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NEWS LETTER
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Indian Pharmaceutical Industry Scores on Compliance with USFDA

After years of struggle, the Indian pharmaceutical industry finally got many things right in 2018 with the American government's drugs regulator. Not only did inspection outcomes improve, far more in line with global outcomes, the number of cases where the USFDA chose classify a production unit under the 'Official Action Indicated' (OAI) category fell sharply.

From 27 cases of OAI in 2014 and 22 in 2017, the number shrank significantly to seven. After an inspection, the USFDA classifies a plant as either OAI, VAI (Voluntary Action Needed) or NAI (No Action Needed).

This change came even as FDA registered drug facilities rose 63 per cent in India between 2011 and 2018. In comparison, there was a 51 per cent increase in China, of 25 per cent in the European Union and a 10 per cent decline in the US itself.

A study by Indian Pharmaceutical Alliance (IPA) and consultancy firm McKinsey showed India had six per cent of FDA global inspections in 2014. This steadily roe to 14 percent of global inspections in 2018. Of the total fo 174 such inspections in India last year only seven were classified as OAI; 91 were VAI and 76 as NAI.

"There has been a reduction in data reliability, and investigation and root cause assessment related errors," noted the study. It says gaps in manufacturing systems and laboratory controls are now a leading source of non-compliance.

Companies are increasingly investing on improving such compliance. Rajiv Desai, executive vice-president for global quality at Lupin said the industry was adopting more of automation, investing in training and competence building of personnel to have a better understanding on compliance issues.

CDSCO and state food and drug control administrations have also got inspectors from the FDA and other global agencies to train Indian inspectors on compliance parameters, on how to inspect factories. H.G. Koshia, commissioner of the Gujarat Food and Drug Control Administration says these efforts have been consistent.

Only recently, we, in collaboration with the USFDA, trained 100 inspectors on equipping drug manufacturers on audit readiness and regulatory compliance" he stated.

Big firms have been investing in automation and electronic data management over the years, to improve compliance.

Production data at Indian companies was earlier largely recorded manually. Now, however, with electronic data management and recording, the earlier data integrity issues with the FDA are largely s thing of the past. "The new generation of operators are more keen to adapt to new technology and this is helping automation," he added. (Source: Business Standard)

Strides to Acquire Full Stake in Vensun Pharma

Strides Pharma Science Limited has announced that its step down subsidiary Strides Pharma, Inc has entered into an arrangement to acquire 100 per cent stake in Vensun Pharmaceuticals, Inc, a US-based Generics Company.

The board of directors of Strides have taken the same on record. Vensun was founded in 2011 with an asset-light partner-driven business model to develop products for the US generics markets. It entered into a partnership with the erstwhile Shasun Pharmaceuticals Limited for a range of difficult to develop products on a 50:50 profit share arrangement.

Vensun has a strategic focus on niche ANDAs with a portfolio of 16 commercialized ANDAs, four of which are partnered with Strides and constitute a significant part of Vensun's current revenues of US$ ~17 Million. Its portfolio also comprises additional 13 filed ANDAs which includes Strides Competitive Generic Therapy (CGT) designated product with US$ 400 Million market opportunity. Vensun also has a development pipeline with two other partners for ten products.

WHO Chief Unveils Reforms, With More Science, Apps and an Academy

The abrupt exit of the US FDA commissioner Scott Gottlieb after a nearly 2-year stint under the Trump administration throws Indian pharma into uncertainty on what would be the stance of the next commissioner on generics drug pricing, pace of approvals and regulatory inspections.

India, with the maximum US FDA-approved manufacturing sites outside the US and supplying 40 per cent of the generic formulations marketed in the US, is bound to feel the impact. The past two years have been a difficult phase for Indian pharma companies that export low-cost generic drugs to the US market.
With the Trump government keen on bringing down drug prices and containing the opioid crisis in the US, it remains to be seen whom the administration chooses to helm the agency.

Gottlieb, a medical doctor, oversaw a tenure that saw the speeding up of the drug approval process, curbs on the use of e-cigarettes among the youth, and facilitating qthe reduction in drug prices. He also played a role in initiating the generic drug user fee program. Data from Bloomberg show that the FDA approved a record 971 generic drugs in the fiscal year ended September 30. The total number stood at 937 in fiscal 2017 and 835 in fiscal 2016.

According to a Bloomberg Intelligence report, the sudden resignation of the FDA chief is not expected to slow down the agency's aggressive efforts to speed up reviews of both new medicines and generic versions of the older, off-patent drugs that lack competition.

"Gottlieb had approved drugs faster, laid down a foundation to make the FDA more communicative that helped companies expedite drug launches. Now it goes back to the square one," said Surjit Pal, a pharma analyst with brokerage firm Prabhudas Lilladher.

A slowdown in the approvals will be a negative for Indian pharma busy building pipeline of limited competition products to be launched in the US. Companies would also be apprehensive of an increase in FDA inspections and renewed pressure on drug pricing. (Source: Health World)

Spain Named World's Healthiest Country

Spain just surpassed Italy as the world's healthiest nation. That's according to this year's edition of the Bloomberg Healthiest Country Index, which ranks 169 countries based on factors that contribute to overall health.

Six of the top 10 countries were in Europe, with Italy ranking second. In contrast, the United States didn't even break into the top 30, ranking at number 35, one notch worse than last year.

The top 10 healthiest nations, according to the report, were:

Spain, Italy, Iceland, Japan, Switzerland, Sweden, Australia, Singapore, Norway, Israel

To come up with the rankings, Bloomberg researchers graded nations based on several factors including life expectancy, while giving penalties for health risks such as obesity and tobacco use. Environmental factors like access to clean water and sanitation were also taken into account.

The results mirror other research that came out last fall looking at future life expectancies in 195 countries and territories around the world. In that study, published in the international medical journal The Lancet, Spain also ranked first, with a projected life expectancy of 85.8 years by 2040. The United States ranked 64th.

Experts say the eating habits of the Mediterranean diet may provide clues for why Spain and Italy enjoy such good health. This heart-healthy diet is rich in fruits, vegetables, fish and whole grains, along with healthy fats like olive oil, nuts and avocados.

A number of studies have shown the Mediterranean diet reduces the risk of heart disease and may have numerous other health benefits, including reduction of LDL, or "bad," cholesterol, as well as a decreased risk of Alzheimer's disease, Parkinson's disease and cancer. One study published in British Journal of Nutrition found that following a Mediterranean diet was associated with a 25 percent lower chance of death from any cause.

People in Spain also benefit from a national health system focused on preventative care, according to a review by The European Observatory on Health Systems and Policies, which praised its "principles of universality, free access, equity and financial fairness." (Source CBS News)

Aurobindo Acquires 7 Oncology Products From US Company for $300 mn

Aurobindo Pharma said, it has completed the acquisition of seven marketed oncology injectable products, intellectual property and commercial infrastructure from Spectrum Pharmaceuticals Inc, a US-based global branded oncology company by Acrotech Biopharma.

In January, Aurobindo Pharma had said it will acquire a portfolio of seven branded oncology injectable products from Spectrum Pharmaceuticals Inc in a $300 million deal which includes an upfront cash payment of $160 million.

"We would like to inform you that the acquisition has been completed on March 1," Aurobindo Pharma said in a regulatory filing to the BSE.

According to the definitive agreements inked between the two companies, Acrotech Biopharma LLC, a subsidiary of Aurobindo, will pay an upfront purchase price of $ 160 million in cash plus up to $ 140 million on achieving regulatory and sales-based milestones for the seven products.

Acrotech will be acquiring the product portfolio on a debt free and cash free basis, Aurobindo Pharma Ltd said in a regulatory filing earlier.

The acquisition will help Hyderabad-based company to enter the branded oncology market in the US with a range of products which are well recognised in the segment, it added.

As part of the deal, the drug firm will also acquire a well-established and experienced branded commercial infrastructure in the US to continue commercialising these brands, the company had said.

The product portfolio is expected to generate a revenue of around $100 million for first 12 months after completion of the transaction for Aurobindo, the company had said.(Source: Business Standard)

New Pill Can Deliver Insulin

An MIT-led research team has developed a drug capsule that could be used to deliver oral doses of insulin, potentially replacing the injections that people with type 2 diabetes have to give themselves every day. About the size of a blueberry, the capsule contains a small needle made of compressed insulin, which is injected after the capsule reaches the stomach. In tests in animals, the researchers showed that they could deliver enough insulin to lower blood sugar to levels comparable to those produced by injections given through skin. They also demonstrated that the device can be adapted to deliver other protein drugs.

"We are really hopeful that this new type of capsule could someday help diabetic patients and perhaps anyone who requires therapies that can now only be given by injection or infusion," says Robert Langer, the David H. Koch Institute Professor, a member of MIT's Koch Institute for Integrative Cancer Research, and one of the senior authors of the study.

Giovanni Traverso, an assistant professor at Brigham and Women's Hospital, Harvard Medical School, and a visiting scientist in MIT's Department of Mechanical Engineering, where he is starting as a faculty member in 2019, is also a senior author of the study. The first author of the paper, which appears in the February 8 issue of Science, is MIT graduate student Alex Abramson. The research team also includes scientists from the pharmaceutical company Novo Nordisk.

Several years ago, Traverso, Langer, and their colleagues developed a pill coated with many tiny needles that could be used to inject drugs into the lining of the stomach or the small intestine. For the new capsule, the researchers changed the design to have just one needle, allowing them to avoid injecting drugs into the interior of the stomach, where they would be broken down by stomach acids before having any effect.

The tip of the needle is made of nearly 100 percent compressed, freeze-dried insulin, using the same process used to form tablets of medicine. The shaft of the needle, which does not enter the stomach wall, is made from another biodegradable material.

Within the capsule, the needle is attached to a compressed spring that is held in place by a disk made of sugar. When the capsule is swallowed, water in the stomach dissolves the sugar disk, releasing the spring and injecting the needle into the stomach wall.

The stomach wall has no pain receptors, so the researchers believe that patients would not be able to feel the injection. To ensure that the drug is injected into the stomach wall, the researchers designed their system so that no matter how the capsule lands in the stomach, it can orient itself so the needle is in contact with the lining of the stomach.

"As soon as you take it, you want the system to self-right so that you can ensure contact with the tissue," Traverso says.

The researchers drew their inspiration for the self-orientation feature from a tortoise known as the leopard tortoise. This tortoise, which is found in Africa, has a shell with a high, steep dome, allowing it to right itself if it rolls onto its back. The researchers used computer modeling to come up with a variant of this shape for their capsule, which allows it to reorient itself even in the dynamic environment of the stomach.

"What's important is that we have the needle in contact with the tissue when it is injected," Abramson says. "Also, if a person were to move around or the stomach were to growl, the device would not move from its preferred orientation."

Once the tip of the needle is injected into the stomach wall, the insulin dissolves at a rate that can be controlled by the researchers as the capsule is prepared. In this study, it took about an hour for all of the insulin to be fully released into the bloodstream. (Soure: World Pharma News)

Korean Govt to Inject $2.6B to Develop Biotech in 2019

According to reports from the Korean Herald, the government of Korea will spend US$2.61 billion this year to develop new biotechnology, as part of efforts to become the leading industrial hub.

The 2019 biotech support budget, which received a 2.9 per cent increase from a year earlier, aims to develop critical medical sectors, such as genomes and brain science, the Ministry of Science and ICT said, as quoted by the leading news agency.

The funding aims to boost Korea's innovation capabilities. Most of the budget will be allocated to support R&D and the development of the latest technologies centred on new drugs and promising medical instruments.

In recent years, local bio companies have become more competitive on the global stage on the back of robust R&D spending and policy support from the government, the ministry said. However, Korea still lags behind leaders in the development of new drugs, especially so-called blockbuster pills.

The ministry said the government will make utmost efforts to build up biotechnology that enhances people's quality of life and can help find remedies for such diseases as Alzheimer's, reported Korean Herald.

The ministry said the government will strengthen innovative technology and foster new industries through a regulatory sandbox system.

A regulatory sandbox is a term mostly used in the fintech industry and refers to a mechanism for developing regulations that keeps up with the fast pace of innovation.

Of the total budget set aside for 2019, 1.15 trillion won is allocated to the Ministry of Science and ICT, followed by 539.5 billion won to the Ministry of Education and 457.1 billion won to the Ministry of Health and Welfare. (Source: Bio Spectrum)

Prices of 390 Non-Scheduled Cancer Medicines Slashed by up to 87 Percent

New Delhi, The maximum retail price of 390 non-scheduled cancer medicines have been reduced by up to 87 per cent, which would result in annual savings of around Rs 800 crore (USD PLEASE) for the patients, the government said.

The National Pharmaceutical Pricing Authority (NPPA) on February 27 had brought 42 non-scheduled anti-cancer drugs under price control, capping trade margin at 30 per cent. Manufacturers and hospitals were directed to convey the revised MRP, to be effective from March 8, based on the trade margin formula.

"The NPPA under Ministry of Chemicals and Fertilisers has put out list of 390 anti-cancer non-scheduled medicines with MRP reduction up to 87 per cent. The revised prices would come into effect from March 8, 2019," an official release said. A total of 390 brands -- that is 91 per cent of the 426 brands reported by the manufacturers -- showed downward price movement, it added. This move is expected to benefit 22 lakh cancer patients in the country and would result in annual savings of around Rs 800 crore to the patients, the release said.

"The trade margin rationalisation for 42 anti-cancer drugs was rolled out as Proof of Concept, stressing on the new paradigm of self-regulation by the industry. The manufacturers of these 42 drugs have been directed not to reduce production volumes of brands under regulation," it said.

While the MRP of 38 brands has been reduced by 75 per cent and more, 124 brands have seen a reduction between 50 per cent to 75 per cent.

The MRP of 121 brands has been reduced between 25 per cent to 50 per cent, while the maximum retail price of 107 brands have been reduced below 25 per cent, the release said. (Health World)

Researchers Develop Reversible Antiplatelet Therapy to Fight Clotting, Cancer Metastasis

A new reversible, drug-free antiplatelet therapy could reduce the risk of blood clots and potentially prevent cancer metastasis, according to a study published in Science Translational Medicine. The therapeutic approach involves modifying human platelets to create "decoys" that are still capable of binding to some cells but will not aggregate or carry out the other normal platelet functions, including chemical signaling associated with the clotting process.

"The reversibility and immediate onset of action are major advantages of our platelet decoys, and we envision them to be useful in hospital-based situations," Anne-Laure Papa, an assistant professor of biomedical engineering at the George Washington University, said. Dr. Papa was a postdoctoral fellow at Harvard University's Wyss Institute when the research was conducted. "The therapy could prevent clotting in high-risk patients just before they undergo surgery, or be given to cancer patients alongside chemotherapy to prevent existing tumors from spreading."

Platelets play a vital role in halting bleeding and help protect against minor and life-threatening bleeding. However, hyperactive platelets can also contribute to various disorders, including severe blood clots, heart disease and cancer. While several antiplatelet drugs fight clots, their effects are not easily reversible, leaving patients vulnerable if they develop unexpected severe bleeding or are in need of an emergency surgical procedure.

Platelets also play an important part in cancer metastasis by binding to tumor cells and protecting them both from the body's immune system and shear stress as they circulate in the bloodstream. Platelets may also help the cancer cells exit through blood vessels and seed distant tissues during the process of metastasis.

To create the decoy platelets, the research team used a detergent treatment and centrifugation to strip natural human platelets of their inner structures and remove their basic activation and aggregation abilities. These decoy platelets became about one-third the size of a regular platelet while retaining a majority of adhesion receptors on their surface. This allows them to bind to other cells in the bloodstream, such as cancer cells, but not become active during the blood clotting process. (Source: World Pharma News)

Indian Government Plans to Colour Code Generic Drugs

In a move to promote low-cost generic medicines, the government of India plans to colour code such drugs to enable consumers to differentiate between generic medicines and other drugs and take an informed decision while purchasing them from chemists.

New Delhi, In a move to promote low-cost generic medicines, the government plans to colour code such drugs to enable consumers to differentiate between generic medicines and other drugs and take an informed decision while purchasing them from chemists. Apart from colour coding, the government is also considering use of symbols to make generic medicines easily identifiable.

Of late, the health ministry has taken various measures to encourage sale of generic medicines over branded ones. The drug regulator has also asked companies to print generic names on their labels in a font which is two font sizes larger than the brand name.

The proposal to colour code generic medicines was discussed at a recent Drugs Consultative Committee meeting. The coding system is likely to be similar to that used in food products to differentiate between vegetarian and non-vegetarian food. The government is expected to soon draw a detailed proposal on the matter, which will be put out for stakeholder consultations.

International agencies like the World Health Organisation has said increased use of generics can reduce the burden of out of pocket expenditure on healthcare. Currently, essential medicines constitute over 60% of pocket expenditure on healthcare in India. (Source: Health World)

Pfizer Secures Exclusive Option to Acquire Gene Therapy Company Vivet Therapeutics

PARIS & Vivet Therapeutics ("Vivet"), a privately held gene therapy biotech company dedicated to developing gene therapy treatments for inherited liver disorders with high unmet medical need, and Pfizer Inc. (NYSE: PFE) announced that Pfizer has acquired a 15% equity interest in Vivet and secured an exclusive option to acquire all outstanding shares. Pfizer and Vivet will collaborate on the development of VTX-801, Vivet's proprietary treatment for Wilson disease.

Jean-Phillippe Combal, Co-Founder & CEO of Vivet, said, "We welcome Pfizer as a shareholder and partner that can help us advance our efforts to develop therapies for patients burdened with inherited liver disorders. This investment demonstrates the clear value of Vivet's innovative approaches to gene therapy."

Mikael Dolsten, Pfizer Chief Scientific Officer and President, Worldwide Research, Development, and Medical, said, "Pfizer strives to provide meaningful enhancements to the lives of patients with rare diseases. Our partnership with Vivet offers an important expansion of Pfizer's commitment to collaborate with the scientific community and to accelerate our leading AAV-directed gene therapy portfolio."
(Source: World Pharma News)

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