REVA Pharma
Caring for Healthier Lives

NEWS LETTER
For Private Circulation only

Congressman, Industry and Doctors Favour Accelerated Traction on India-US Synergies for Universal Health

Council For Healthcare and Pharma (CHP) Supports Concerted

The Council for Healthcare and Pharma hailed its recently concluded Legislative day at Capitol Hill DC as engaging and successful. The forum received overwhelming support and consensus for greater traction between India and the US to fully utilise mutual synergies and complementarities in the pharma and health space for the cause of universal healthcare.

Over 20 US Congress leaders, representatives from industry and trade, medical fraternity and board of management AAPI, supporting the need for greater affordability, accessibility and accountability in keeping populations healthy, attended the 'Legislative Day'.

Dr Gurpreet Sandhu, President, CHP, said, "For universal healthcare to become a reality, we must pull out all the stops to optimise the sourcing and delivery of each element of the health value chain. This calls for extensive deployment of the best-known bases and practices around the world for high-quality medicines, technologies and skill sets. The logic, natural synergies and complementarities between India and the US in healthcare are compelling and the potential to realise accelerated gains from bringing these together is enormous and immediate."

A strong proponent of affordable medicare, Congressman Steny Hoyer emphasised the need for government to work for improving healthcare access and affordability and to ensure that all Americans have access to affordable health coverage. Further, Congresswoman Tulsi Gabbard who is a champion for universal healthcare expressed her commitment towards working proactively for the same. Senator Roger F Wicker was of the view that one of the biggest concerns facing the US in the arena of health is the lack of affordable health insurance coverage. Expressing his support to the cause of women's healthcare, Congressman Raja Krishnamoorthi was categorical that America succeeds when women succeed in their quest for affordable healthcare. He also expressed his commitment towards accessible and affordable medicines to achieve the goal of 'health for all'.

Congressman Frank Pallone who serves as the Chairman of the Energy and Commerce Committee was of the opinion that all Americans should have access to high-quality affordable healthcare. He assured the gathering that he is committed to work steadfastly to protect the integrity of medicare and medicaid programmes. The American Association of Physicians of Indian Origin applauded the council and its members in its committed support towards the TB elimination programme in India. Furthering their collaboration, the two organisations have entered into a joint dialogue to offer affordable oncology medicines for women, especially for cancers of the breast and cervix.

The Indian Ambassador to the US, HE Harsh Vardhan Shringla, hailed the contribution of the Indian generics industry in its drive towards affordable care. He also applauded the role of the AAPI community in the US healthcare system. The opportunity to lower cost clearly lies in emphasising a high-quality generic formulary, realising supply chain efficiencies, complementing R&D strengths to amplify drug development efforts, locating manufacturing where advantageous, leveraging new technologies like robotics, AI and blockchain for greater efficiencies, better health surveillance, early detection of disease, improved treatment protocols, enhanced patient experience with significantly better outcomes. These opportunities can be made feasible through a 'Make in USA' or 'Make in India' initiative.

India has critical mass in providing affordable, high-quality generic medicines to the US and the world. India additionally has strengths in IT and a vibrant start-up environment for frugal innovation with interesting health applications being developed that have the potential to significantly enhance the efficiency and outcomes in delivering healthcare.

On the other hand, American firms can outsource significant parts of their R&D efforts with considerable savings in new drug discovery as well as to amplify their shortlist of drug candidates for further research and development. These drugs, in turn, can be marketed not only in the US, but also in India and other populous countries. In addition, there are medical challenges of significant proportions like AMR which continue to deplete our arsenal of antibiotics by rendering them ineffective on account of overuse and misuse. The US has done a lot of work in alleviating this global problem and both countries can collaborate to mount a sizeable programme to mitigate this menacing challenge and such others. The Council for Healthcare and Pharma (CHP) is an integrated, not-for-profit, global think tank that advocates the development of sustainable health systems around the world. It looks at engaging with governments and other stakeholders to adopt rational approaches that capture benefits, accrue through the optimisation of the ecosystem and value chain involved in treating diseases and keeping people healthy. CHP members include domestic and global pharmaceutical companies, providers of diagnostics, medical device manufacturers, hospitals and adjunct services.

Headquartered in New Delhi, the council focusses on Africa, Brazil, China, France, Germany, India, Japan, UK and the USA. It's important areas of work are in ease-of-doing business; increasing competitiveness; broadening access to safe, efficacious and affordable healthcare services and medicines. CHP is guided in its work by expert advisory committee in Intellectual Property, market access, regulatory policy, key therapeutics – women's health, oncology and tropical diseases, research and development , artificial intelligence (AI), environment and healthcare startups.As a significant and credible stakeholder in alleviating the burden of disease, the CHP brings to bear the collective wisdom of industry and policy makers on health issues that stand to make a positive contribution to society in bringing about universal healthcare. (Source: Express Healthcare)

"Million Insights - World's Fastest Growing Market Research Database"

According to a report available with Million Insights, the doxorubicin industry is estimated to grow at a significant CAGR of 6.4% over the forecast period as the scope and its applications are rising enormously across the globe.

Global Doxorubicin Market is expected to reach USD 1.38 billion by 2024. Doxorubicin is an anticancer chemotherapy drug, a generic name for the trade name drug Rubex and Adriamycin. It is injected into a vein. It is an essential medicine on the World Health Organization's List, the safest and effective medicines needed in a health system. The Doxorubicin Market is estimated to grow at a significant CAGR of 6.4% over the forecast period as the scope and its applications are rising enormously across the globe.

Growing presence of cancer patients across the globe, increasing number of manufacturers in the market to control the shortage of drugs, and developed laboratories with the latest technological equipment's for research are documented as the major driving factors for Doxorubicin Market. Also, inclusion of doxorubicin drug in several applications like neuroblastoma, AIDS-related Kaposi Sarcoma, and others may boost the overall market in the years to come.

However, side effects of drugs and high cost of treatment are the factors that may restrain overall market growth in the coming years. Doxorubicin Industry is segmented based on formulation, cancer type, distribution channel, and region. Doxorubicin injection and lyophilized doxorubicin powder are the formulations that could be explored in Doxorubicin in the forecast period.

There are several types of cancer like Leukemia, Breast Cancer, Stomach Cancer, Prostate Cancer, Bladder Cancer, Ovary Cancer, Lung Cancer, and others that could be explored in Doxorubicin in the forecast period. Breast cancer and prostate cancer accounted for the majority market share in 2017 and are estimated to lead the overall market in the years to come. This may be because of rising number of people suffering from breast and prostate cancer.

The market may be categorized based on distribution channel like E-Commerce, Retail Pharmacies, Hospitals Pharmacies, and others could be explored in the forecast period. Globally, North America accounted for the substantial market share of Doxorubicin in 2017 and is estimated to continue with its dominance in the near future. The reason behind the overall market growth could be presence of developed healthcare infrastructure, presence of key manufacturers in the region, and increasing number of cancer epidemiology. The United States is a major consumer of Doxorubicin in this region.

Europe and the Asia Pacific are also estimated to have a positive influence on the future growth. Europe is the second largest region with significant market share. However, Asia Pacific is estimated to grow at the fastest pace in the foremost period. The aspects that may be ascribed to the growth comprise rising pharmaceutical market, developing healthcare infrastructure and growing occurrence of cancer mainly gastric cancer and lung cancer among population. The developing countries like India, Japan, and China are the major consumers of Doxorubicin in this region. (Source: Million Insights)

Herbal Meds, Anti-TB Drugs can Cause Liver Failure

Alter native and "herbal" medicines may not always be without side-effects. Doctors say unmonitored use of such medication, as also long-term drugs for ailments such as tuberculosis and body-building protein supplements, may lead to liver failure even among patients with no history of liver disease.

Take the case of Rashmi Khare (name changed). The 27-year-old Delhi girl was admitted to Institute of Liver and Biliary Sciences (ILBS) with acute liver failure resulting in internal bleeding and fatigue. She had been on medication for TB for a long time but the drug's effect on the liver was not monitored.

"She is being managed with plasma exchange therapy. But the need for a transplant in future cannot be ruled out," said Dr S K Sarin, director, ILBS. Dr Sarin added that he gets one-two cases of drug-induced liver failure every week. "Alternative medicines or herbal drugs are the most common culprits followed by anti-TB medications, body-building protein supplements, painkillers and antibiotics," he said.

Dr A S Soin, head of liver transplant unit at Medanta Medicity, Gurgaon, and Dr Subhash Gupta of Apollo hospital confirmed the trend. (Source: Times of India)

India's Domestic Pharma Companies Eye Robust Growth From US

Domestic pharmaceutical companies are expecting buoyant growth from the US market in FY20 on the back of product launches, easing of price erosion and withdrawal of certain drugs by top companies.

The generics drug business has been showing signs of stability over the past few months. While companies continue to face regulatory pressure leading to higher costs, they see an uptick from the launch of differentiated and high-margin products. "We expect FY20 to be fairly strong with most of our focused markets expected to show reasonable growth in the coming financial year . Our growth will be driven by wider portfolio, limited competition and complex generic launches," said a Dr Reddy's Laboratories (DRL) spokesperson.

DRL's fourth quarter revenue growth remained flat on a sequential basis but the result was boosted by one-offs like sale of dermatology drugs in the US. The firm also continues to face pressure on profit margin but is hoping for improved performance in the coming financial year. "Overall generic pricing environment has been relatively stable over the past couple of quarters. Barring a couple of products that have witnessed higher competition, base business for the company is holding up well," the spokesperson said and added that the company would capitalise on the opportunities created by supply disruptions in the US market.

"Some of the larger peers like Teva and Mylan have undertaken rationalisation of their portfolios. This volume share, given by them, has been largely taken up by incumbents from India, including Lupin, based on cost competitiveness and customer relationships," said Nilesh Gupta, MD, Lupin. Gupta said price erosion was now reduced from double digits to single digit.

"Overall, there is stability in the US market. Price erosion between 6 and 10 per cent is normal. If it exceeds 10 per cent, it would be a cause for worry," said Kedar Upadhye, global chief financial officer (CFO) of Cipla.

Cipla is a late entrant in the US and earned 21 per cent of its revenue from the market in FY19. Also, unlike its peers, a single product does not contribute more than 10 per cent to Cipla's consolidated revenue. The company is targeting double-digit growth in the US in the coming financial Year.

Contribution of launches and strong growth from all its key markets like India, US and South Africa resulted in 19 per cent revenue growth on a year-on-year basis in the fourth quarter of FY19.(Source: Business Standard)

Glenmark Launches Anti-Diabetes Drug Remogliflozin In India

Pharma major Glenmark has become the first company in the world to launch its novel, patent protected and globally -researched sodium glucose co-transporter-2 (SGLT2) inhibitor Remogliflozin etabonate (Remogliflozin) in India. The drug is indicated in the treatment of type-2 diabetes mellitus in adults.

Remogliflozin is an innovative, patent-protected sodium glucose co-transporter-2 (SGLT2) inhibitor indicated in treatment of type-2 diabetes mellitus in adults. According to a report, SGLT2 inhibitors are cutting-edge, globally-accepted latest class of oral anti-diabetes drugs that provide glycemic control, induce weight loss and reduce cardiovascular risks. Remogliflozin has been studied in 26 clinical trials globally, covering about 2,500 patients from various ethnicities.

SGLT2 inhibitors are novel anti-diabetic drugs that help achieve glycemic control by acting on the SGLT2 receptors in the proximal tubule of the kidney, thereby preventing renal reabsorption of glucose and promoting excretion of glucose in the urine. SGLT2 drugs provide glycemic control, induce weight loss and reduce cardiovascular risks, the report added.

Glenmark is the first company in the world to launch the novel SGLT2 inhibitor Remogliflozin and India is the first country to get access to this innovative drug. Glenmark will commercialize Remogliflozin in India under the brand names 'Remo' and 'Remozen'.

Glenmark received regulatory approval for Remogliflozin etabonate 100 mg tablets, twice daily, after successfully completing Phase-3 clinical trials in which Remogliflozin demonstrated good efficacy and safety profile in a head-to-head comparison against Dapagliflozin.

Remogliflozin, the latest drug in SGLT2 inhibitors' class to get regulatory approval in the world, has been studied in 26 clinical trials globally, covering around 2,500 patients from various ethnicities.

Remogliflozin was discovered and developed by Japanese firm Kissei Pharmaceutical Co. Ltd. and later developed by GlaxoSmithKline plc and Glenmark collaborator BHV Pharma, a wholly owned subsidiary of Avolynt, Inc. which is based in North Carolina, USA. Glenmark secured certain rights to Remogliflozin through a licensing collaboration agreement with BHV Pharma, and conducted the Phase-3 clinical trial.

"Globally, SGLT2 inhibitors are emerging as a preferred treatment for management of type-2 diabetes and Glenmark is proud to introduce a novel molecule in this class, which is cutting-edge and researched extensively. Diabetes is a key area of focus for Glenmark and with the launch of Remogliflozin, the company aims to improve access to SGLT2 inhibitors by providing an effective, high quality and world-class treatment option to patients in India," said Sujesh Vasudevan, President, India Formulations, Middle East and Africa at Glenmark Pharmaceuticals.

India is estimated to have around 72 million adults living with diabetes, according to the International Diabetes Federation's Diabetes Atlas 2017.1.(Source: Healthworld.com)

Post USTR Special 301 Report, Pragmatism Wins Over confrontation?

Less than a fortnight after the release of USTR's 2019 Special 301 report, a delegation of around 100 companies from the US spent a week in India in early May scouting for business opportunities. Organised by the US Commercial Service Trade Winds Indo-Pacific Forum and Mission, the week included 'business matchmaking appointments' with pre-screened potential buyers, agents, distributors and joint-venture partners in New Delhi, Mumbai, Ahmedabad, Bengaluru, Chennai, Hyderabad and Kolkata.

This proves that even though India is part of the list of countries pulled up for 'long-standing IP challenges facing US businesses in India' and is on the USTR's Priority Watch List for the 27th year running, the sheer size of the India market cannot be ignored.

Besides the oft-quoted instances of Section 3(d) and compulsory licensing, this year's report quotes studies depicting India as the one of the top five source countries for counterfeit goods, including medicines.

But both governments seem to have decided to take a pragmatic rather than confrontational stance. A multi-ministerial delegation from India travelled to Washington, the week after the release of the USTR report, to convince the US government to extend the benefits it provides to India under the generalised system of
Government is in place. Thus Indian exporters have won some breathing space. The give-and-take between the two governments is further evident when other reports hint of a climb down by the Indian government on price caps on medical devices.

Consider the trade figures. According to data from the US Department of Commerce, pharmaceuticals ($6.1 billion) was the second largest category of US imports from India in 2017. Across sectors, bilateral US-India trade expanded to $126.2 billion in goods and services in 2017 even as overall levels of global trade volumes decreased. The US remained India's largest trading partner, with exports of US goods and services to India reaching $49.4 billion (up 16 per cent from 2016), and imports from India hitting $76.8 billion (up six per cent from 2016). The US also remained India's top export market – and its $27.3 billion trade surplus with the US is its largest with any country – while India was the 15th biggest export market for US goods in 2017.

The US would clearly like to correct what it sees as a trade imbalance and hence the pressure to ease off on US companies. Flashpoints over the past year included Harley-Davidson motorcycles, Amazon, Wal-Mart, as well as the US-based medical device and pharma companies. While both governments continue the dialogue, there are various groups working to find a middle path. One such group is the New Delhi-headquartered Council for Healthcare and Pharma (CHP) which advocates the development of sustainable health systems around the world. With members from domestic and global pharma companies, diagnostics providers, medical device manufacturers, hospitals and adjunct services, CHP members are looking to engage with governments and other stakeholders 'to adopt rational approaches that capture benefits, that accrue through the optimisation of the ecosystem and value chain involved in treating diseases and keeping people healthy.'

In early May, soon after the release of the USTR report, the Council organised a Legislative Day at Capitol Hill DC with over 20 US Congress leaders, (a mix of Democrats and Republicans) as well as representatives from industry and trade, the medical fraternity and the board of management of American Association of Physicians of Indian Origin (AAPI). Speakers reportedly supported the need for greater affordability, accessibility and accountability in keeping populations healthy.

Commenting on the latest USTR's Special 301 report, CHP President, Dr Gurpreet Sandhu concedes that while equitable trade balance is an important aspect, the need to bring affordable healthcare is equally important and hopes the USTR "will walk this fine line." Agreeing that fakes and counterfeits are a problem which the authorities must deal with a stern hand, he emphasises that legitimate products introduced following patent expiry or in countries which do not have a patent regime serve a significant purpose in battling the burden of disease, and therefore their important role must be acknowledged in lowering the cost of healthcare globally.
But this fine line is often a moving line in the sand. Will India's incoming administration succeed in maintaining an independent voice in spite of the risk of sanctions and isolation? (Source: Express pharma)

Generic Drugs Can Reduce the Economic Burden of Diabetes

Diabetes is rising like an epidemic in India. According to Diabetes Atlas 2017 published by International Federation of Diabetes, 72.9 million people are living with diabetes in India.

Diabetes is rising like an epidemic in India. According to Diabetes Atlas 2017 published by International Federation of Diabetes, 72.9 million people are living with diabetes in the country. This number is expected to become 134.3 million by years 2045. Moreover, 42.2 millions of Indians are living with undiagnosed diabetes, which constitutes 57.9% of the total population living with diabetes. The number of patients living with diabetes is bound to increase in the near future due to ongoing large-scale urbanizationand increasing life expectancy.

Diabetes is a physiological state in which there is a persistently higher level of glucose in the blood. This situation may adversely affect the organs like eye, heart, kidney, and skin to name a few. According to reports, a person living with diabetes has two times higher chance of getting a heart attack, which is a major cause of mortality in the case of diabetes. With the progression of diabetes, we witness the comorbidity and hence increase in the cost of diabetes management.

The economic burden of diabetes has two components namely direct cost and indirect cost. The direct cost includes consultation fee, medicine cost, and hospitalization cost. The indirect cost includes the cost of travel and the cost of lodging, as patients have to travel from remote areas to urban areas, to avail the healthcare facilities. Another indirect cost associated with diabetes is a loss of productivity due to illness.

One approach to bring the medicine cost in chronic care like diabetes down is the prescription of generic drugs. Generic drugs are bioequivalence of brand-name drugs that have exactly the same dosage, intended use, effects, side effects, route of administration, risks, safety, and strength as the original drug. The pharmacological effects of branded drugs are exactly the same as those of their generic counterparts but are being sold at an exorbitantly higher price compared to generic drugs.

The major challenge in the adoption of generic drugs is distrust from both patients and doctors towards its effectiveness and quality. In addition to this, the prescription of generic drugs hurts the profitability of the healthcare providers as well as pharmaceutical companies. Indian healthcare is dominated by private hospitals, which constitutes more than 75% of the total healthcare being provided. The combination of generics as a percentage of original drugs may work well for all parties. The policymakers need to come up with an incentive strategy for generic drug prescription. The provision of financial incentive to doctors can further strengthen the development of generics market.

In countries like France, bonuses are awarded to doctors who have high prescription rates of generics. Ministry of health should launch awareness campaigns targeting the general public about generics safety and bio-equivalence. According to Kobayashi et al (2011), Japan's health ministry has issued a handbook with the authorized medicinal products and their therapeutic equivalence evaluations in order to inform both patients and healthcare professionals for the generics. India can emulate the same for better acceptability of the generics.

According to the Indian Brand Equity Foundation (IBEF), India is the largest provider of generic drugs globally. Indian pharmaceutical sector industrysupplies over 50 per cent of global demand for various vaccines, 40 per cent of generic demand in the US and 25 per cent of all medicine in the UK. The confidence of patients and doctors in generics can be increased by ensuring the quality of the processes at pharmaceutical companies producing these drugs. These companies should use ISO-quality management system certifications and follow rules of good manufacturing practices (GMP)
(Source: HealthWorld.com)

Three Companies in the Fray to Acquire Debt-Hit Orchid Pharma

Chennai, India: Three privately held pharmaceutical companies – Accord Life Sepc, Dhanuka Laboratories and Covalent Laboratories – have shown interest and submitted a resolution plan to take over the beleaguered Orchid Pharma, which is under the corporate insolvency process. The winning bidder may be announced later.

The resolution professional (RP) appointed by the National Company Law Tribunal (NCLT) had called for the second round of bids after Ingen Capital's bid was rejected due to failure to produce the promised money upfront.

In a regulatory filing, Orchid Pharma said, "The CoC, after considering the resolution plans received and after negotiating with the three resolution applicants, has decided to declare the H1 (highest) bidder. The RP will be submitting the resolution plan of the H1 bidder to the adjudicating authority if the same receives approval of the CoC with 66% voting share."

The key is the valuation. We understand that it fcould be significantly lower than what Ingen offered," a source said. (Source: Times of India)

Upcoming Events:

10 June 2019, IPHEX- International Exhibition for Pharma and Health Care
Gandhinagar, Gujarat, India

18-20 June 2019, CPhI China: SNIEC, Shanghai, China

22-23 July 2019, Cosmo Tech Expo: New Delhi, India

29-31 July 2019, APHM International Healthcare Exhibition, Kuala Lumpur, Malaysia

May 2019
Issue 3 Vol. 2

For feedback and query
Email: news@revapharma.com