

Amazon Launches Its Online Pharmacy

(Source: An article by Sandra Levy for Drug Store News, an article by CNBC, and an article by Eric Percher of Nephron Research)

Amazon announced the launch of its online pharmacy business with two unique pharmacy offerings, each with direct implications for the pharmaceutical supply chain.

Amazon has been quietly building out its pharmacy business since 2017. The Amazon Pharmacy store is built on PillPack's infrastructure but is distinct and looks to improve on the current mail order pharmacy experience.

There are three core competencies/advantages that Amazon has enjoyed in other markets: 1) improvement in the consumer experience; 2) a broader selection of offerings; and 3) significant price competition. Amazon brings these competencies to its pharmacy launch. This is Amazon's biggest push into the US\$300 billion market and will likely affect the dominance of traditional pharmacies such as CVS and Walgreens, as well as large retailers with pharmacy services such as Walmart and Target.

The most important implications for wholesalers and distributors are not with respect to distribution but with respect to their independent pharmacy units. The combination of lost volume and increased use of discount cards could be far more severe for independents than it is for the largest chains. AmerisourceBergen has been supplying PillPack and may be the frontrunner to supply Amazon. However, its current arrangement with Walgreens could prove complicated should it build on its PillPack relationship to supply Amazon Pharmacy.

Other areas that could see significant impact include pharmacy benefit management companies. Amazon could potentially accrue market share Amazon Prime Prescription Savings Benefit (enabled by Cigna/Evernorth subsidiary InsideRx) that can be utilized via Amazon Pharmacy and at 50K pharmacies participating in the InsideRx program. Cigna confirmed that InsideRx is a wholly owned subsidiary with Evernorth providing all brand and generic discounts. (InsideRx was initially launched with ESI providing brand discounts and GoodRx providing generic discounts.) The partnership between Amazon and Evernorth allows Amazon to challenge GoodRx for lead position as the digital consumer healthcare platform and may lead to a more adversarial relationship between Evernorth and GoodRx.

It is no secret that the landscape of the retail pharmacy market has been evolving over the years, and particularly in 2020 as individuals increasingly rely on mail delivery for the prescription needs as they look to minimize exposure to the coronavirus. This could be an indication of a permanent shift in the public mindset.

"We wanted to make it easy for people to get their medication, understand the cost and get it delivered to the home," said TJ Parker, Amazon's vice president of pharmacy, who previously co-founded PillPack. "The hard work is to make it easy...there were a number of complications behind the scenes."

Customers over the age of 18 will have access to the pharmacy

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In Brief..

- ♦ Japan's largest wholesalers' operating profits tumbled nearly 80% April-September due to COVID-19, discount pressure from healthcare providers and price competition. **Alfresa Holdings, Medipal Holdings, Suzuken and Toho Holdings** posted combined sales of ¥3.74 trillion (US\$35.9 billion), down 5.6% year-over-year, and operating profit falling 79.1% to ¥11.19 billion (US\$114.3million.) **Crecon Research and Consulting** also reported that ethical drug sales slid 9.6% in September year-over-year on a wholesaler shipment basis, reflecting a pullback from the prior year when healthcare providers stockpiled certain drugs ahead of ad-hoc repricing associated with a consumption tax hike in October of 2019.

- ♦ **CVS Health** announced that Executive Vice President and President of Aetna, *Karen Lynch*, will take the helm as President and CEO effective February 1, 2021. She will replace *Larry Merlo* who will continue to serve on CVS Health's board of directors until the company's next annual stockholder meeting in May of 2021, and will serve as a strategic advisor to assist with the transition until his retirement on May 21, 2021. Lynch will also be joining the board of directors upon assuming her new role.

- ♦ A **World Health Organization (WHO)** co-sponsored partnership is in process to lay the groundwork for a worldwide distribution plan of US\$6 billion worth of COVID-19 drugs with proven efficacy, including cutting monoclonal antibodies treatments. The move comes as the world works to ensure that

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COVID-19 Vaccines Cross Major Hurdles with Successful Phase III Trials

(Sources: Articles by Andrew McConaghie and Jessica Merrill for Scrip, an article by Eric Saganowsky for FierceBiotech, an article by Sandra Levy for Drug Store News)

Both Pfizer (and its partner BioNTech) and Moderna have announced major late stage Phase III trial successes with their respective COVID vaccines. Pfizer's BNT162b2 vaccine (which requires two doses three weeks apart) showed an initial efficacy of 90% but the company has revised that number to nearly 95%. Moderna's mRNA-1273 vaccine also shows an almost 95% success rate. While the two vaccines are frontrunners in the race to find a solution to the COVID-19 pandemic, there are substantive differences in how these vaccines move through the supply chain.

Moderna's vaccine requires two doses four weeks apart and can be kept at refrigerated temperatures of 36°F to 46°F for 30 days, reducing hurdles for a potential large-scale rollout. It is also stable for 12 hours at room temperature. For longer-term storage and shipping, the vaccine needs to be kept at freezer temperatures of -4°F, a temperature that distributors are very familiar with

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Amazon (cont.)...

service this week in 45 states, exclusive of Hawaii, Illinois, Kentucky, Louisiana and Minnesota. Amazon expects to service those remaining states over time. Most forms of insurance will be accepted, and individuals without insurance may be eligible for other cost savings, including flexible spending accounts or health savings accounts to buy prescriptions on the service.

Before customers order medication for the first time, the site might ask them a series of health questions required by law to prescribe medications/pharmacy care. Doctors can also send prescriptions directly to Amazon Pharmacy or patients can request a transfer from an existing pharmacy retailer. Amazon says it has the tools to verify that a physician legitimately ordered each prescription to circumvent potential fraud.

Amazon Prime customers will be eligible for free two-day delivery, although first-time customers may experience up to a five day wait time on initial prescriptions. Commonly used medications such as birth control, insulin, steroid creams, and migraine medications will be available, however, Schedule II controlled medications such as opioids will not be available. Also, Amazon noted that patients who take multiple doses of daily medications or who prefer sorted dose packaging should continue to use the PillPack service.

Vaccine (cont.)...

Pfizer's vaccine, another frontrunner, requires colder storage at -94°F and will only last for 24 hours at refrigerated temperatures. But the company has an aggressive plan to tap experienced shipping partners to transport doses in newly designed, GPS-enabled storage containers.

Moderna's stability profile will "likely make it easier to widely distribute compared to Pfizer's vaccine, according to industry analysts. Pfizer is working on a powder version of its vaccine that is stable at room temperature. While Moderna and Pfizer are the only two players reporting early large-scale efficacy numbers thus far, the Sputnik 5 candidate also showed initial strong efficacy, a host of other players are advancing vaccines expected to be stable at refrigerated temperatures. CureVac, a German biotech in mid-stage testing, said last week its vaccine is stable for at least three months at refrigerated temperatures, and up to 24 hours at room temperature. The stability profile "has the potential both to enable decentralized storage and to significantly facilitate large-scale vaccination efforts during the current pandemic," chief production officer Florian von der Mülbe said in a statement.

Other vaccines using various technologies, such as programs from Sanofi, AstraZeneca, Novavax and Johnson & Johnson, are also pursuing refrigerated storage. Moderna said it is on track to have about 20 million doses of its vaccine ready to ship in the U.S. by the end of the year. It is expecting to be able to produce 500 million to 1 billion doses next year.

Pfizer has an agreement with the U.S. government to provide 100 million doses to the U.S. in exchange for US\$1.95 billion, with an option to acquire an additional 500 million doses. According to Pfizer CEO Albert Bourla, the company is confident in the supply and the isothermic boxes Pfizer has developed to transport the vaccine at the subzero temperature required, along with a GPS tracking device. The boxes will be shipped overnight for next-day delivery and can hold 1,000 to 5,000 doses each. The vaccine can

be kept in the box for two weeks, stored in special medical freezers for months or stored for several days in a typical freezer.

Pfizer also announced that it is launching a four state COVID-19 vaccine distribution pilot program as the timeline for potentially delivering the first commercial vaccine to the public inches closer. Bourla confirmed that the safety threshold required for its vaccine to be considered for an emergency use authorization by the U.S. Food and Drug Administration has been reached.

When asked about the Pfizer vaccine, Bourla said, "It's a human moment. You know the news are expecting to hear are the news that billions of people are hoping to hear from you." He added, "When I heard the over 90% efficacy, I felt that I was living a dream."

In Brief (cont.)...

high-income countries do not dominate available new therapy supplies as they arrive on the market. The proposed *Basket of Medicines* would be procured under the auspices of the WHO's *ACT Accelerator*, a collaboration with seven other UN and global health agencies and philanthropies, including **Unitaid** and the **Wellcome Trust**.

- ◆ **Citigroup** announced that it has been selected as the firm to act as financial advisor to **GAVI, the Vaccine Alliance's COVAX** facility. Citi will provide expert advice on structures to mitigate sovereign, credit and operational risk as the COVAX facility seeks to facilitate pooled procurement and equitable distribution of safe and effective COVID-19 vaccines from multiple pharmaceutical manufacturers to all COVAX participating economies once they reach licensure.

- ◆ Brazilian regulatory authorities have suspended a local final stage trial for **Sinovac Biotech Ltd.'s** COVID-19 vaccine after reports of the death of one participant. The Phase III study, being carried out with local partner **Butantan Institute**, is one of the largest for the Beijing-based firm's candidate outside China, and is a result of collaboration between the two parties signed on June 11, 2020. Local media said the suspension was due to the death of one volunteer in the trial, but no specific details were given.

- ◆ For the first time since the beginning of the COVID-19 outbreak and pandemic, Africa may be poised to reshape rapid testing for the virus on the continent. **The Pasteur Institute**, a biomedical research center based in Senegal's capital city of Dakar, said it is close to producing an affordable handheld COVID-19 diagnostic test kit that can give results in a matter of minutes. **Amadou Sall**, director of the Pasteur Institute, stated that the test kit can cost as little US\$1 per unit.

- ◆ Global vaccine maker **Seqirus** is working overtime to churn out doses amid a key influenza season. Subsequently, it has chosen Australia as the home of an ambitious manufacturing center and will invest US\$800 million to build a cell-based vaccine biomanufacturing facility in Melbourne to support a 10-year supply pact with the Australian government. The new plant will be located in Tullamarine in the Melbourne Airport Business Park and is set to go online in 2026 with more than 1,000 employees. The company did not disclose the planned footprint by square footage in a release.

(Sources: *CNN World, Drug Store News, FiercePharma, FierceBiotech, Pharma Japan, and Scrip Intelligence*)