FOCUS

Vol. 25, Vol. 14 International Federation of Pharmaceutical Wholesalers July 12, 2018

Amazon Enters the US Pharmaceutical Market

(Source: edited excerpts from an article prepared by Zachary Tracer - with assistance by Anna Edney, Robert Langreth, and Jared S Hopkins - and published by Bloomberg.com; Wall Street Journal)

Amazon.com Inc. entered the U.S. pharmaceutical business with the acquisition of online pharmacy PillPack, for about US$1 billion. PillPack is a five-year-old Boston startup that has regulatory approval to deliver medicines throughout the country. With this purchase Amazon is hoping to take its price-chopping, consumer-friendly approach to prescription drugs.

"Their scale will allow them to negotiate prices in a way that the drug industry has never seen before," said Lisa Bielamowicz, president of the consultancy Gist Healthcare "They have a company ethic of returning these kinds of savings to consumers."

High drug prices in the U.S. have drawn increasing scrutiny, as consumers face climbing out-of- pocket costs and drugmakers announce new treatments with six-figure price tags.

Before the PillPack deal, Amazon had signaled dissatisfaction with the current state of affairs with respect to the cost of healthcare, leading to the formation of a joint venture with JPMorgan Chase & Co. and Berkshire Hathaway Inc. to improve healthcare for their workers. One of the targets of this venture is the cost of drugs.

Tackling drug pricing won't be easy. The eventual price a consumer pays for a treatment is influenced by an opaque system of drugmakers, insurers and intermediaries called pharmacy benefit managers (PBMs). With Amazon's backing, the company could pursue new ways of upending those relationships, with the potential to create savings for consumers.

“This [acquisition] could shake up the pharma supply chain quite a bit,” said a senior adviser at the Robert Wood Johnson Foundation, a philanthropy focused on health. “Another question is to what extent Amazon might ascend the supply chain and start playing more of the PBM-like role. It helps that no one is happy with the current distribution system.”

Acquiring PillPack gives Amazon immediate access to much of the U.S.'s roughly US$329 billion retail prescription drug market, including state regulatory licenses and industry relationships. PillPack sells pre-sorted packets of prescriptions drugs, delivering them to customers in their homes. The closely held firm has software that automates many routine pharmacy tasks, such as verifying when a refill is due, determining co-pays, and confirming insurance.

Ira Loss, senior healthcare analyst at research firm Washington Analysis LLC, said the deal could create a long-term problem for distributors and pharmacies. He said he expects that at some point the costs of drugs will come down, given Amazon's track record. “Everything he [Bezos] gets involved in tends to lower the prices of the products being sold,” Loss said.

Amazon is likely to focus on generics and branded pills, said Ashtyn Evans, a healthcare analyst at Edward Jones & Co. It

(continued on page 2)

In Brief...

- **Sanofi** (France) is investing US$77 million in its new global R&D operations hub in Chengdu, China, focusing on digitalization and big data analysis, specifically the management analysis of global multicenter clinical trials data and files across the company’s therapeutic areas. It will host approximately 300 local R&D experts by 2020. Sanofi already has an Asia-Pacific R&D center in Shanghai.
- Australia-based **Mayne Pharma** has appointed recent **McKesson** executive, *Patrick Blake* to its board of directors. Blake spent more than 20 years at McKesson and most recently served as executive vice president and group president of McKesson’s Technology Solutions division. Blake also served as president of McKesson Specialty Health and president of customer operations during his tenure.
- **AllianceRx Walgreens Prime**, a 2017 collaboration between **Walgreens** and **PBM Prime Therapeutics** has entered into a five-year agreement technology company, **Inovalon**. Under the the agreement, Inovalon will provide cloud-based specialty pharma capabilities through its *ONE Platform*, allowing AllianceRx Walgreens Prime to be differentiated from others in the marketplace by reducing the time needed to fill prescriptions, costs, and providing upgraded quality assurance while giving the company advanced functionality and greater flexibility in order to focus on clinical and quality outcomes. The platform will operate under the name *ScriptMed Cloud.*
- **Bristol-Myers Squibb** has added its name to the list of big pharma companies doing conducting consumer health reevaluations by announcing its intention to sell its French consumer health business, **Upsa.** The unit is potentially worth

(continued on page 3)

The Role of Pharmacies in the Era of Specialty Pharmaceuticals

(Source: an article prepared by Bobbie Riley, RPh and Brian Eidex of Lexisnexis Risk Solutions Health Care and published by Drug Store News)

Sales in the US for specialty pharmaceuticals in 2016 rose to US$181 billion and 50% of drugs sold (by value) in the United States are expected to be specialty pharmaceuticals in three years. Specialty drugs are defined, in part, by their high cost: often $1,000 or more per month and spending on these drugs is growing 15% to 20% a year.

The high price tag is derived from various influences, but generally, the drugs treating complex conditions are advanced in composition and often have unique handling needs. The latter is where specialty pharmacy comes in: the experts manage requirements for quick delivery, temperature-controlled storage and shipping, and biologic demands such as injection or infusion administration. The pharmacists, in turn, also manage the increased human needs of the advanced treatment regimens,

(continued on page 2)

Amazon (cont.)...

wouldn't necessarily affect more complex biological treatments that are expensive and complex to handle, sometimes called specialty drugs. “While Amazon could simplify drug order/delivery for certain pill-based medications, specialty drug costs are the primary driver of total spend increases,” she said.

Nevertheless, "The pharmacy industry has entered its next phase of evolution," said Adam Fein, CEO of Pembroke Consulting's Drug Channels Institute. "Retail pharmacies will find their high-profit cash business under pressure. Expect a pharmacy shakeout over the next five years."

Role of Pharmacies (cont.)...

including patient and caregiver education, chronic disease symptom management - sometimes with the addition of other pharmaceuticals such as controlled substances - and complex consultation scenarios.

Patients can't always simply pick up these cutting-edge pharmaceuticals – whether taken orally, injected or infused - at their local retail pharmacy as currently configured. Specialty pharmaceuticals are prescribed mainly for patients with serious chronic diseases and rare genetic conditions such as multiple sclerosis, cancer, rheumatoid arthritis, severe dermatitis, psoriasis, inflammatory bowel disease, HIV, hemophilia and hepatitis C. These patients, who can reap the benefits of advanced therapeutics, require more than a stop at the pharmacy counter. Specialty pharmacists must carefully explain and review proper administration, side effects, and other regimen demands and considerations. Specialty treatments are often quite different from patients' previous or existing regimens.

The specialty pharmacists themselves work in a variety of practice settings under various ownership entities. About half of all specialty pharmacies in the US are independently owned, while others are under the umbrella of healthcare providers, health plans, or pharmacy benefit managers (PBMs); a small percentage are wholesalers or retailers. The various pharmacy channels are jockeying for control of distribution in this specialty market.

The task of distribution is not a simple one: “disease journeys” are complex and both pharmacists and clinicians must ensure patients have the appropriate understanding. dosage. and coping mechanisms to handle the protocol and the condition at large.

The topic of high costs is always in the forefront. Health plans and PBMs pay particular attention to the use of specialty drugs, which also have a growing list of restrictions and requirements both at the federal and state level. Prescriber validation, substance verification and reimbursement claims collection need to become part of the specialty pharmacy daily workflow if it is to manage risk and ensure payments for ultra-costly therapies. This operational and compliance aspect will only become more important as more specialty medications become available and there are more patients to serve.

What was once just a tiny segment of the pharmaceutical industry is now promising widespread innovation and further advancement. As more and more specialty drugs enter the market, pharmacies must consider how data-driven validation will enable a growth and operational success. This is not the place for pharmacies to falter on compliance or verification: patients requiring high-touch care first require trust.

WBA Adjusts Its Portfolio of Businesses as It Reports 3rd Quarter Financials

(Sources: Walgreens Boots Alliance; articles prepared by David Salazar and published by Drug Store News)

Walgreens Boots Alliance (WBA) is now officially a 40% stakeholder in Chinese pharmacy chain GuoDa. The investment in Sinopharm Holding GuoDa Drugstores was announced in December 2017, but only recently cleared regulatory hurdles. The investment came shortly before WBA reduced its stake in Chinese wholesaler Guangzhou Pharmaceuticals from 50% to 20%.

The minority stake in GuoDa, which is China's leading retail pharmacy chain, was acquired through a capital increase worth roughly US$416 million. WBA said it would account for the stake as an equity method investment.

“We are delighted that we have received regulatory approvals and our investment agreement has now been completed,” WBA executive vice chairman and CEO Stefano Pessina said. “We believe GuoDa holds a strong position in the sector, and as a global pharmacy-led health and beauty enterprise, we are well positioned to support its further growth ambition. We are looking forward to sharing our international best practices and pharmacy expertise. We believe there is great potential in working together to play a transforming role in the evolving Chinese retail pharmacy market.”

In addition, WBA will open care centers focused on senior citizens within some of its stores in partnership with health insurer Humana, the latest illustration of how pharmacies are becoming healthcare hubs and not just mere drugstores.

WBA said it would open two such senior care centers in its stores this fall, offering primary care services and the availability of a Humana representative to answer customers' questions about Medicare [the US government healthcare program for the elderly]. Humana will operate the centers as part of its Partners in Primary Care business.

The tie-up with Humana could position Walgreens to win more business from senior citizens as an increasingly large population as baby boomers move into old age, with older GenXers not that far behind.

“With this new initiative, we can expand the care for seniors that our pharmacists and other team members have provided for decades,” Walgreens Boots Alliance CEO Stefano Pessina said in a statement.

WBA operates some walk-in clinics but those are more general in orientation and not designed for frequent visits. The company has already been adding more health care services to its stores, adding LabCorp testing services to more locations this spring. Humana and Walgreens said they could expand this partnership into other areas and with a view to increase access to healthcare around the clock and online.

For the first nine months of fiscal 2018, net earnings attributable to Walgreens Boots Alliance determined in accordance with GAAP increased 7.2% to US$3.5 billion compared with the same period a year ago, while GAAP diluted net earnings per share increased 16.2% to US$3.51 compared with the same period a year ago. Sales in the first nine months of fiscal 2018 were US$98.1 billion, an increase of 11.4% from the same period a year ago, an increase of 9.5% on a constant currency basis.

(continued on page 3)

Walgreens (cont.)...

Retail Pharmacy USA had third quarter sales of US$25.9 billion, an increase of 15.0% over the year-ago quarter. Sales in comparable stores decreased 1.2% compared with the same quarter a year ago. Pharmacy sales, which accounted for 72.5% of the division's sales in the quarter, increased 19.3% compared with the year-ago quarter, primarily due to higher prescription volume from the acquisition of Rite Aid stores and from central specialty. Comparable pharmacy sales were unchanged from the year-ago quarter, as brand inflation was offset by reimbursement pressure and the impact of generics.

Retail Pharmacy International had third quarter sales of US$3.0 billion, an increase of 6.6% from the year-ago quarter due to favorable currency exchange rates. Sales decreased 2.1% on a constant currency basis. On a constant currency basis, comparable store sales decreased 1.4% compared with the year-ago quarter. Comparable pharmacy sales decreased 1.7% on a constant currency basis. Comparable retail sales decreased 1.3% on a constant currency basis mainly due to Boots UK.

Pharmaceutical Wholesale had third quarter sales of US$6.0 billion, an increase of 12.6% from the year-ago quarter, including the favorable impact of currency exchange rates. On a constant currency basis, comparable sales increased 4.0%, which was behind the company's estimate of market growth, weighted on the basis of country wholesale sales, due to challenging market conditions in certain continental European countries partially offset by strong performance in emerging markets and the UK.

Tariff Cuts Demonstrate That China's Rx Pricing System Needs Reforming

(Source: China Daily)

China exempted tariffs on 28 categories of imported medicines, including some common anti-cancer drugs, on May 1. But the retail prices of these medicines have remained unchanged. Beijing News commented: "It is disappointing that the zero-tariff policy that has been implemented for nearly one and a half months has not yet brought any tangible benefits to patients."

In comparison, after China recently cut tariffs on imported cars, retail prices decreased on some imported vehicles almost simultaneously, raising the question as to why the retail prices of imported medicines have not changed as of the writing of this article.

The main reason for the differential, suggests the article, is because prices of imported vehicles are mainly decided by the market, but medicine prices are fixed by the government according to relevant laws and regulations. Also, the prices of medicines are not decided by one department, but rather on the negotiations of different departments, such as the National Health Commission, the National Development and Reform Commission, the Ministry of Civil Affairs, as well as the government's direct negotiations with pharmaceutical companies, and by purchase bidding.

The complicated procedure means it usually takes several months to adjust the prices of medicines. Also imported medicines are sold by agents or branches of foreign companies, which are located in China, according to a price approved by the authorities. Consequently, the adjustment of a medicine's retail price entails negotiations among all the relevant parties.

Some multinational companies have a strong influence on pricing, particularly in the fields they dominate, The article recommends that China should reform its medicine pricing policies and streamline the pricing mechanism. Further, the methodology and practices used in other countries could be used in developing China's policy such as compulsory licensing and parallel importation.

2017 Ranking of Generics/Biosimilar Companies

(Source: an article prepared by Mike Ward and published by Scrip)

With Mylan close behind, Israel's Teva managed to retain top slot in the latest Generics Bulletin rankings. Severe pricing and margin pressures in the US market made it difficult for generics companies in 2017, with eight of the top 20 firms reporting year on year sales declines.

Year on year, there was little change in the positions of the top ten companies, only Lupin Ltd. slipped out of the top tier, down one place in 11th. With the top seven companies retaining the same positions between 2016 and 2017, Valeant, up eight places on the 2016 ranking, was the top climber in at eighth place. Privately held Stada Arzneimittel AG, like seventh ranked Fresenius Kabi AG, benefited from doing as much business in Europe as it does in the US and saw it rise one place to ninth in the table. With its intention to make more acquisitions in Europe and the MENA region, as well as plans to invest US$100 million in biosimilars in the next three years, it is likely the company might continue its rise in the charts. Endo experienced the largest fall in the ranking, dropping three places to tenth.

The following is the 2017 rankings by revenue *(in US$ billion):* Teva ($11.5), Mylan ($11.1), Sandoz ($9.5), Pfizer Essential Health ($6.2), Perrigo ($4.9), Sun ($3.7), Fresenius Kabi ($3.2), Valeant ($2.7), Stada ($2.6), and Endo ($2.3).

In Brief (cont.)...

up to US$1.8 billion, according to a Reuters source. Included in possible buyers is German generics drugmaker, **Stada**, which would benefit from the acquisition allowing it to expand its consumer health offerings. Upsa was acquired by Bristol-Myers in 1994 and sells a wide variety of over-the-counter drugs.

- The generic use rate in Japan stood at a preliminary number of 74.1% (on a volume basis) for the period of January-March 2018, an increase of 5.2 points over the previous quarter. This marked the largest uptick in the past two years, according to the Japan Generic Medicines Association (JGA) which released the numbers on July 2nd. The JGA also stated the same day that the volume-based generic use rate for FY2017 stood at a preliminary 69.9%, up 4.4 points from FY2016.
- Swiss drug maker **Novartis** will spin off its **Alcon** eyecare business as Novartis continues to focus more on its pharma business. Alcon, which was purchased by Novartis in 2011 for US$52 billion has returned to a growth state, but still is currently only worth about half of the original purchase price. This announcement follows Novartis' decision to divest its stake in its joint venture with GlaxoSmithKline.

Sources: Company Press Releases, Drug Store News, FiercePharma, Pharma Japan, and Reuters)