OPPI

Daily News Monitor

January 21-23, 2017

1. **Abbott to make India hub of global research and development for branded generics – Business Today**

   At a time when multinational drug companies are scaling down their research and development investments in India, citing lax patent rules and increasing regulatory interventions, the US based multinational Abbott is planning to make India its global hub for innovation and development (I&D), in branded generics products. Abbott, the second-largest drug company operating in India in terms of domestic market share, following the acquisition of Piramal Healthcare's formulation division in 2010, is setting up an Innovation and Design Centre in Mumbai, which will take off next year.

   Clear guidelines and consistent application of IP framework will provide better visibility to innovators, as they explore ways to make new drugs and innovations available in India, Mike Warmuth, Executive Vice President, Established Pharmaceuticals Division, Abbott had recently said at the Organisation of Pharmaceutical Producers of India (OPPI) golden jubilee meeting.

2. **If govt is serious about the poor, then set lower GST rates for Pharma – Business Standard**

   Union budget, as the name suggests, is an itemised summary of intended expenditure and expected revenue of the central government. Unfortunately it has become a circus where the people and industry expect the government to perform magic and come up with overnight solutions to all our problems. The right expectation from a budget would be that the government focuses on its deficits and finances to bring down inflation. But we expect the government to make policy decisions in union budgets. It is a fact that tax rates do affect business, but tax rates alone are not responsible for the success of the business. Since our country is now

used to these kind of expectations, we will talk about what the pharmaceutical industry expects from the Budget. But before that, I would like to mention about the current industry scenario.

If we consider recent pharma news, we would come across NPPA (National Pharmaceutical Pricing Authority) and DPCO (Drug Price Control Order) which has been given the mandate to control and fix the MRPs of a number of scheduled bulk drugs and their formulations.

3. **Intellectual property: GST expected to deal with dual taxation in time, but clarity needed in interim – The Financial Express**

Intellectual property (IP) such as patents copyrights and trade secrets and software are classified as intangible property. They are considered intangible because they are totally divorceable from the tangible property in which the intellectual element is embodied. IP law and taxation has been the subject of considerable development, globally and in India, over the past years. From a global perspective, absent any differential tax treatment, most VAT/GST implementing countries are agnostic to characterisation of intangibles. That said, from the perspective of defining tax jurisdictions as well as compliance procedures, intangibles have been accorded the status of services internationally. On the other hand, levy of indirect tax on intangibles in India has always been a matter of dispute, and that dispute is far from being settled.

Under the existing indirect tax laws, intangibles can be taxed under service tax or VAT depending on whether the transaction qualifies as one in services or goods, respectively. However, in certain cases, considering the ambiguity surrounding chargeability of service tax by the Union government and VAT by respective state governments on intangibles, the industry has been playing conservative and discharging both VAT and service tax.

4. **Viewing the Indian pharma sector through the biosimilar lens – Business Standard**

The Indian pharmaceutical market which would rank amongst the top five in terms of volume is also the largest provider of generic drugs globally. This has earned India the sobriquet “pharmacy of the developing world”. It is estimated that Indian pharmaceutical companies supply around 80 per cent of the antiretroviral drugs that are being used on a global scale to deal with AIDS.

The sector, which is valued at around $ 35 billion, is expected to cross $ 50 billion by 2019-20. This sector also attracts considerable Foreign Direct Investment (FDI) with inflows crossing $ 13 billion during the last sixteen years. The last ten years have witnessed numerous big ticket foreign investments in this sector with the prominent ones being the acquisition of Ranbaxy by Daiichi Sankyo, Abbot’s buy-out of Piramal Healthcare and Mylan’s acquisition of Matrix. The present Indian regulations allow up to 100 percent FDI subject to certain conditions. In June 2016 the government decided to permit up to 74 percent FDI under automatic route in brownfield pharmaceuticals. However any FDI beyond 74 percent in brownfield pharma sector would require FIPB/government approval.

5. **Foster PPP to percolate benefits of affordable healthcare to the masses – Business Standard**

With a population of 1.4 billion we are the third largest economy spending Rs 6 trillion on healthcare. Despite this huge spending India’s challenges are immense and there is still a need to address communicable diseases and non-communicable diseases (NCDs) affecting a greater mass especially in the semi-urban and rural areas.

Even though India declared itself to be polio and tetanus free (in 2014 & 2015), much needs to be done in the healthcare sector. Women and child mortality is still rampant requiring quick action. A current study indicates that 44,000 women die every year due to pregnancy complications and a child dies (under age of 5 years) of pneumonia and diarrhea every two minutes.

The greatest bane is the unorganised nature of our health sector. If the government aims to achieve as planned the universal health coverage by 2030, it will bring in the much needed transformation in the healthcare sector with a multi-sectorial plan for next few years starting with Budget 2017.

6. **In pursuit of medicines that drug companies no longer produce – The Hindu Business Line**
"Sun has let patients like me down." The message could not be more telling, coming from someone trying to buy Sun's generic version of anti-viral drug adefovir for about four months now. Another generic drugmaker that makes similar versions of this medicine is Cipla. But it too has discontinued making the medicine here. Faced with a dwindling supply of medicine critical to his treatment, the patient was left with no option but to import from a Canadian retailer the drug made by Sun Pharma, but at a higher price (over 10 times more expensive) than he would have got in India. The pursuit of medicine does not end there. For future regular supplies of the drug, he then had to get in touch with the original maker of the medicine, Gilead, based in the US.

   This is not the first we know of medicine shortages in a country feted as being "pharmacy to the world". The disturbing truth is that patients suffer when drug companies discontinue making a certain medicine for reasons of market competition, viability or regulatory action. Which is why they need to show greater responsibility to the patient who has been buying and is dependant on their drug.

7. **Diagnostics can help in effective implementation of healthcare budget – Business Standard**
Budget 2017 is round the corner and like any other year, every industry is trying to speculate about what's going to come on their shares. As far as the healthcare sector is concerned, there are a lot of expectations. The previous budget made it clear that the government is aiming to move forward by a steady inclusion of healthcare insurances in order to make utility affordable and available for everybody. We also saw the coming in of many schemes such as the Jan Aushadhi Yojana, The Health Protection Scheme etc.

   Apart from this, the government also started National Dialysis Service programs for poor patients. The total budget for health insurance was Rs 1,500 crore but as far as diagnostics is taken into consideration, it still accounts for a mere 2 percent mention in the budget. India currently spends 4.2 percent of its GDP on healthcare, with just 1 percent being contributed by the public sector. There is a clear need to focus on a collaborative outlook for the coming budget.

8. **Next month, volunteers may knock on your door for cancer, diabetes tests – The Times of India**
The Union health ministry is set to roll out a massive free door-to-door screening programme next month for the early detection of cancer, heart disorders and diabetes, which account for over 35% of all deaths in India. The programme is likely to be flagged off by PM Modi on February 4, which is World Cancer Day. Under the initiative, the government aims at testing over one-third of the population in a year — a scale that has not been attempted before. We are aiming to cover 200 districts across the country by 2018. At a later stage, we will also add testing for asthma under the Programme," an official told TOI. The programme is among the preventive-care measures planned by the health ministry, and is targeted at people in the age group of 30-69 years, who constitute almost 37% of the total population. This population is also highly vulnerable to noncommunicable diseases (NCDs) like cancer and diabetes that are responsible for 55% of the premature mortality in the same age group.

9. **Health ministry asks states to screen antibiotics sale – Daily News and Analysis**
In reaction to the reports of death of a 70-year-old woman from US, who allegedly contracted New Delhi metallo-beta-lactamase (NDM-1) strain infection — superbug from India — a drug control department has alerted the States to strictly keep a check on sale of antibiotics without prescription.

The Central Drugs Standards Control Organization (CDSCO) under Ministry of Health and Family Welfare has also directed pharmaceutical companies and consumer associations to strictly adhere to laws and regulations regarding sale of medicines in India and spread awareness about hazards of antibiotic abuse. “To contain anti-microbial resistance, we have been advising the supply chain system in India to follow strict requirements of Schedule H and H1 for sale of medicines,” said Dr GN Singh, Drugs Controller General of India in his letter to all the Drugs Controllers of the State and Union Territories, Pharmaceutical companies and Consumer Associations.

“Stakeholders have been advised for strict compliance of the requirement of the Drugs & Cosmetics Act and Rules made thereunder by taking strong policy measures including stringent regulatory action on the over the counter (without prescription) sale of high end antibiotics included in the above Schedules,” said Dr Singh. “The law may also be complied by raising awareness through consumer associations about the side effects of taking antibiotics without prescription, so that the antibiotic microbial resistance could be avoided for patient safety, their well-being and protection of their health,” he said.

10. **Indian pharma pads up to fight Republican border tax – Business Standard**
After the swearing in of the 45th US President Donal Trump on Friday, fears of the border adjustment tax (BAT) — proposed by the Republican Party — has again raised its head for Indian pharmaceutical companies. Republican senators propose to slap a BAT as a tax reform. Under the proposal, US companies would not be taxed for profits from exports. But, manufacturing costs incurred overseas would not be deductible while calculating taxes. Simply put, there would be a tax on imports. Indian generic drug makers said this would hurt their profitability.

11. **Pneumococcal vaccination: How vaccinating children helps fight superbugs – Hindustan Times**
India will start providing free vaccination against pneumococcal diseases this year as part of its universal immunisation programme. Beginning in phases with five states -- Himachal Pradesh, Bihar, Uttar Pradesh, Rajasthan and Madhya Pradesh -- pneumococcal vaccination will be scaled up to cover all states over the next two years. There’s need for the live-saving vaccine. Pneumococcal infections kill one child every three minutes in India, with more than 180,000 children dying of the infection each year. The symptoms include high fever, chills, a productive cough with breathing difficulty, and pain in the lungs, which can lead to septicaemia (blood poisoning) and death. Pneumococcal infections spread from person to person through close contact and take more lives each year than HIV, malaria, tuberculosis, Zika and Ebola, combined. It’s not just children who get sick. Lower respiratory tract infections, including pneumonia, are the fourth common cause of all deaths in India, after heart disease, chronic obstructive pulmonary disease and stroke, reports The Global Burden of Disease 2015. Anyone can get pneumococcal disease, but children under two years, adults 65-years-old and above, smokers and people with compromised immunity because of disorders such as chronic lung conditions, liver disease, kidney disease or heart disease are at higher risk.

12. **CCI approves Aspen Global-GlaxoSmithKline deal – The Economic Times**
Competition Commission has cleared Aspen Global's deal to purchase certain drug brands from GlaxoSmithKline. Ultiva, Tracrium, Nimbex, Mivacron and Anectine/Midarinecertain brands would be acquired by Aspen along with goodwill and the intellectual property, among others. In a tweet, Competition Commission of India (CCI) said it has approved "acquisition of Ultiva, Tracrium, Nimbex, Mivacron and Anectine/Midarine brands of GlaxoSmithKline by Aspen Global. As per the notice submitted to the regulator seeking approval for the deal, Aspen would buy the five brands as well as the goodwill and the intellectual property, marketing authorisations, contracts, business information and business records associated with them. These would be acquired from Glaxo Group and GlaxoSmithKline Intellectual Property Ltd. Aspen Global is a holding company for the Aspen Group's

international businesses. Glaxo Group's subsidiaries produce pharmaceuticals, sports nutrition, and food products for infants.

13. **Trump order paves way for agencies to weaken health law – Reuters**
President Donald Trump is ordering federal agencies to undermine Obamacare through regulatory action, a move that could weaken enforcement of the requirement for Americans to buy health coverage and give insurers leeway to drop some benefits. Trump's first executive order, signed hours after taking office on Friday, directs the federal government to scale back regulations, taxes and penalties under President Barack Obama's healthcare law, the Affordable Care Act (ACA). Republican lawmakers, who are working on new legislation to repeal and replace Obamacare, praised the order as showing Trump's commitment to gutting the program and lowering steep healthcare costs they blame on the law. Trump did not specify which parts of the program would be affected by his order, and any changes are unlikely to affect the government-funded or subsidized insurance plans covering more than 20 million people in 2017. Trump's nominee to head the U.S. Department of Health and Human Services, Georgia Representative Tom Price, has said there was no plan for "pulling the rug out" on millions of Americans' healthcare as a replacement is designed.

14. **Orphan drugs likely to deliver best revenue opportunities: CPhI Worldwide experts – Pharmabiz.com**
With the traditional blockbuster drug era widely considered to have passed, orphan drugs and neglected diseases are, in the short-term, likely to deliver pharma's best revenue opportunities, according to CPhI Worldwide expert panel. Over the medium term, developing world economies and cost reductions from new technologies and working practices like Quality by Design (QbD) and continuous processing should help sustain profits, the panel added.

Significantly, continuous processing and QbD will also lead a "paradigm shift at instrument companies" with new models – particularly in spectroscopy – specially created for process monitoring and control. CPhI expert, Emil W. Ciurczak, President of Doramaxx Consulting, added: "The instrument companies will cooperate with software vendors to produce a more cohesive operating system(s) that will allow multiple instruments to smoothly work in unison for PAT/QbD applications. In many ways this will be similar to the unification of chromatography terms/specifications and the emergence of international standards for dissolution testing".