line
Edition: National
Date: August 25, 2014
Opinion piece: David Taylor, Emeritus Professor of Pharmaceutical and Public Health Policy at University College, London
Headline: Not by cheap medicines alone (link unavailable, scan attached)

Synopsis: Drug price controls in affluent nations are mainly focused on ensuring that new products that have intellectual property protection are profitable enough to encourage ongoing research spending, yet are also affordable to the population. In Western Europe, access to pharmaceutical treatments and the diagnostic and other services needed to deliver health good outcomes is funded via health care systems, in turn funded through taxation or regulated health insurance schemes. However, the social and economic conditions, that permit both the successful use of market mechanisms to control generic medicine prices and good provision of health services, do not yet exist in economies like India.

Publication: The Hindu
Edition: National
Date: August 25, 2014
Opinion piece: Rahul Prithiani, Director, Crisil Research, a division of Crisil
Headline: A feel good order for consumers, but a pain for the pharma industry

Synopsis: The latest government order to control prices of certain drugs in the cardiovascular and anti-diabetic segments may only cause some near-term growth wobbles in the affected therapies but the larger fear that it has ignited within the pharma industry is that of similar such interventions in future in non-essential drugs. We believe multinational companies such as Sanofi, AstraZeneca and Merck will be the worst affected because of their higher exposure to the drugs covered under the new notification and the premium pricing they enjoy. As a result, the revenue loss for these companies could be in the range of 8-10 per cent of their domestic pharmaceutical market in 2014-15.

Publication: The Financial Chronicle
Edition: National
Date: August 25, 2014
Headline: Impact of new policy on drug prices soon (link unavailable, scan attached)

Synopsis: The Indian pharmaceuticals market (IPM) achieved 7.2 per cent growth in July and 7.7 per cent growth in H1 of calendar year 2014. While the pharma market achieved double-digit growth in June, IPM's return to single digit growth was due to the impact of NPPA's new guidance on pricing premium of non-NLEM drugs. NPPA issued price ceiling list for 49 molecules (108 formulations) in diabetes and cardiac segment in June. The regulator also guided other therapeutic areas' non-NLEM drugs with a suggestion of ceiling upto 25 per cent premium to the SAP (simple average price) of drugs (branded and generics) in a therapeutic segment. We believe this has reduced inventory movements in July, which is reflected in the volume growth of non-NLEM drugs at 0.5 per cent in July compared with 4.3 per cent in June.

Publication: The Asian Age
Edition: National
Date: August 24, 2014
Headline: Pharma companies challenge price fixing

Synopsis: In response to pharmaceutical companies challenging the legality behind the National Pharmaceutical Pricing Authority (NPPA) fixing the price of 50 cardiovascular and diabetic drugs, civic societies have written a letter to the union health minister Dr Harsh Vardhan and the union chemicals and fertilizers minister Ananth Kumar to remain firm on price control. The letter has been forwarded by the All India Drug Action Network (AIDAN), Jan Swasthya Abhiyan, Low Cost Standard Therapeutics (LOCOST), Medico Friends Circle, Third World Network- India, All India People's Science Network (AIPSN) and National Working Group on Patent Laws.

Publication: The Western Times
Edition: Ahmedabad
Date: August 25, 2014
Headline: Pharma Cos. Go to court over new price controls (link unavailable, scan attached)

Synopsis: Major Indian pharmaceutical companies have filed a petition in the High Court in Mumbai protesting the prices cuts ordered by the National Pharmaceuticals Pricing Authority NPPA a fortnight ago which they feel would be detrimental to industry interests. The Indian Pharmaceutical Alliance whose members include leading Indian pharmaceuticals manufacturers such as sun Pharmaceuticals, Lupin, Cadila, Healthcare, and Dr. Reddy's Laboratories, filed the petition.

Website: Pharmabiz
Edition: Online
Date: August 25, 2014
Headline: NPPA issues draft Internal Guidelines for dealing with cases of price revision under Para 19 of DPCO, 2013

Synopsis: The National Pharmaceutical Pricing Authority (NPPA) has issued draft Internal Guidelines for dealing with cases of price revision under Para 19 of DPCO, 2013. As per the draft guidelines, the price revision under para 19 shall be initiated only if the weighted average price of any API used in scheduled formulations based on the immediate last six months purchases goes up by more than 25 per cent as compared to previous six months. The concerned company/companies having market share more than 50 per cent may submit relevant purchase data to NPPA duly supported with evidences for revision of ceiling price, clearly demonstrating the impact of increase in price of API on the ceiling prices of the scheduled formulation with specified dosage and strength.

Website: Pharmabiz
Edition: Online
Date: August 23, 2014
Headline: NPPA fixes/revises ceiling and retail prices of 56 formulation packs

Synopsis: The National Pharmaceutical Pricing Authority (NPPA) has fixed or revised the prices in respect of 56 formulation packs both ceiling and retail price packs under Drugs Prices Control Order (DPCO), 2013. The formulation packs whose prices have been fixed or revised by the NPPA are based on the bulk drugs neomycin + bacitracin, phenylephrine, phenytoin sodium, polygeline, pyridoxine, sodium meglumine diatrizoate, cefotaxime, chlorpromazine, paracetamol+mefenamic acid, dicyclomine HCl with combination, atorvastatin with combination, cyclosporine with combination, pyrimethamine with sulphamethoxypyridazine (Malarce), metformin hydrochloride with gliclazide+pioglitazone, tramadol + diclofenac, cetirizine HCl with paracetamol + phenylepherin HCl, bisoprolol fumarate with amlodipine and glimepiride + metformin hydrochloride (Azulix 4 MF & Azulix 3 MF).

Website: Firtspost
Edition: Online
Date: August 23, 2014
Headline: Drug price debate; Don't cow down to pharma pressure, activists tell govt

Synopsis: Several civil society groups working in the public health sector have asked the Union government not to cow down to the pressure of the pharmaceutical industry regarding its progressive steps to cap the pricing of essential and lifesaving medicines. The first of the government steps was a Drug Prices Control Order in 2013 (DPCO 2013) that brought 348 medicines under an essential list, followed by another order in July this year that released a new set of price notifications for 50 cardio vascular and diabetes medicines.

Publication: Economic & Political Weekly
Edition: Online
Date: August 23, 2014
Headline: Pharma Price Control Policy

Synopsis: Despite the government's and pharmaceutical lobby's claims and counterclaims, the Drugs (Prices Control) Order, 2013, which covers only 18% of the total domestic market of Rs 71,246 crore, has had very little positive effect as a price control policy. This article points out that the Order leaves out much that should have been included, while including much that should have been left out. Its provisions have made the playing field more uneven, with multiple ceiling prices, which is very unfair to consumers already dealing with an irrationally priced market.

Publication: The Hindu Business Line
Edition: National
Date: August 24, 2014
Headline: Business Line Twenty Years Ago Today- Drug policy leaves many questions unanswered

Synopsis: "Delightfully vague". That was the comment of a top executive in an Indian drug company on the drug policy. Pushed to explain, the executive said it was delightful as the number of bulk drugs under price control will come down from 143 to 73. It was vague as the Government statement does not dwell on details. By accepting the turnover limit of Rs. 4 crores per drug, the Government has given the indication that all bulk drugs and their formulations above this limit will come under price control. It is quite likely that the price controlled drugs will have Maximum Allowable Post Manufacturing Expense (MAPE) of 100 per cent. The twin-tier price control system with 75 per cent and 100 per cent MAPE as at present will go.

Patents/ IPR/ Compulsory licensing

Publication: The Financial Express
Edition: National
Date: August 24, 2014
Headline: IPAB admits Pfizer's plea against rejection of patent for arthritis drug

Synopsis: US pharma major Pfizer Products was on Friday allowed to appeal against the rejection of its patent application for Tofacitinib, a drug for treating rheumatoid arthritis. Allowing a condonation of delay (CoD) petition by the drug major, the Intellectual Property Appellate Board (IPAB) said that the company had cited sufficient and valid reasons for the delay of 33 months and 12 days. The board has allowed it to file an appeal against the rejection by the assistant controller of Patents & Designs, Mumbai, through an order dated June 9, 2011.

Clinical trials

Publication: The Indian Express
Edition: National
Date: August 25, 2014
Headline: '76 clinical trials approved under new norms'

Synopsis: With uncertainty looming over the fate of global clinical trials in India, the government has informed the Supreme Court that it has approved 76 clinical trials after re-examining them under the new regulatory regime and complying with the court orders on the issues of safety of the subjects and

their benefits to India.
Out of these 76 cases of global clinical trials involving new pharmaceutical compounds, 64 trials are ongoing while 12 are yet to begin. The Technical Committee and the Apex Committee, entrusted with evaluation of clinical trials, have however suspended two other clinical trials, relating to patients with advanced HIV diseases. These two cases failed the test of assessment of risk versus benefit to the patients.

Publication: The Hindu
Edition: National
Date: August 25, 2014
Headline: A landmark ethical clearance *(editorial)*

Synopsis: On August 11, for the first time a 12-member World Health Organization panel unanimously agreed that the use of "unproven interventions" in humans as potential treatment or prevention options for the Ebola virus disease is ethical in the West African countries of Liberia, Guinea, Sierra Leone and Nigeria. The interventions would also be evaluated for safety and efficacy in the best possible clinical trial settings. But the tricky ethical issue of ensuring "fair distribution" among the affected populations and countries will be looked into later. The green signal is specific to the circumstance of this outbreak, and subject to certain conditions like "transparency about all aspects of care, and informed consent" being met. The factors that played a vital role in the WHO's decision were the continued spread of the disease, about 55 per cent mortality rate and the lack of vaccines/drugs to prevent infection or treat the disease. As on August 22, the number of people infected with the virus was 2,615 (1,528 confirmed) and the mortality figure, 11,427. But it was the controversy over the use of an untested drug, ZMapp, on two Americans who came down with the disease that forced the WHO to look into the ethics of using it in the four countries.

Unethical medical practices

Publication: The Times of India
Edition: National
Date: August 24, 2014
Headline: A heartless profession?

Synopsis: It is the Holy Grail for almost every Indian parent: that their son and or daughter go to medical college, become doctors, and embark on a thriving career that brings laurels - and sure, some lolly. It's no different with NRIPIO parents, in the US, UK, or elsewhere, which is why the nearly 100,000 Indian American physicians in the US includes some 20,000 who are either born or have grown up in America and graduated from US medical schools. Dr Sandeep Jauhar has been there, done that - and not liked it one bit. And he's blown the whistle on his profession - or ripped it apart with a scalpel. Medicine, as practiced in the United States, is sick - very, very, sick. In a devastating - and immensely self critical - book that is making waves in the US, the Indian-American physician, with specialization in cardiology, describes how the medical profession has become a pitiless, mercenary medical profession, money ripping vocation where doctors treat patients as revenue generators rather than human beings, keep patients in hospital longer than necessary to bill them more, order needless tests to generate profits, and cozy up with drug reps helping predatory pharmaceutical companies sell dangerous drugs. American doctors - and that includes Indian-Americans like himself -are suffering from a "collective malaise" of discontent, insecurity, and immoderation.

Health ministry

Publication: Business Standard
Edition: Online
Date: August 23, 2014
Headline: Health assurance plan to cover diagnostic services

Synopsis: The health ministry's ambitious proposal for the National Health Assurance Scheme, which aims to provide insurance cover for all, would also include diagnostic services. The ministry intends to partner with the private sector to outsource some of the services concerned and also make these

affordable. The insurance scheme, which has been on the government's priority list from the beginning, might be launched by the end of this year, Lov Verma, secretary, ministry of health and family welfare, said. "We are hopeful of launching the National Health Assurance Scheme this year itself. The scheme will also have a basket of diagnostic services and we intend to partner with the private sector for it," Verma said.

Publication: The Times of India
Edition: Online
Date: August 22, 2014
Headline: WHO, health ministry working on 'preparedness plan' on Ebola

Synopsis: The World Health Organization (WHO) is working with health ministry to formulate a "preparedness plan" in case there is an outbreak of Ebola in the country. "Preparation is a very critical aspect. WHO is working with the ministry of family welfare and planning to ensure that we put into place preparedness measures. It doesn't mean it is going to happen, but we are prepared if it happens," Asheena Khalakdina, team leader, communicable disease, WHO country office for India said. She said the countries should be prepared to deal with in case of an outbreak scenario. "We have outbreak measures in place and in India we are looking at airports and other entry points."

Publication: The Hindustan Times
Edition: Online
Date: August 23, 2014
Headline: All central hospitals under scanner for graft: Vardhan

Synopsis: The central government has placed all systems at its hospitals, including the premier All India Institute of Medical Sciences, under a "critical review" to identify and end corrupt practices, Union health minister Harsh Vardhan on Saturday. "There are many aspects to corruption in hospitals, which as a medico, I know exist. If money is made in the allocation of beds or as kickbacks from suppliers, it is sleaze. What is equally corrupt is the silent practice of reserving beds and facilities for employees or VIPs. I intend rectifying both these forms of corruption," Vardhan said in a statement.

Similar reports in-

Deccan Herald- Central hospitals under scanner: Harsh Vardhan
International Business Times (India)- Centre Plans Crackdown on Graft in Health Care Sector

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Publication: The Times of India
Edition: Online
Date: August 24, 2014
Headline: 'AIIMS officer shifted to preserve sanctity of CVC'

Synopsis: Union health minister Harsh Vardhan, who has faced severe criticism for shunting out whistleblower officer Sanjiv Chaturvedi from AIIMS, claimed on Saturday that he was committed to transparency at the country's leading medical institute. Vardhan said he had placed all systems in the country's central hospitals, including AIIMS, under critical review to end systemic and symptomatic corruption. He also defended the government's decision to remove Chaturvedi from the post of the chief vigilance officer (CVO), citing disapproval of Chief Vigilance Commission (CVC) in the matter.

Publication: The Times of India
Edition: Online
Date: August 23, 2014
Headline: Sack Harsh Vardhan for removing AIIMS top official: AAP

Synopsis: Stepping up its attack on the Union health minister over the removal of AIIMS chief vigilance officer Sanjiv Chaturvedi, Aam Aadmi Party (AAP) on Friday called for immediate sacking or resignation

of Harsh Vardhan. AAP's national convenor Arvind Kejriwal alleged that Chaturvedi was removed because he brought corruption cases of a senior IAS officer of Himachal Pradesh who worked as a deputy director (administration) in AIIMS, to light.

Similar report in-

The Hindu Business Line- AAP demands Vardhan's resignation over removal of whistleblower IFS officer

Modi government/ WTO

Publication: The Times of India
Edition: National
Date: August 23, 2014
Opinion piece: Arvind Panagariya, professor of Indian Political Economy at Columbia University
Headline: Unfairly vilified at WTO: Modi government has justified grouse against Bali package but can do still better

Synopsis: Complexity of World Trade Organisation (WTO) agreements has meant that much of the commentary on the recent decision by the Narendra Modi government against ratifying the Bali package has been marred by confusion. Officials from most countries and commentators from around the world, including many from India, have nearly uniformly criticised the government for blocking a deal that had taken 12 long years to negotiate. The government and its handful of defenders have argued the contrary, but mostly unconvincingly. Who is right? Contrary to the vast majority of analysts who have uncritically accepted the usual developed country accusation that India has played its conventional role of an obstructionist and a spoiler in the negotiations, the answer is more nuanced and equivocal.

Publication: Business Standard
Edition: Online
Date: August 23, 2014
Opinion piece: Harsha Vardhana Singh, senior associate at the International Centre for Trade and Sustainable Development, and a former deputy director-general of the WTO
Headline: Moving beyond the WTO deadlock

Synopsis: India and the United States have a good chance of energising world trade negotiations. Several who were deeply disappointed with the breakdown of the Doha Round discussions on July 31 would strongly disagree with such a proposition. Nonetheless, the September meeting of Prime Minister Narendra Modi and President Barack Obama provides a major opportunity. Both these leaders need to contribute for converting this opportunity into effective progress. India has to succinctly explain the substance, scope and direction of its new reform policies, and take some steps in the Doha negotiations. The United States has to understand how India's political position on food security is combined with steps to reform both economic policies and the domestic food security system. There is a danger however that, instead of substantive issues, the focus of the talks may be on India's statements on its stand at the WTO.

FDA/ Drug regulation

Publication: The Telegraph
Edition: National
Date: August 24, 2014
Headline: Drug makers to inject cash

Synopsis: Indian companies may be wary of scrutiny by the US Food and Drug Administration (FDA), but they are also likely to invest more over the next four years to comply with the strict norms set by the regulator. Ratings firm Crisil has said in a report that capital expenditure by the top 20 pharmaceutical companies from India is expected to go up to Rs 50,000 crore by 2018. This translates into an average capex of Rs 12,500 crore annually compared with Rs 9,000 crore in each of the last four years. According to Crisil, one of the reasons for this rise are stricter regulations of the US FDA that will prompt companies

to invest more in upgrading their facilities.

Publication: Daily News & Analysis
Edition: Online
Date: August 22, 2014
Headline: FDA raids bogus Ayurveda practitioner and seizes medicines

Synopsis: Food and Drug Administration (FDA) officials raided an allegedly bogus Ayurveda practitioner in Malegaon and seized medicines worth Rs 5 lakh, official sources said on Friday. These medicines were being given to cancer patients by the bogus Ayurveda practitioner Vaidya Sureshkumar Chetandas Jethvani, FDA Joint Commissioner Dushyant Bhamre said.

Website: Pharmabiz
Edition: Online
Date: August 25, 2014
Headline: Maha FDA orders stop use of cefotaxime injection following death of a patient

Synopsis: Following the death of 47-year-old Saira Shaikh hours after suffering from adverse drug reaction (ADR) in civic run Kurla Bhabha Hospital, FDA officials have instructed stockists and hospitals to stop use of cefotaxime injection manufactured under the brand name, Sanocef, by Sanjivini Parenteral Drugs, Navi Mumbai. Food and Drug Administration (FDA) officials seized treatment records of the deceased who died within 24 hours of having taken the antibiotic jab of Schedule H1 drugs - cefotaxime and ceftriaxone. However, state FDA says death could not yet be directly linked to a drug reaction for which samples of cefotaxime, ceftriaxone and water for sterility have been drawn for investigation and analysis.

Publication: Mid Day
Edition: National
Date: August 25, 2014
Headline: Learn lessons from antibiotic scare

Synopsis: It is shocking that the same antibiotics which caused the death of a person in one civic hospital were administered to patients at another civic hospital. There should have been prompt and urgent action following the death of the woman in Bhabha hospital and the drugs should have been stopped from being used anywhere at all until they were tested properly. Instead of a committee being formed immediately to ascertain the problem with the antibiotics, however, the same drugs were used at another hospital. It is fortunate that there were no deaths at Rajawadi and the patients who fell ill were given immediate treatment. Now, of course, the Food and Drug Administration (FDA) has stepped in with samples of the drugs sent for testing. Reports also state that the antibiotics have been withdrawn and a network of hospitals has been informed not to administer injections of the drugs.

Public Health

Publication: The Indian Express
Edition: Online
Date: August 25, 2014
Opinion poiece: Arvind Virmani, IMF executive director and former chief economic advisor, ministry of finance. He was involved in many of the economic reforms from 1991 to 2009
Headline: The wrong end of the right debate

Synopsis: In an article in The Indian Express ('The pragmatic PM?', August 22), Ashutosh Varshney of Brown University asserts: "It is Amartya Sen, the nemesis of neo-liberals, who would emphasise toilets as much as growth." This is perhaps true in the exalted world of Western academia and among many academic followers of Sen in India, but not in the trenches of Yojana Bhavan, North and South Block, where many of these and related issues were decided. It is the followers of Sen (neo-communists?) who emphasised increased "private health spending" over "public health" spending on sewers and sanitation.

It is the “neo-communists” who emphasised “right to food” as a means of eliminating malnutrition, as against sewers, sanitation and toilets.“Market liberals” like me have showed that the absence of these is the main cause of child malnutrition.

Website: IBN Live
Edition: Online
Date: August 23, 2014
Headline: Children can't want: Will India take the 500 day challenge?

Synopsis: August 18 marks a significant marker to 500 days left to meet Millennium Development Goals (MDGs) targets. Today, the world is on the brink of a major breakthrough to ensure mothers, newborns and children everywhere survive. If there's one place to trace the seeds of this brewing revolution, it's India. MDGs: the world's "to do list" to improve lives agreed upon in the year 2000 by representatives from 189 countries including India to framework that would steer development agenda for the next 15 years.

Innovation

Publication: The Economic Times
Edition: Online
Date: August 24, 2014
Headline: No country can progress without innovation: President Pranab Mukherjee

Synopsis: President Pranab Mukherjee has expressed concern over India lagging behind other countries in having patents, and said no country can progress without innovation. "No country can progress without innovation. Higher educational institutions can take a leading role in encouraging innovative activities," Mukherjee said Saturday in his address to students of Krishnath College in Baharampur here.

Similar report in-

Daily News & Analysis- President Pranab Mukherjee calls for promoting atmosphere conducive for research

General Industry

Publication: The Economic Times
Edition: National
Date: August 25, 2014
Headline: Argentina Opens Up Drug Market to Indian Pharma Firms

Synopsis: Argentina has fully opened its $6-billion drug market to Indian companies, increasing the scope of exports to finished pharmaceuticals formulations from just raw materials earlier. India was not allowed to do so earlier due to local laws. PV Appaji, director general of Indian Pharmaceuticals Export Promotion Council, said that with effect from August 8, the Latin American nation has included India on the list of countries that can supply medicines to it.

Similar report in-

Pharmabiz- Argentina govt allows imports formulations from India, becomes 27th country to export

Publication: Business Standard
Edition: National
Date: August 25, 2014
Headline: Delhi Medical Council reiterates 'no ayurvedic prescription' stand

Synopsis: The Delhi Medical Council (DMC) has underlined that allopathy practitioners are not to prescribe ayurvedic drugs, though they are classified as over-the-counter (OTC) products. The move is

likely to impact companies such as Himalaya, Baidyanath and Charak selling popular ayurvedic pharmaceutical brands such as Liv52, Cystone, Aquagest, Septilin and others mainly through practitioners of modern medicine. The Council has cited Section 30 of the Delhi Bharatiya Chikitsa Parishad Act, 1998, and said "crosspathy" is punishable under the law. The provision of the Act states, "false assumption of medical practitioner under this Act to be an offence. Any person who falsely improvises that he is a practitioner… and practises Bharatiya Chikitsa (Indian System of Medicine), shall be punishable with rigorous imprisonment of up to three years and a fine of up to Rs 50,000".

Publication: The Economic Times
Edition: Online
Date: August 25, 2014
Headline: India, Serbia likely to sign MoU on yoga, traditional medicine

Synopsis: India and Serbia are likely to sign a Memorandum of Understanding (MoU) soon to enhance bilateral cooperation in yoga and traditional medicine. Union Health Minister Harsh Vardhan has extended an invitation to his Serbian counterpart Zlatibor Loncar to visit the country for signing of the agreement between the Ministry of Health & Family Welfare and the Ministry of Health of the Republic of Serbia, Embassy of India in Belgrade, said in a statement.

Publication: The Times of India
Edition: Online
Date: August 23, 2014
Headline: Ranbaxy faces Rs 240cr fine in US

Synopsis: Ranbaxy Laboratories will reportedly need to cough up a Rs 240 crore fine to the US authorities due to violations found at its active pharmaceutical Ingredient (API) manufacturing factory in Toansa, Punjab. The US FDA had banned the facility from supplying products to the US market in January this year. Ranbaxy declined to comment on the matter. The FDA had earlier banned Ranbaxy's three other plans for failing to meet its manufacturing standards.

Publication: Mail Today
Edition: National
Date: August 24, 2014
Headline: Cancer in the Capital's air: How Delhi's pollution poses a health risk to millions

Synopsis: The air in Delhi, one of the world's most polluted cities, is loaded with Polycyclic Aromatic Hydrocarbons (PAHs). Many areas in the city of nearly 18 million people have high concentrations of toxic PAHs posing major health risks, a Central Pollution Control Board (CPCB) study found. Published in the International Journal of Environmental Sciences, the study was done after collecting ambient air samples from major areas of Delhi like ITO, Janakpuri, Nizamuddin, Pitampura, Shahzada Bagh, Siri Fort and Shahdara.