Top Story

EMA Warns of Staff Exodus and Potential Public Health Crisis

The European Medicines Agency (EMA) has told the EU Commission that there is a risk of a 'public health crisis' if it is moved to a location where it was unable to retain most of its staff.

Following an internal staff-retention survey, it said the 'best case scenario' was that it would be able to retain 81 percent of its employees—however the results suggested that some cities would result in a staff-retention rate of less than 30 percent.

"This would mean that the Agency is no longer able to function and, as there is no backup, this would have important consequences for public health in the EU," the agency said in a statement.

Although the EMA did not name the cities it had asked employees about, it is thought that Amsterdam came out on top and would result in the fewest staff losses. It is believed that Barcelona and Vienna were staff's second and third preferred choices.

The body said it has been working on a business continuity plan aimed at ensuring that the assessment of medicines is not disrupted before, during and after the move, and that patients in Europe continue to have access to high quality, safe and effective medicines.

The final decision on the EMA's relocation rests with EU leaders, who will try to reach a deal at their next summit in October, with a final decision expected in November.

Products & Pricing

Gilead Gets China Approval for Sovaldi HC

China's FDA has given the go-ahead in China for Sovaldi, the company's first Hepatitis C medication, to be marketed to China's 10 million patients.

For China, hepatitis B has been one of its biggest health issues, with an infected population of nearly 100 million. Until recently, the authorities have channeled much of its resources in controlling that direction.

But now it is also trying address the public health concerns over hepatitis C.

Pricing for Sovaldi is not yet know. However, competing in China will not be easy for Gilead, as in addition to Sovaldi, AbbVie had 2 medications approved at the same time as Gilead, Bristol-Myers Squibb's was granted hep c drug approval in April and Merck's Zepatier application for approval was accepted by China's FDA last month.

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Mixed Fortunes for Sanofi and J&J with RA Treatments

Some patients with rheumatoid arthritis living in England and Wales should get 'routine' NHS access to Sanofi's Kevzara after the UK's cost regulatory—The National Institute for Health and Care Excellence—deemed the drug cost effective.

It is backing the use of Kevzara as an option for treating severe active rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with a combination of conventional disease-modifying anti-rheumatic drugs.

Sanofi has agreed a patient access scheme that will reduce the cost of the drug to the NHS, but the details have not been revealed.

Rheumatoid arthritis affects around 450,000 people in the UK, of whom around 15 percent have the severe form of the disease.

The drug's approval in Europe in June was based on results from seven Phase III trials of more than 3,300 adults with moderately to severely active RA who have had an inadequate response or intolerance to one or more biologic or non-biologic treatments, showing the drug to have induced statistically significant, clinically-meaningful improvements in patients.

Meanwhile, the FDA has expectedly rejected Johnson & Johnson's rheumatoid arthritis drug Sirukumab with a 12 to 1 vote against which leaves J&J with a decision of whether to try again or call it a day. The company says it plans to meet with the FDA to discuss exactly what it will need for drug approval before deciding.

Hurricane Shuts Much of Puerto Rico's Pharma Manufacturing

Pharma manufacturers in Puerto Rico are struggling to restore production following the devastation left by Hurricane Maria last week.

Although some facilities are operating with backup power, many of the 50 pharmaceutical plants in Puerto Rico are idle at present, according to USA Today. Power to the island is not expected to be restored for up to six months, and loss of production could potentially lead to some short-term drug shortages.

The FDA says that it was working closely with pharmaceutical companies to prevent shortages.

Pharmaceuticals made up 72% of Puerto Rico's 2016 exports valued at $14.5 billion, according to the U.S. Bureau of Labor Statistics. Puerto Rico represents 25% of total U.S. pharmaceutical exports.

Amgen, AbbVie, Merck, Eli Lilly and AstraZeneca are among pharmaceutical companies with operations in Puerto Rico.

Markets, Finance & Funding

CVC Talks $4B Alvogen Sale with Shanghai

The private equity owners of Alvogen— including CVC Capital Partners— are considering their options for the New Jersey based drugmaker, which could be valued at up to $4 billion, with a sale of Alvogen's U.S. business to Shanghai Pharmaceuticals Holding Co. being a possibility.

CVC and its controlling shareholders—who gain their share in 2015 deal which then valued Alvogen at $2 billion—have held on-and-off talks with Shanghai, according to Bloomberg.

One potential scenario, could see Alvogen holding onto its operations in Asia and Europe, which include Alvogen Korea Co., a plant in Romania, and a packaging center in Serbia. Shanghai, though, would pick up Alvogen's biggest market,

where it sells generics in areas such as oncology, cardiology and neurology and provides third-party services including contract manufacturing in clinical research.

For Shanghai, the buy would be a boost following its failed bid for German generics maker Stada, which is going through the sale process with Bain Capital and Cinven.

Amgen and Simcere Target China in Cancer Biosimilar Deal

In a co-development deal with Simcere, Amgen has signed an agreement with China for four undisclosed biosimilars in oncology and inflammation.

Amgen will be responsible for development, filing for approval from China's FDA and manufacturing of the biosimilars, while Simcere will take care of distribution and commercialization in its home country.

The particular drugs covered and the financial terms were not disclosed.

Teva Finishes Women's Health Sale with $2.38B Deals

Teva concluded the sale of its women's health divisions in deals worth $2.38 billion Proceeds will go towards to pay down of debt.

It has sold its Paragard product to CooperSurgical for $1.1 billion and sold its contraception, fertility, menopause and osteoporosis products to CVC Capital Partners Fund VI for $703.

These products generated $258 million in sales last year.

Simultaneously, they sold their emergency contraception brands to Foundation Consumer Healthcare for $675 million. These brands generated $140 million in sales last year.

All-in, the agreements represent women's health divestitures totaling $2.48 billion.

Teva originally acquired its women's health unit from Merck for €265 million in 2010.

It's all part of an effort to refocus and pay down debt, after picking up Allergan's generics offerings for $40.5 billion in 2015. It has just hired a new CEO, Kare Schultz, from Lundbeck and has announced a major round of 7,000 job losses—in an attempt to improve its fortunes, not least in its share price which has dropped 64% in a year.

Novartis New York Plant Bought for $18M and Resold for $30M

A vacant Novartis manufacturing facility in Suffern, New York, that initially sold for $18 million has been resold to a Manhattan-based developer for $30 million.

Novartis sold the 162-acre campus with its 585,000 square-foot building comprising office space, laboratories, manufacturing areas and warehouse space, to RS Old Mill in early September, whereupon RS Old Mill then flipped the property to Suffern Partners—an affiliate of Bridgewater Capital Partners. The new owner has not declared what it intends to do with the site but it is currently zoned only for light industrial use.

In 2014, Novartis announced its plan to close about 20 sites as part of a restructuring of its pharma division. The decision to close Suffern was in line with the company losing exclusivity on its patent for the blood-pressure drug Diovan, which had also seen a decline in demand.

At its peak, the facility once employed more than 500 people.

Catalent Acquires Cook Pharmica for $950M

Catalent has agreed to pay $950 million to buy Cook Pharmica and acquire its 875,000 square foot biologics manufacturing and development facility in Bloomington, Indiana.

New Jersey based Catalent says it will pay $750 million to the privately-held Cook Group on closing and the balance in $50 million tranches over the next four years.

It will also take on its 750 employees, including its executive team.

The Cook operation was founded in 2004 and has capabilities in sterile formulation and fill/finish across liquid and lyophilized vials, prefilled syringes, and cartridges.

The company generated revenues of $179 million last year.

Catalent has been building up its biologics and currently offers fill-finish services in Brussels, Belgium and Limoges, France, and conjugation technology in Emeryville, California. It has a biologics development and biomanufacturing facility in Madison in which it currently is investing about $35 million in single-use bioreactor capacity that it expects to be online in November.

Gates Invests in U.K. Immunocore's Infectious Disease R&D

The Bill & Melinda Gates Foundation is investing up to $40 million in Immunocore to spur research into the use of T cell receptor (TCR)-based therapeutics to treat tuberculosis and HIV.

Immunocore is primarily known for its work in cancer. That is what prompted AstraZeneca, Eli Lilly, GlaxoSmithKline and Roche's Genentech to strike deals with Immunocore, and what underpinned its $320 million (€268 million) round in 2015. However, Immunocore's early-stage teams are also working on autoimmune and infectious disease programs.

U.K.-based Immunocore's infectious disease work has attracted the attention of the Gates Foundation, prompting the world's largest charitable foundation to invest up to $40 million in the company. Immunocore will use the money to advance programs against tuberculosis and HIV.

Fosun Offers Revised $1.1B Bid for Stake in India's Gland Pharma

China's Fosun has issued a revised bid for a stake in India's Gland Pharma, after its $1.26 billion deal for an 86% stake was vetoed by India's cabinet.

Fosun has now tempered its offer to $1.1 billion for 74% which is sufficient to circumvent the Indian government's intervention.

Fosun didn't cite the regulatory blockade as its primary reason for revising its offer. In a statement to the Shanghai Stock Exchange said that, "given that Gland Pharma's operation is in good condition, the founder shareholders intend to maintain a higher stake without impacting on Fosun obtaining a controlling share."

However, it did also mention that the transaction does not require approval from the India Foreign Investment Promotion Board and India's Cabinet Committee on Economic Affairs (CCEA).

In an effort to boost the country's pharma sector, the Indian government in June loosened up its rules for foreign investment, allowing an automatic permit route for investments in existing biopharma businesses of up to 74%. Only foreign investment in a pharma company above that threshold requires government approval.

Gland Pharma specializes in generic injectables. At $1.1 billion, it would make the transaction the largest made by a Chinese pharma abroad.

Alexion Plans Hundreds of Layoffs and a HQ Move

Alexion's new management team is rolling out an overhaul that includes cutting 20% of its workforce—625 people—and moving its headquarters to Boston's biopharma hub over the next 12 months.

Previously based in New Haven, Connecticut, the biotech will close multiple manufacturing facilities and regional and country offices, outlined in a September announcement. Cuts will also hit the R&D organization, which already restructured once this year which created 200 job losses.

All-in, the company expects to save about $250 million in annual expenses by 2019. The company says the restructuring will cost $340 to $440 million.

CEO Ludwig Hanston said the corporate overhaul is intended to help Alexion grow its rare disease business, focus R&D efforts, pursue business development opportunities and reorganize its infrastructure.

The company plans to begin closing its Rhode Island site this year because it does not have a "multiproduct". The site currently makes lead drug Soliris. It is expected to close by mid-2018. The site has 250 employees but has a history of manufacturing lapses. It was issued an FDA Form 483 last August.

Going forward, the company plans to reduce production in the U.S. and move it to Ireland when its new $100M facility comes on stream there.

In moving its HQ to Boston, Alexion is joining many biopharma peers such as Takeda, Amgen, Biogen, Novartis, Pfizer and Sanofi and Merck KgaA who have also centralized in specific scientific hubs with larger talent pools.

China's 3SBio JV to Buy Canadian Therapure Biopharma CDMO for $290M

China's 3SBio, in a joint venture with CPE Funds is looking to acquire Canadian Therapure Biopharma's contract development and manufacturing business for $290 million subject to shareholder approval.

3Sbio say he purchase is part of their plans to enter the growing North American biopharma sector and build its global biologics business.

If completed, 3SBio would gain than 340 biologics professionals in North America, with a skill base in operations, management, market development, R&D and manufacturing.

The US biologics market has been expanding at a notable pace of late.

In July, CMC Biologics which was acquired earlier in the year by Japanese conglomerate AGC Asahi Glass, said it would hire up to 150 more employees at its operation in the Seattle area, as it makes the location the center of its expanding biologics-based CDMO business.

Other Japanese companies also have made the move into biologics. Fujifilm, with a view of expanding beyond its declining film business, entered biologics manufacturing in 2011 when it reportedly paid about $490 million to buy biologics plants in North Carolina and in Middleborough UK and created Fujifilm Diosynth Biotechnologies.

BioMarin Expands Facility to Manufacture Medicine for Rare Genetic Diseases

BioMarin Pharmaceutical Inc has recently extended its site footprint to 20 acres in Cork, Ireland, as the company continues to experience a rise in the global demand for its therapies to treat rare genetic diseases that mostly affect children.

Since 2011, the company has grown to 2,400 employees globally. BioMarin focuses on developing first-in-class and best-in-class therapeutics that have the potential to improve clinical outcomes of patients with rare genetic diseases. The company currently has six approved products that are the only drugs available on the market today for patients who suffer from diseases, so rare, difficult to diagnose and progressively debilitating where the entire afflicted population may number as few as 1,000 worldwide.

BioMarin was certified by the European Medicines Agency (EMA), in Q1 2017 and its site in Cork, Ireland was subsequently licensed for commercial supply by the US FDA in May this year for a range of activities including bulk production, Quality Control testing, Quality Assurance release, final product secondary packaging and distribution.

Legal, Regulatory & Compliance

AbbVie’s and Amgen Settle Humira Patent Dispute

AbbVie's has reached a patent settlement with Amgen, holding off that company's Humira biosimilar until 2023.

Under the arrangement, Amgen will have to wait until Jan. 31, 2023, to launch its Humira rheumatoid arthritis (RA) biosim in the U.S.

However, Amgen expects to launch it in Europe next October, which could start to make inroads on sales of Humira's industry-leading product.

Despite this, AbbVie executives think Humira will continue increase it $16 billion in annual sales, suggesting $20 billion as their peak sales potential.

Amgen won FDA approval for its biosim last year but until now, it has been unable to take it to market due to patent litigation. The settlement provides sales licenses on a worldwide, country-by-country basis.

Humira generated about $10.4 billion in the U.S. last year and $5.6 billion internationally, accounting for 63% of the company's total sales.

Other companies with Humira biosims include Sandoz and Fujifilm Kyowa Kirin Biologics. Both of their versions are with European regulators.

AmerisourceBergen to Pay $260M Over Production of Sterile Cancer Medicines

AmerisourceBergen has agreed to pay a $260 million federal misdemeanor fine and finally lay to rest a 5-year-long Justice Department probe into its sales of prefilled cancer drug syringes that were shipped from a facility that was never registered with the FDA.

The federal misdemeanor charge claimed that between 2001 and 2014, two of the company’s Alabama-based subsidiaries, Oncology Supply Co. and Medical Initiatives, prepared millions of cancer drug syringes, including Aloxi and Anzemet as well as generics Neupogen and Procrit, at an FDA unapproved facility.

The probe dates to 2012, when the U.S. Attorney in the Eastern District of New York began looking into how the drug wholesaler was handling intercompany transfers involving its prefilled syringe program overseen by the now-defunct Medical Initiatives, the company's oncology distribution center and its group purchasing organization for oncologists.

This is the company's second time in two months that it has settled federal probes around violating federal laws or standards. In August, it agreed to pay more than $13 million to settle federal allegations that its specialty pharmacy unit had pushed patients to get refills of Exjade in return for higher rebates from the Novartis. Novartis, for their part settled out of court with the Justice Department two years ago for $390 million.

Chinese Drugmaker Issued FDA Warning Over False Test Results

The FDA has issued Chinese drugmaker Shandong Vianor Biotech with a warning letter and placed the company on an import alert following an inspection that uncovered falsified test results and during which officials barred investigator access.

During the May inspection, Vianor Biotech management admitted to regulatory inspectors that they falsified analytical test results used to release many of its products to the U.S.

Additionally, the agency claimed the company reported a batch of one of its products was within specification in its certificate of analysis (CoA) despite lab analysis indicating the product was sub potent.

"When questioned about why the CoA reported passing results even though the batch actually failed, your quality unit manager stated, 'I made a mistake,'" the FDA said in its letter sent to Vianor Biotech this week.

The inspection also found "rusted and corroded screws, fluid and debris and metallic mesh material on the product contact surfaces," at the plant located in Linyi, China.

During the inspection, the agency said, company officials prevented an investigator from entering a room identified as a laboratory. Later, when allowed to enter the room, the investigator found no lab equipment in situ. The company said the laboratory was actually offsite, and that "it was not a convenient time" for the investigator to inspect those premises.

Talcum Powder Lawsuit Plaintiffs Claim J&J Knew of Talc Danger in 1970s

Plaintiffs pursuing talcum powder lawsuits in Missouri state court claim that newly unsealed documents show that Johnson & Johnson has known since the 1970s that its talc-based powders contained asbestos fibers, which could increase the risk of ovarian cancer in women who used the products daily.

According to Bloomberg, the documents were unsealed earlier this month in Missouri's 22nd Circuit Court for St. Louis, where more than 1,000 plaintiffs accuse Johnson & Johnson of failing to warn consumers of the ovarian cancer risk allegedly associated with its Baby Powder and Shower-to-Shower products.

The unsealed documents include a May 1974 memo authored by an official at the Johnson & Johnson's Windsor mine that recommended "the use of citric acid in the depression of chrysotile asbestos" from talc extracted from the site to "provide protection against what are currently considered to be materials presenting a severe health hazard and are potentially present in all talc ores in use at this time."

In a 1973 report, a Johnson & Johnson official noted that sub-trace quantities of two types of asbestos had occasionally been identified in the company's talcum powder, and that "these might be classified as asbestos fiber."

Missouri is scheduled to convene its sixth talcum powder ovarian cancer trial on October 16, 2017. Four Missouri juries have already awarded talcum powder plaintiffs compensatory and punitive damages ranging from $55 million to $110 million. Only one jury has found for Johnson & Johnson.

More than 5,000 talcum powder lawsuits have been filed against Johnson & Johnson in courts nationwide. California's first talcum powder trial concluded last month in Los Angeles Superior Court, with the jury awarding $417 million, including $340 million in punitive damages, to a woman with terminal ovarian cancer.

Aegerion to Pay $35M to Settle Juxtapid Marketing Breaches

Aegerion Pharmaceuticals will pay $35 million in fines for violating marketing rules in the promotion of its cholesterol lowering drug, Juxtapid.

According to the US Department of Justice, Aegerion has agreed to a $7.2 million plea deal on criminal charges plus a $28 million civil settlement for two violations of the Food, Drug and Cosmetic Act, following allegations that it promoted Juxtapid outside of the drug's FDA approval and broke risk-management and anti-kickback laws.

Juxtapid won its U.S. approval in 2012 to help lower cholesterol in patients with the rare condition, homozygous familial hypercholesterolemia. However, U.S. officials claim Aegerion sold the medication as a drug for high cholesterol generally.

Amongst the charges, prosecutors alleged that company sales representatives were briefed to advise doctors and patients that Juxtapid would “take patients out of harm’s way” and prevent “impending” heart attacks and strokes, despite the lack of data supporting the claims.

It’s not the first time Aegerion has encountered trouble over its Juxtapid claims. In 2015, fired its CEO Marc Beer, for overhyping the product’s efficacy, leading to an FDA warning letter and a Department of Justice subpoena over its marketing claims. Aegerion merged with QLT last year to form rare disease drugmaker, Novelion. According to Novelion, the company generated $101 million in sales in 2016 with Juxtapid accounting for about two-thirds of total sales.