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Drug Pricing Controversy has Returned

(Sources: an article prepared by Sy Mukherjee and published by Fortune.com; articles prepared by Donna Young and by Ian Schofield that were published by Scrip)

While U.S. lawmakers have spent a significant amount of time criticizing Turing Pharmaceuticals Inc. for its pricing practices, it was the model that the company and other firms like Retrophin Inc. and Valeant Pharmaceuticals International Inc. based their businesses on – buying up sole-source medicines and significantly raising their prices, rather than engaging in research and development activities.

The latest reworks over Mylan NV's price increases on *EpiPen (epinephrine)* could trigger more than just an investigation into the company's pricing practices. It could turn into a wider examination of industry's use of patient assistance programs (PAPs), which already are being probed by U.S. federal prosecutors and state attorneys general.

Mylan's US$600 price tag for the emergency treatment for allergic reactions, a 500% price increase since 2009, has captured widespread media attention and prompted new letters from several members of Congress. And while it has many of the hallmarks of previous pricing controversies, there are signals in the letters that some of the steps industry is taking to offset high prices don't seem to satisfy lawmakers.

Mylan said it offers two types of assistance for EpiPen: a PAP, for which the company does not disclose the amount of help eligible patients can receive, and a so-called savings card, which is essentially a coupon worth up to US$100. The card is intended to offset out-of-pocket costs like copays and deductibles for patients with commercial health care insurance, and covers up to three EpiPen 2-Pak or EpiPen Jr 2-Pak cartons at a time.

Members of the U.S. Senate complained to Mylan that the US$100 discount card wasn't enough to cover patients' high copays and deductibles for EpiPen. One Senator criticized Mylan's PAP for EpiPen as "both inadequate and presented in a manner that could be misleading to consumers."

Other lawmakers already have been delving into PAPs, who have been in hot pursuit of Valeant Pharmaceuticals International Inc. and Turing Pharmaceuticals AG – the two companies that have been at the center of the drug pricing issue in the past year

With respect to the Mylan's EpiPen pricing issue, a Senator stated, "There does not appear to be any justification for the continual price increases of EpiPen," She contended EpiPen's manufacturing costs have been stable "and Mylan does not need to recover the product's research and development costs" because the drug had been on the US market years before the company acquired it. Mylan has been able to hold 90% of the epinephrine market mostly because of the lack of competition, thus stimulating a possible Federal Trade Commission review.

The pricing controversy has turned political in the US presidential campaign. While a proposal by presidential candidate

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In Brief . . .

- **Walgreens Boots Alliance** and **AmerisourceBergen Corporation** (ABC) agreed to amend the second tranche of warrants held by Walgreens Boots Alliance to purchase AmerisourceBergen common stock, to allow for an immediate exercise of these warrants (originally scheduled to be exercisable in March 2017). WBA then exercised the warrants and purchased 22,696,912 shares of ABC common stock for approximately US$1.19 billion, increasing its ownership stake to approximately 23.9% of ABC's outstanding equity. "Today's announcement builds on the strong and collaborative working relationship our companies have built together, and further strengthens the long-term strategic relationship we launched in 2013," said Executive Vice Chairman and CEO *Stefano Pessina*.
- The **IMS Institute for Healthcare Informatics** opened a new branch in Singapore to support improved healthcare outcomes across Asia. The new team will develop relationships with the public and private sectors to provide regional markets with tools they need to make better and more cost-effective healthcare policy decisions. *Xavier Xuanhao Chan, PhD*, will serve as director of the IMS Institute in Asia.
- Six national medical centers affiliated with Japan's **Ministry of Health, Labor and Welfare** (MHLW) achieved an average generic use rate of 73.8% (on a volume basis) in FY2015, surpassing the government target deadline of 70% by mid-2017. **The National Cancer Center** (NCC) scored the highest, with a rate of 82.19% in the year ended March 2016.
- Non-profit organizations across the U.S. were awarded grants from the **Cardinal Health Foundation** to help fight prescription drug misuse by improving their communities' medication disposal programs. "One of the simplest and most effective ways to fight prescription drug misuse is to encourage the proper disposal of unused or expired medication," stated *Betsy Walker*, community relations director and Generation Rx program manager at Cardinal Health. "Cardinal Health Foundation is investing US$360,000 to support these programs and help educate on proper disposal." Learn more at: http://www.generationrx.org/
- **Takeda** has joined the global effort to create a Zika vaccine, signing a collaboration agreement with the U.S. government that could be potentially worth US$312 million if a candidate were brought through Phase III trials and FDA review. Takeda's candidate purportedly differs from other vaccines already in human trials in that it is not a DNA vaccine and given that it contains inactivated Zika virus, rather following than the more common attenuated-virus approach. The Japanese pharma joins GlaxoSmithKline, Sanofi and a host of other biotech companies and organizations working to advance Zika vaccine prospects as the virus continues to spread, how having reached 60 countries.

(Sources: Business Wire, Drug Store News, FiercePharma, IMS Health, Pharma Japan and Scrip)

Pricing (cont.) . . .

Hillary Clinton aimed at penalizing biopharmaceutical makers whose prices are deemed "unjustified" currently is targeted at older medicines, it could result in bringing all drug costs under the microscope. The proposal aims to regulate price increases through various measures, including the creation of a federal panel of health and consumer protection officials, which would get to decide what prices are fair based on the advice they receive from patient advocates and independent non-government pricing and comparative effectiveness experts, among others.

Clinton's proposal, released September 2nd, continues the political heat over Mylan NV's price increases on its emergency allergy therapy EpiPen (epinephrine). It's an issue that's not going away, analysts caution, and Clinton's plan has dangerous implications for industry. "We often ignore political statements," Bernstein analyst Aaron Gal said in a September 2 research note, "but this one is worth noting: assuming this is serious, it is essentially drug price regulation." Clinton's plan is a "step across the chasm," he said. While Clinton's proposal targets life-saving treatments that have been "longstanding" on the US market, it may not take much for all areas of biopharmaceuticals to come under examination by the government panel, which would be given the legal power to act against offenders, like forcing them to pay fines, Gal pointed out. "While the initial focus is narrow, once you create a group with the capabilities of assessing the 'relative value to patients' of drugs and vest with them the power to act to protect 'public health,' the boundaries get very fuzzy," he warned.

Under Clinton's proposal, the federal panel, with the advice of outside groups, would determine what's an unjustified, outlier price increase based on its trajectory, the cost to produce the medicine and the relative value to patients, among other factors "that give rise to threatening public health."

The U.S. market is not the only market exposed to price constraints. The drug pricing agreement between the Irish Pharmaceutical Healthcare Association (IPHA) and the Irish government, which is expected to bring savings of €785m (US$886.5 million) through across-the-board annual price reductions over the next four years. Under the new framework agreement, pharmaceutical prices will be reduced each year until 2019. Prices will be set at an average of price levels in 14 European countries (Reference Pricing), and will generate direct savings to the state in hospital and pharmacy supplies. Leisha Daly, president of IPHA, said this was "the largest single package of savings the pharmaceutical industry has ever delivered to the state," and that the deal would offer stability in the supply of medicines to patients and clinicians. She said the government negotiating team had "set a demanding challenge to us," and that IPHA had "worked hard on all aspects of pricing to respond with a commercially-viable, substantial package."

In China, the second quarter has been a period of stabilization for multinational drug makers, where the challenges of cost cutting and a national policy to encourage domestic generics remain. Companies including Novartis and Roche are voluntarily reducing prices for major products, to help them compete, reflecting a new willingness to improve patient access in one of the world's largest pharma market.

The industry is concerned about these negative events. Allergan CEO Brent Saunders tried to convey a simple message to investors and customers: I'm not on board with unreasonable price hikes for life-saving drugs. Saunders laid out what he called Allergan's "social contract with patients," including promises to keep price hikes on branded medications to an acceptable level and to balance the profit motive with legitimate investments in R&D that could yield life-saving drugs. He also condemned the controversial price increases which have placed the biopharma industry in the political hot seat. "I understand the public outcry and add my voice to the condemnation of these [price-gouging] behaviors," Saunders wrote.

The Allergan chief went on to explain that while a reasonable profit is necessary for drugmakers to continue to take risks and innovate new products, there is a fundamental social agreement between pharma companies and consumers that's taken a hit in recent years. "It was designed to be a win-win-win," he wrote. "New medicines for patients. Lower overall cost or damage of disease. An appropriate return on capital for those taking risk by investing time and talent in the arduous and uncertain task of developing new treatments. Those who have taken aggressive or predatory price increases have violated this social contract!"

Barcode Labeling Implementation in Japan

(Source: The publication, Pharma Japan)

The rate of barcode labeling of product codes for oral and topical drugs in dispensing package units (blister packs and ampules) rose sharply at the end of September 2015 compared to the previous year, Japan's health ministry announced on September 2nd.

According to the results of a survey on progress in the barcode labeling of ethical drugs, the rate increased from 61.4% to 97.5% for oral drugs and 47.1% to 95.6% for topical drugs. The product code labeling for these products has been required since July last year. In April, the "Ryukaikon" council for the improvement of ethical drug distributions agreed on making new barcode labeling mandatory for sales package units and shipping package units from April 2021.

The survey results indicated that companies are adopting barcoding ahead of the schedule.

Sales package units labeled expiration dates for 14.2% of oral drugs (8.5% a year earlier), 30.7% of injectable drugs (up from 15.9%), and 3.5% of topical drugs (up from 1.7%). Shipping package units labeled product codes for 72.4% of oral drugs (up from 50.4%), 66.3% of injectable drugs (up from 43.4%), and 64.9% of topical drugs (up from 34.5%). Expiration dates were labeled for 70.5% of oral drugs (up from 46.9%), 63.3% of injectable drugs (up from 41.3%), and 58.3% of topical drugs (up from 28.2%).

One hundred percent of wholesalers (up from 91.7% the previous year) said that they use new barcodes for sales package units at their distribution centers, and 79.4% (up from 69.4%) for shipping package units. The survey targeted 205 drug makers and 51 drug wholesalers and received valid responses from 197 and 48, respectively.

Due to IFPW's upcoming 2016 General Membership Meeting, the next issue of the FOCUS Newsletter will be September 29th, 2016. We look forward to seeing everyone in London!