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"Medicine Use and Spending in the U.S."

(Source: A Report by Murray Aitken for the IQVIA Institute for Human Data Science)

The IQVIA Institute for Human Data Science has released a report "Medicine Use and Spending in the U.S." which details a review of 2018 as well as an outlook into 2023.

The report details medicine use in the U.S. as a critical factor influencing the health outcomes of millions of Americans. Drug pricing as The allocation of costs among patients, employers, health plans, intermediaries and states; and federal government agencies all require significant attention.

In 2018, Americans filled 5.8 billion 30-day prescriptions. This number is up 2.7% year-over-year and averages 17.6 prescriptions per person. Chronic conditions account for two-thirds of all prescriptions. Increasingly these are filled for 90 days at a time in order to improve adherence to the prescribed regimens. Specialty medicines, which account for 2.2% of volume, grew by more than twice the rate of other drugs. Additionally, more than half of the volume in key therapy areas are now dispensed through retail channels, bypassing administration in a hospital, clinic or doctor's office.

2018 also saw substantial rise in the number of patients who were treated with newer specialty medicines used across a number of disease areas, including oncology, migraine and atopic dermatitis (eczema). The availability of a new shingles vaccine caused, in part, a surge in vaccinations by more than 6.5 million. Also, immune-oncology checkpoint inhibitors (which were launched in 2014) were used to treat more than 200,000 patients with a variety of cancer types in 2018. This represents nearly double the number of patients treated in 2016 with these same medicines. Medicines used to treat auto-immune diseases saw an uptick of 20% in 2018 with the advent of new treatments for ulcerative colitis, and psoriasis, as well as other related conditions.

Notably, lower-cost prescription medications in the form of generics and biosimilars saw only a modest jump in volume during 2018. This is partially due to small molecule generics being dispensed 97% of the time they are available, with the market share of generics reaching 90%. The approval rate of generics increased dramatically which contributed to deflationary pressure on drug prices. Three novel biosimilars launched in 2018, bringing the total to seven molecules. Biosimilar share of volume exceeded 30% for those medicines but represented less than 1% of biologic volume. Total biologics spending grew by 9.5% in 2018 and 13% of the total market is now subject to biosimilar competition.

Prescription opioid volume continued to steeply decline in 2018 with changes to regulations and clinical guidelines (accompanied by high public awareness) drove consumption down by 17% in total morphine milligram equivalents (MME) dispensed. The most significant decline was attributed to the most potent and dangerous high-dose prescriptions.

Growth in total medicine spending (net of rebates, discounts

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In Brief...

- **Merck & Co.** has acquired **Pelaton Therapeutics** for just over US$1 billion as an addition to their portfolio of cancer treatments. Pelaton, a privately-held biotech company, specializes in small molecule medicines that target a specific protein that, when mutated, can promote tumor development. Currently, Pelaton's most advanced drug is under investigation for kidney cancer. Merck's immunotherapy, *Keytruda*, has enjoyed tremendous success, including its most recent approval for use in renal cell carcinoma. Sales of *Keytruda* total over US$2 billion per quarter.
- **Johnson & Johnson** is planning ten potential blockbuster filings by 2023, each potentially delivering more than US$1 billion. Among those with positive advancements are *Tremfya, Erleada, Spravato* and *Balvarsa*. Others added to the list cover a variety of treatments for diseases such as multiple myeloma, non-small cell lung cancer, and a gene therapy for retinal disease.
- **World Courier**, a subsidiary of **AmerisourceBergen**, will continue to invest in technology by expanding its commercial third-party logistics storage and global distribution depots. The specialty logistics services company will expand in 11 of 14 of its pharmaceutical depots, each of which is located in a strategic global healthcare market. Locations include Argentina, Australia, Brazil, Chile, Colombia, India, Japan, Mexico, Perú, Russia and Singapore.
- All of Japan's four top pharmaceutical wholesalers achieved operating margins of over 1 percent, which is seen as

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Exploring the Distributor's Role in Delivering Innovative Drugs to Market

(Source: Akin Odultola of Amerisourcebergen Corporation for Research & Development Magazine)

It is a challenge that occurs frequently in today's pharmaceutical market: a potentially significant medicine or therapy awaits FDA approval. The pharmaceutical manufacturer has incurred years of research, development and investment surrounding this new drug therapy and a large number of potential patients await its release so that their lives can be transformed and improved by it. Behind the scenes, the manufacturer is working fervently on a channel strategy and selects a distribution partner to get it to market once it receives approval. If the manufacturer is disciplined with commercial planning a complex pharmaceutical supply chain is ready to be put into motion. Within 24 hours of approval, the drug could be on its way to thousands of sites to give patients access, and revenue streams kick in right away.

While this may sound like something too good to be reality, the truth is it happens with regularity. Having the appropriate partners in place prior to FDA approval is critical to a successful product launch. The critical partner in such a process is the pharmaceutical distributor. They are the key to efficient access

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Medicine Use (cont.)...

and other price concessions) remained at historically low levels in 2018, increasing 4.5% to US$344 billion. An adjustment for population and net inflation brings the amount to US$1,044 per person, up US$10 (or 0.9%) from 2017. Net spending for traditional medicines decreased 3.4% on a per capita basis 2018 while specialty medicines increased 5.8%, now accounting for US$517 of the total US$1,044 per person medicine costs.

Total net spending growth in 2018 was largely driven by more patients receiving existing branded drugs as well as newly launched drugs coming to market. These new drugs contributed US$24.2 billion to growth, most notably from the oncology, autoimmune, diabetes and hepatitis C treatments (which in total account for 75% of growth.) Price increases contributed only US$800 million to growth (based on a net price basis, down substantially from prior years to 0.3%.) This also reflects lower list price increases and sustained increases on price concessions made by manufacturers across the board, but particularly in diabetes, asthma/COPD and viral hepatitis.

Total patient out-of-pocket costs climbed to an estimated US$61 billion in 2018, with Medicare patients facing higher costs than patients in commercial plans or those who are covered by Medicaid. Patients with out-of-pocket costs over US$500 annually represent 8.8% of total patients, but 20% of Medicaid Part D patients. Patients covered under commercial plans are turning to manufacturer coupons to offset costs. Average final out-of-pocket costs remained at US$42 per brand prescription, similar to those levels in 2017. One of the most troublesome issues is patients not receiving necessary medicines due to abandonment of prescriptions at retail pharmacies when these out-of-pocket costs rise or when their insurance includes a deductible. Patients abandon more than 20% of new-to-brand prescriptions when their cost is above US$50. This figure rises to 50% when out-of-pocket costs to the patient rises to US$125.

The largest driver of growth will be the launch of new brands that are forecasted to contribute US$73 billion of new spending, attributed to clinical development efforts across the pharmaceutical industry which will result in new drug approvals and uptake. An offset to the impact of new brands will be patent loss and exclusivity of certain brands. This could result in a savings of as much as US$78 billion over the next five years.

Potential policy changes focusing particularly on drug pricing and patient out-of-pocket costs are currently under consideration and could lead to alternative scenarios based on their impact on payer types, channels, and therapy areas, as well as impact invoice spending, net spending, and out-of-pocket costs in different ways. For example, where reforms are limited to Medicare programs, patient out-of-pocket costs could see declines of 30%, or approximately US$14 billion. This would mostly be in the case of Medicare patients but may include some reduced costs for commercially insured patients. Net spending could also be reduced by as much as 6% into 2023. These net spending scenarios are attributable in large part by cost reductions coming from manufacturer price reductions but could also result in smaller declines for manufacturers with different relative splits of impact between health plans, manufacturers and beneficiary insurance premium increases, all of which could vary significantly.

For the complete report from IQVIA, please visit *https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023*.

Distributor's Role (cont.)...

and are highly effective logistics partners. Beyond logistics, they also enable access through the financial services they provide, including fee-for-service arrangements. In these arrangements, distributors take financial ownership of the manufacturer's product, and become responsible for collecting payment from their customers/providers. Distributors also provide short-term financing for these providers, due in large part to the tight cash flow and reimbursement that providers deal with constantly.

It is because of this system that patients can feel confident that they will have access to the medicines they need through their provider when they need it. Likewise, manufacturers aren't concerned with getting paid. As expected, the fee for this service is based on a percentage of the product list price paid by the distributor and how much product the distributor purchases and assumes responsibility for throughout the entire supply chain and logistics process.

The distributor is fairly compensated for assuming this financial risk or carrying and warehousing the product, selling the product, and collecting payment from the providers. It is conceptually similar to an interest payment arrangement.

While pharmaceutical prices may increase it can appear that distributors are benefiting disproportionately. However, while revenues will inherently increase, it does not reflect true profit margin. To the contrary, distributors are known for operating with very lean profit margins.

As an example, Mr. Odultola cites AmerisourceBergen's profit margins, which hover around one percent. Comparatively, players in the courier and delivery services industry operate between 5 and 10 percent. The transportation and logistics industry, as a whole, operates at around 6.5 percent as of the third quarter 2018.

As cost constraints continue to apply pressure on all aspects of the healthcare supply chain, distributors remain dedicated to working with industry partners to address these challenges. This will require more creative and collaborative approaches with regard to logistics and financial models as new and more complex therapies come to market. Distributors are prepared to be part of the solution to ensure that patients have access to the latest products in pharmaceutical care.

In Brief (cont.)...

the threshold for "reasonable profit rates" in their wholesale business. The average margin rose 0.2 percent over the previous year to 1.33 percent, according to **Crecon Research and Consulting**. The ethical drug market remained flat for the period April 2018 – March 2019. However, the negative impact of NHI price revisions in FY2018 was offset by growth in sales of new hepatitis C treatments and anti-cancer drugs. Included in these top four wholesaler spots is **Alfresa Holdings, Medipal Holdings, Suzuken, and Toho Holdings**.

- **Verily**, **Alphabet's** life sciences-focused subsidiary, announced early details of collaborations aimed at driving trial recruitment and fast-forwarding clinical evidence. Among those targeted in these collaborations are **Pfizer, Novartis, Sanofi** and **Otsuka**, and will use Verily's technology data tools in clinical studies "over the coming years" giving pharma companies the promise of improved patient engagement in trials and better management of data.

(Sources: Biopharma Dive, FiercePharma, In-Pharma Technologist.com, Pharma Japan, and Scrip)