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U.S. Pricing Policies Likely to Disrupt Global Drug Prices

(Source: An article by Jessica Merrill for Scrip Citeline)

The pharmaceutical industry will certainly have to grapple with the global implications of lower drug prices in the U.S., particularly in Europe. Expectations are that some of the cost burden will shift to countries outside the U.S., which have historically paid lower prices.

Industry experts spoke about this paradigm shift at the BioFuture Conference in New York. Changing commercial dynamics may impact future drug launches in markets that are viewed as "commercially challenging".

"You're going to see more and more emphasis on launching in the U.S. first at the correct price, knowing that around the world there will be these effects – like slower access outside the U.S.," said EntityRisk CEO Neal Masia during a drug pricing panel on October 14th. *(EntityRisk is a drug pricing consultancy that collaborates with manufacturers to design and implement pricing and value strategies.)*

"You're going to see this bifurcation between the U.S. market and everywhere else because the ability to pay here and the willingness to pay here is still the highest in the world," Masia stated.

The current U.S. administration has been touting drug pricing reform, mainly through voluntary measures, while also threatening sector tariffs on pharmaceuticals for companies that are non-compliant. Pfizer and AstraZeneca have already inked agreements with the U.S. government that remove the threat of tariffs in exchange for relatively small concessions on U.S. drug prices that include offering "most favored nation" (MFN) pricing for drugs sold to state Medicaid programs. However, in realistic terms, this represents a small segment of their business.

Drug companies are also being encouraged by the U.S. to exhibit a tougher stance in price negotiations with other countries the goal being to raise prices outside the U.S. and end what is seen as an unfair advantage for other countries at the expense of Americans.

Drug companies have already begun to make inroads to appease the U.S. with Bristol Myers Squibb and AbbVie announcing plans to launch new drugs at one global price. Pfizer and AstraZeneca implemented agreements with the U.S. that includes a commitment to set launch prices in the U.S. equal to those in comparable economies outside the U.S., although it is not clear if that commitment is based on list or negotiated prices.

"The big pharmas are still sort of trying to figure out a global story around a drug which involved doing cost effectiveness work, trying to match what a price will look like market by market, and all that is still happening. Part of me thinks there's a phantom limb element to that because the truth is, most of the profits are in the U.S. market," Masia said.

As for smaller drug companies, he said he has seen a shift away from even discussing ex-U.S. launches.

(continued on page 2)

In Brief...

- **Cencora's** Board of Directors has appointed Lead Independent Director *D. Mark Durcan* as Chairman. Durcan, who replaces *Steven H. Collis*, assumed the role of Chairman on October 1, 2025. Collis served as Cencora's chairman since 2016 and CEO from 2011 to 2024. "Our Board is confident that Mark's public company CEO and board experience, along with this strategic planning and technological innovation experience, make him the right person to step into this role and support Cencora's continued leadership as a healthcare company," said *Robert P. Mauch*, President and CEO of Cencora.
- **Merck** has begun construction of a new US$3 billion facility at its manufacturing campus in Elkton, Virginia. The investment is part of the company's plan to invest more than US$70 billion on manufacturing, R&D, and capital projects in the U.S. The planned 400,000 square-foot facility will add to Merck's presence at the massive site in Virginia's Shenandoah Valley. The complex already covers 1.2 million square feet and employs more than 1,000 people.
- Pharma manufacturer **Novo Nordisk** will pay US$4.7 billion in cash for **Akero**, the maker of three leading FGF21 analogs for metabolic associated steatohepatitus (MASH). The deal also includes a contingent value right for its fibroblast growth factor 21 analog *efruxifermin* (a potentially best-in-class treatment for MASH) of US$500 million, totaling US$5.2 billion. *Efruxifermin* became the first candidate to demonstrate a fibrotic benefit in cirrhotic MASH patients in 96-week data from the Phase IIb SYMMETRY trial.
- **Cardinal Health** announced plans for a new flagship forward

(continued on page 2)

SITCO Pharma Joins IFPW

IFPW is pleased to announce that SITCO Pharma is the newest IFPW member.

SITCO Pharma (Saudi International Trading Company Ltd.), a leading pharmaceutical distribution company in Saudi Arabia and a wholly owned subsidiary of Saudi Chemical Company Holding. SITCO is the only publicly traded pharmaceutical distributor in the Kingdom, operating under the umbrella of Saudi Chemical Company Holding and operates in a high-growth market driven by demographic expansion, increasing chronic disease prevalence, and significant government investment in healthcare infrastructure. These factors, combined with SITCO's operational scale, ownership synergies, and strategic partnerships, make it an attractive platform for long-term value creation in Saudi Arabia's healthcare sector.

IFPW welcomes SITCO to IFPW as a wholesale member and looks forward to having SITCO's leadership team participate in upcoming meetings. We look forward to hearing their insights and perspectives on the Middle East region and the overall global market.

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

"I don't hear them talking that much about anything other than their U.S. launch," he said. "I've heard that – the quotes are direct – in light of or until I know what's happening with MFN, I'm just not even thinking about it anywhere else in the world."

According to Masia, U.S. drug pricing changes could push drug companies' decision to out-license ex-U.S. rights to avoid deciding on a global pricing strategy, but dealmakers that spoke on a separate deals panel suggested that option is a fading opportunity due to commercial challenges outside the U.S.

"One of the key moves for small biotech in the playbook was 'I'll keep my U.S. rights, and I'll go do some ex-U.S. deal' ...that's getting harder and harder," said Nouhad Husseini, Regeneron's senior vice president of business development. He continued, "The commercial attractiveness and the economics available to any buyer in the U.S. market has always been dramatically better than any ex-U.S. market, but it was good enough outside the United States where you could build a business case, and I'm not saying that there's going to be zero deals or zero companies that are specialized in commercializing outside the United States, but I see that opportunity shrinking,"

EY Americas sector leader for life sciences, Arda Ural, said he has heart similar commentary.

"Ex-U.S. rights were the chip to play to get some capital – to help with the Phase III and the commercialization. That playbook is now thrown out," Ural said.

CDC's Advisory Committee on Immunization Policy Issues New Guidance on Several Vaccines

(Source: An article by Heather Landi for FiercePharma)

After two days of debate, the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) members voted on a number of vaccination policies. Members voted to not recommend the combined MMRV vaccine for any patient under four years old, reversing current guidance. The new recommendation allows for children to receive an MMR shot and a varicella shot separately as their first dose in a two-vaccine sequence.

For the MMR vaccine, ACIP members cited data presented by the CDC Immunization Safety Office showing a small increase in risk of febrile seizures after the MMRV vaccination after the first dose, which is currently recommended at 12 to 15 months of age. In comparison, there is no evidence of an increased risk of febrile seizures with MMRV vaccination in children ages four to six years of age when the second dose is recommended

The ACIP was also set to vote on whether to uphold universal hepitits B (HBV) vaccination recommendations for infants at birth. The committee members discussed moving the first does of HBV vaccine from birth to 30 days but decided to table the decision and ultimately chose to not vote on a decision.

It was recommended by the committee that COVID-19 vaccines be based on "individual-based decision-making" meaning that patients should speak with their doctor or clinician about risks and benefits first. This recommendation is actually broader than the U.S. Food and Drug Administration's approach, which restricts the vaccine's use to patients 65 and older as well as adults and children over six months of age who have risk factors for developing acute/severe COVID-19. The ACIP's recommendations are narrower than some professional organizations.

The ACIP's recommendations still need to go before the CDC for final approval. Medical associations and scientific experts have expressed concern about the newly revamped ACIP, saying the new committee members have discounted expert input, focus on questionable data and do not follow established process for developing new vaccine recommendations.

Regarding COVID-19 vaccines, pharmacists can continue to provide vaccines in all 50 states using shared clinical decision-making. COVID-19 remains a significant public health threat, according to Harold Wimmer, president and CEO of the American Lung Association. He noted that from October 1, 2024 through September 13, 2025, there were 370,000 to 530,000 COVID-19 hospitalizations and up to 61,000 deaths.

In an unprecedented move, several states and medical societies are now breaking with the CDC's ACIP and are drafting their own vaccine recommendations. This is a significant departure from longstanding national immunization policy.

In Brief (cont.)

distribution center in Indianapolis, Indiana. The new center will further expand and modernize its national pharmaceutical distribution network and will feature automation and technology advancements in support of distribution of more than 70,000 pharmaceutical and specialty deliveries across the United States.

- China has approved the world's first domestically developed drug designed to achieve a functional cure for hepatitis B, marking a significant step in the global fight against the chronic liver infection. The injectable drug, named *Pegbing*, was developed by **Amoytop Biotech** based in Xiamen, Fujian province. It is approved for use in combination with antiviral medication to achieve sustain clearance of hepatitis B surface antigen in adults with chronic hepatitis B, according to a notice released by the **National Medical Products Administration**.
- U.S. pharmacy chain **Rite Aid** announced that it has closed all of its locations as of October 3, 2025. The company announced on its website, "All Rite Aid stores have now closed. We thank our loyal customers for the many years of support." The company also stated that customers can request prescription and immunization records online. Despite more than 60 years in the pharmacy business, Rite Aid has suffered financial challenges for years.
- Japan has elected its first female prime minister. *Sanae Takaichi* was confirmed, giving the country a leader who advocates for close ties to the U.S. and a stronger Japanese military. In parliamentary voting for the position, Takaichi won by a slim majority in the lower house on her first attempt with help from the Japan Innovation Party. A run off was required in the upper house after falling just short of a majority in the first vote. Japan hopes to heal ties with the U.S. that have been strained over global trade negotiations.

(Sources: China Daily, Company Press Releases, FiercePharma, Scrip Citeline and Wall Street Journal