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Direct-to-Patient Programs and "Most Favored Nation" Pricing Influencing Decision-Making of Manufacturers

(Sources: An article by Alaric DeArment for Scrip, an article by Andrea Park for FiercePharma, and a Pfizer Inc. Press Release)

Several drugmakers have announced plans to lower prices for certain products, including augmenting existing direct-to-patient sales programs or creating new ones. These announcements were made just days before the September 29th deadline set by the U.S. Administration for drugmakers to make binding agreements to bring U.S. drug prices in line with international prices under the U.S. "most favored nation" (MFN) drug pricing executive order.

The Sept. 29th deadline for 100% tariffs on pharmaceuticals stems from letters the Trump Administration sent on July 31st to 17 biopharma companies – BMS, AstraZeneca and Sanofi among them – that gave them 60 days to voluntarily take actions to achieve MFN drug pricing in the U.S., which suggested direct-to-patient sales as a strategy for lowering prices for U.S. patients. Failure to meet the terms laid out by the administration in a timely manner would result in a 100% tariff. Currently, the enforcement of the September 29th deadline has been put on hold by the administration while negotiations with manufacturers continue.

The majority of manufacturers are either considering or have already established direct-to-patient (DTP) programs, eliminating middlemen to offer services like virtual care consultations, payment support, at-home diagnostics and digital pharmacies. A survey of pharma representatives showed that approximately 50% of respondents believe that DTP programs will become standard practice across most brands within the next five years. Additionally, another 44% believe that the programs will become common among "certain therapeutic areas".

Pfizer Inc. also announced a historic agreement with the Trump Administration that will ensure U.S. patients pay lower prices for their prescription medicines while strengthening America's role as the global leader in biopharmaceutical innovation.

In response to the four points covered in President Trump's July 31st letter to pharma manufacturers, Pfizer has voluntarily agreed to implement measures designed to ensure Americans receive comparable drug prices to those available in other developed countries and pricing newly launched medicines at parity with other key developed markets. Pfizer will also participate in a direct purchasing platform, TrumpRx.gov, that will allow American patients to purchase medicines from Pfizer at a significant discount. The majority of the company's primary care treatments and some select specialty brands will be offered at savings that will range, on average 50%, and as high as 85%. Specific terms of the agreement were not announced.

"We are proud to join President Trump at the White House to celebrate this landmark agreement that is a win for American patients, a win for American leadership, and a win for Pfizer," said Albert Bourla, Chairman and Chief Executive Officer of Pfizer.

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In Brief...

- The corporate venture capital arm of drug manufacturer **Sanofi** will add US$625 million into its evergreen fund to back earlier-stage innovators. The fund will remain focused on Sanofi's core areas of immunology, rare diseases, neurology and vaccines, but will also consider "emerging opportunities that support the company's long-term strategy." The additional cash investment will increase the company's total assets under management to over US$1.4 billion. Since 2012, the fund has deployed over US$800 million across more than 70 companies in biotech and digital health.
- **Cardinal Health** announced plans for a new distribution center in Indianapolis, Indiana. The center will feature automation and technology advancements in support of the segment's distribution of more than 70,000 pharma and specialty deliveries across the U.S. "We're continuing to make strategic investments in our core distribution network to drive service, enhance efficiency and meet the evolving needs of our customers with even greater reliability and responsiveness," said *Debbie Weitzman*, CEO of pharmaceutical and specialty solutions.
- *Dame Emma Walmsley* will step down as **GSK** CEO. Walmsley, who has overseen a period of significant change at the company, will remain with the business under notice period expires at the end of September 2026 "to support an orderly transition." During her tenure, GSK spun off **Haleon**, its consumer health division, and moved to refocus on oncology. She will be succeeded by *Luke Miels*, who joined GSK in 2017.

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Pharmacies and Wholesalers in Japan Split on Weekend Deliveries

(Source: An article published in Pharma Japan)

A disagreement over weekend drug deliveries dominated the Central Social Insurance Medical Council (Chuikyo) meeting on September 17th with pharmacies urging seven-day service and wholesalers desiring no service on weekends due to staffing shortages.

Masahira Mori, Vice President of the Japan Pharmaceutical Association (JPA) representing healthcare providers at the meeting, noted that pharmacies nationwide are reporting the increasing challenges of dispensing medicines promptly due to wholesalers cutting weekend deliveries. He asked that wholesalers "ensure a distribution system that reflects the reality on the ground."

Responding on behalf of the Federation of Japan Pharmaceutical Wholesalers Association (JPWA), Hiromi Miyata, JPWA's Chair, cited mounting challenges faced by wholesalers in securing drivers, a shortage compounded by the logistics industry's workstyle reforms known as the "2024 problem".

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Direct-to-Patient *(cont'd.)*...

"By working closely with the Administration, we are lowering costs for patients and enabling greater investment in the U.S. biopharmaceutical ecosystem by ending the days when American families alone carried the global burden of paying for innovation. This is about putting all patients first and ensuring America remains the world's leading engine of medical breakthroughs. We now have the certainty and stability we need on two critical fronts, tariffs and pricing, that have suppressed the industry's valuations to historic lows."

Pfizer and the Trump Administration agreed to a three-year grace period during which time Pfizer products under a Section 232 investigation won't face tariffs, provided further investment in manufacturing in the United States is made. Additionally, a balanced global pricing approach has been established that continues to recognize the value of innovation while ensuring prices in the U.S. and other developed countries are both reasonable and sustainable, maintaining the strength of the U.S. market alongside other developed nations.

Many companies including AstraZeneca, Bristol Myers Squibb (BMS), Boehringer Ingelheim and Novartis are laying out their respective plans to enter the DTP area.

BMS announced on September 25th that it would offer direct-to-patient sales of the psoriasis drug *Sotyktu (deucravacitinib)* starting in January 2026, two months after the announcement of a similar program for BMS and Pfizer to sell the blood-thinning drug *Eliquis (apixaban)* direct to consumers.

On September 26th, AstraZeneca announced that under AstraZeneca Direct, starting October 1, the company will allow direct purchases by patients who have prescriptions of A*irsupra (albuterol/budesonide)* for asthma and *Farxiga (dapagliflozin)* for type 2 diabetes and chronic kidney disease. Also on Sept. 26, Sanofi announced an expansion of its Insulins Valyou Savings Program offering 30-day supplies of Sanofi insulin products for$35 starting on Jan. 1, 2026.

Novartis' DTP platform plans to target only eligible cash-pay patients in its offer of a sizeable discount for its immunology drug *Cosentyx*. The platform launches November 1st and will allows U.S. patients prescribed *Cosentyx* to purchase it directly for 55% off the list price. This will bring the price of drug from US$7,936 for a month's supply of the self-injectable to a discounted cash price of US$3,572.

Boehringer Ingelheim's DTP platform, "Boehringer Ingelheim Access" is set to offer direct home delivery of certain medication, starting with its *Spiriva Respimat* inhalation spray for asthma and chronic obstructive pulmonary disease (COPD) with a variety of payment options.

Pharmacies *(cont'd.)*...

He also noted that wholesalers are struggling to recruit enough pharmacists, with some branches unable to meet staffing requirements and forced to consolidate.

Miyata stressed that while he cannot dictate policy to individual JPWA member companies, he would relay concerns expressed by JPA. "I will make sure our members are aware of the request, and leave management decisions to each company," he said.

Mori acknowledged the difficulties but maintained his call for weekend deliveries, saying "I understand the circumstances, but medical facilities operate seven days a week." He committed to continuing discussions with JPWA in the future.

In Brief (cont.)

- The **U.S. Food and Drug Administration (FDA)** has launched a new pilot prioritization program intended to accelerate approval review times for generic drug makers that test and manufacture their products in the U.S. Under the program, generics companies that file abbreviated new drug applications that meet the FDA's domestic production and bioequivalence testing requirements, including the use of "exclusively domestic sources for APIs", will become eligible for priority review. The pilot program aligns with current U.S. policy that encourages onshoring.
- Japanese officials announced that the country has secured most-favored-nation (MFN) status for pharmaceutical tariffs under its trade agreements with the U.S. Revitalization Minister, *Ryosei Akazawa* emphasized that it is expected that the rate for Japanese drugs will be capped at 15%, the same rate as the European Union. Officials also outlined new investment initiatives under the the U.S.-Japan bilateral memorandum of understanding, which will include Japan's strategic investment that backs overseas expansion by Japanese companies across nine priority sectors, including pharmaceuticals.
- **Eli Lilly** announced that the second of four planned large-scale manufacturing facilities that it plans to construct in the U.S. will be in Houston, Texas. The US$6.5 billion facility will produce active pharmaceutical ingredients for oral drugs. Lilly plans to add 615 employees to the facility and the project will generate 4,000 construction jobs. Additionally, the company will invest more than US$1 billion in its operations in India, with plans to work with local partners for productions deals. The investment will help to bolster the supply of key Lilly drugs for obesity, diabetes, Alzheimer's disease and autoimmune conditions.
- **Kenvue**, the maker of the popular pain reliever *Tylenol*, is preparing for litigation after warnings were announced by the Trump administration issued warnings that the drug's active ingredient could potentially cause autism. The **U.S. FDA** is notifying physicians of the potential link, and recommending that pregnant women use the lowest dose and for the shortest duration if it is determined by their doctor that the drug is medically necessary for treatment of pain or fever. In 2023, *Tylenol* generated 10% of the company's US$15 billion in annual sales.
- The **American Society of Health System Pharmacists (ASHP)** is launching the **ASHP Center for Next-Generation Therapeutics**, a new initiative supporting hospital and health system pharmacy in navigating the rapidly evolving healthcare landscape of cell and gene therapies and other high-cost cutting-edge treatments. ASHP said that breakthrough therapies are transforming healthcare and offering life-changing and sometimes curative options for patients who previously faced few or no treatments.

(Sources: Drug Store News, FiercePharma, PharmaVoice, Pharma Japan and Scrip)