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Pharma Industry Reaches Landmark Spending Deal with UK Government

(Source: An article by Angus Liu for Fierce Pharma)

After protesting the U.K.'s drug pricing policy, the pharma industry has secured a new government spending deal featuring a higher revenue cap and an innovative drug-friendly rebate mechanism.

In a "landmark" deal announced by the British government, NHS England and the Association of the British Pharmaceutical Industry (ABPI), the U.K. has agreed to increase the allowed annual growth rate for branded drugs from 2% in 2024 to 4% by 2027.

The new scheme, named the *Voluntary Scheme for Branded Medicines Pricing, Access and Growth*, governs the five years through the end of 2028.

Under the previous system that started in 2019, the U.K. has been capping the annual growth rate for branded medicines at 2%, which the ABPI and its pharma members called "arbitrary." Beyond that level of growth, any additional sales had to be paid back to the government. By ABPI's calculations, those revenue "clawbacks" rose from about 5% of industry revenues to nearly 27% in just three years thanks in large part to a surge in drug spending during the pandemic.

Despite the higher revenue threshold, the new framework is expected to save the NHS £14 billion (US$17.5 billion) over five years versus savings of £7 billion (US$8.9 billion) under the previous version.

In another measure aimed at rewarding innovation, the new policy introduces a mechanism that treats older and new drugs differently.

For older medicines that haven't had their prices reduced, the policy will require an additional rebate rate of up to 25% in addition to a base rebate of 10%. The extra rebate "tapers down" for older drugs that have seen price reductions, "ensuring we recognize when competition has worked effectively to make savings for the NHS," according to a joint statement.

This mechanism will support lower payment rates for newer drugs, making it "explicitly pro-innovation and pro-competition," the parties said.

As part of the deal, the British government, the NHS and the pharma industry will explore and pilot new ways of paying for advanced therapies such as cell and gene therapies.

In exchange for the more favorable policy, the pharma industry has agreed to invest £400 million (US$508.5 million) over five years in the U.K. to support clinical trials, manufacturing and health tech assessments. Pharma companies had previously warned that the U.K.'s original policy would discourage investments in the country's drug industry and hurt availability of the newest drugs.

The industry's investment adds to another £650 million

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In Brief...

- **Walgreens Boots Alliance** announced the sales of its **Cencora** common stock pursuant to variable prepaid forward transactions executed in reliance on Rule 144 under the *Securities Act of 1933*, as amended, for current proceeds of approximately US$424 million and potentially additional proceeds at maturity. In addition, WBA entered into a concurrent share repurchase by Cencora for proceeds of approximately US$250 million. WBA's ownership of Cencora remains at approximately 15%.
- Saudi Arabian wholesaler and distributor **Salehiya** announced that biopharma company **Lifera** has acquired majority shares of **Saudi Biotechnology Manufacturing Company (SaudiBio)**, which Salehiya ramains a shareholder. The partnership reaffirms Salehiya's efforts and vision to expand the availability of locally manufactured biologics, and better positions SaudiBio to continue its journey to develop local manufacturing capabilities to enhance the pharmaceutical security in Saudi Arabia.
- **Eli Lilly & Co.** has received approval from the **U.S. Food and Drug Administration (FDA)** for its GIP/GLP-1 compound *tirzepatide (Zepbound)* to treat obesity, allowing for broader access to treatment in the U.S. *Zepbound* is the same formulation as Novo Nordisk's *Mounjaro*, which was approved by the FDA in May of 2022 and has gained widespread, off-label use to treat obesity.
- *Thomas Cueni*, Director General of the **International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)** and Secretary of the **Biopharmaceutical CEO Roundtable (BRC)** will retire from his positions in April of 2024. He will be succeeded by *David Reddy*, CEO of **Medicines for**

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The Power of Genomics-based Healthcare Remains Largely Untapped

(Source: An article by Alexandra Pecci for PharmaVoice)

Pharma manufacturer GSK and 23andMe has extended a data licensing collaboration for drug target discovery and other research. It's a partnership that makes sense given 23andMe's 14 million-person-strong database. But there are other uses for genomics that the healthcare industry has yet to tap into going forward.

"There's real potential for having genomics-based medicine," Anne Wojcicki, 23andMe co-founder and CEO, said. "The same way you have genomics-based drug discovery, you can have genomics-based healthcare."

However, that's not yet the reality, and there are several reasons why.

"The genome is not integrated in healthcare for all kinds of reasons," Wojcicki said. "Doctors are overwhelmed, doctors are

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Pharma Industry (cont.)...

(US$826.4 million) in funding that the U.K. government pledged in May to boost the country's life sciences industry.

"This landmark agreement will not only save the NHS money, but help patients get access to the very best medicines and treatments for years to come," U.K. Chancellor of the Exchequer Jeremy Hunt said in a statement. "With significant new industry investment in research, clinical trials and manufacturing, this deal will bolster Britain's position as the largest life sciences hub in Europe and support a sector so critical to our country's health, wealth and resilience."

Richard Torbett, Ph.D., chief executive of the ABPI, called it a "tough deal" that the industry supports "despite its restrictions."

"Allowing the sector to grow faster than it has under the previous scheme should increase the UK's international competitiveness over time," Torbett said.

Genomics (cont.)...

not trained on it, and the reimbursement structure is poor."

Indeed, an article published in the journal Nature Medicine titled, "We need a genomics-savvy healthcare workforce," argued that 20 years after the completion of the Human Genome Project, genetics' "clinical potential can be realized only with the development of a multidisciplinary healthcare workforce."

Here are three ways pharma and the wider healthcare industry could leverage genomics.

Clinical trial recruitment. The FDA encouraged the use of genomics in clinical research in its "Genomic Sampling and Management of Genomic Data Guidance for Industry," writing that the "identification of genomic biomarkers underlying variability in drug response may be valuable to optimize patient therapy, design more efficient studies, and inform drug labeling."

Of course, precision medicine is already aiming to do this, but it could start even sooner and in a more patient-centric manner. For instance, the authors of an article in the journal Genome Medicine argued "next-generation trials need to be patient-centered (i.e., therapeutic agents matched to patients based on their tumor biomarkers) rather than drug-centered (i.e., patients matched to specific clinical trials)."

In addition, trial sponsors could also use genomics to focus clinical trial recruitment. However, the industry isn't quite there yet.

Prescribing decisions. Whether it's efficacy or side effects, people respond to drugs differently. That's why pharmacogenetics "absolutely makes sense for consumers," said Wojcicki.

In a clinical setting, this information has the potential to help steer prescribing decisions. The National Human Genome Research Institute point out that it "allows the possibility in some instances of picking the right drug at the right dose for the right person instead of the 'one size fits all' approach to drug therapy."

For example, if someone is genetically predisposed to side effects from statins, they can either start with a different drug or get a heads up to watch for certain symptoms. Wojcicki also believes it could create more targeted prescribing practices for antidepressants, which typically require a trial-and-error approach. But adoption has been slow. Part of the challenge is that having this information may not change prescribing behavior without a broader structure in place.

Choosing one drug or another to prescribe "is not necessarily a cost-savings measure" for the larger healthcare industry, Wojcicki pointed out.

Risk prediction. Genomics can be used to predict risk for many conditions, from breast and ovarian cancer to susceptibility to severe COVID-19. But it has the potential to be used for a lot more.

"To date, newborn screening for treatable inherited conditions represents the most successful human genomic application in public health, but population screening across the lifespan for other genetic conditions is increasingly possible," authors of a paper in the journal Genome Medicine wrote.

Yet insurance and reimbursement remains a significant barrier. Wojcicki noted that 20% to 30% of 23andMe customers with the BRCA gene variant that increases risk for certain cancers "never would have qualified for a test."

Wojcicki also pointed to limited reimbursement structures around prevention in general.

"Prevention is that keyword," she said. "So many aspects of healthcare today are focused on chronic disease management, and very few are heavily focused on prevention."

In Brief (cont.)

Malaria Ventures (MMV). His appointment has been endorsed by the leaders of the biopharmaceutical industry including the BCR and the IFPMA Council. Reddy bring more than 30 years' experience in the development and commercialization of medicines, including 13 years as the head of MMV.

- **IQVIA** has released a new report, *"Drug Shortages in the U.S. 2023: A Closer Look at Volume and Price Dynamics"*. IQVIA's report notes that shortages by the U.S. Food and Drug Administration as assessed in conjunction with sales and volume data of these medicines in the U.S. market. Characteristics of shortages, including product type, for and the number of manufacturers are evaluated. To download the report visit ***https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023***.
- A new subvariant of the highly infectious omicron COVID variant is rapidly gaining speed and overtaking other variants. Known as HV.1, it accounted for 29% of all new COVID-19 infections in the U.S., according to the **U.S. Centers for Disease Control (CDC)**. The emergence of HV.1 demonstrates how the SARS-CoV-2 virus can mutate and give rise to new highly contagious variants. While the new COVID booster offers protection against newer variants, very few American have received the shot.
- **Moderna** has reported a net loss of US$3.6 billion in its Q3 earnings, compared to a new income of US$1 billion during the same period last year. This is in line with the decreasing COVID-19-related revenues seen across the sector this year. Revenues also saw a decline of 32% to US$3.4 billion down from US$5 billion year-over-year. Moderna attributed the drop in revenues to the expected decline in global revenue generated by the COVID-19 vaccine *Spikevax*.

(Sources: Company Press Releases, Drug Store News, FiercePharma, NBC News, Scrip and World Pharma News)