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A New Study Shows Distrust by Patients in Pharma Supply Chain

(Source: A Press Release by Business Wire)

A study, the *Pharmaceutical Supply Chain Vision Study*, was released by Zebra Technologies, an innovator at the front line of business with solutions and partners that deliver a performance edge. The study revealed patients' distrust of the medications they are receiving and segments within the global pharmaceutical supply chain, including the entities who manufacture, distribute, prescribe and dispense those drugs. Forty-three percent fear more illness and/or death could result from contaminated or tainted medications without supply chain improvements.

Three-in-four patients stated they are either somewhat or very concerned about the ineffectiveness of medication in helping with their condition or illness. And seven-in-10 are concerned about receiving: 1) an improper dose due to labeling errors, and the harm it could potentially cause them; 2) stolen, contaminated, tainted, expired, or counterfeit medicines; and 3) medications that were improperly handled/stored during transit and could have damage or diminished efficacy. Additionally, patients say it is somewhat or very important they can verify a medication is not counterfeit nor tampered with and confirm temperature sensitive medications have stayed within the prescribed range.

According to the survey, patients around the world also expect drug manufacturers to disclose how their medications are manufactured/handled and transported/stored. Patients think it is important to verify the sources of medication ingredients including the country of origin and local standards for the medication itself.

In addition, 79% of those surveyed want to know the source of their medication is sustainable with confirmation the manufacturer is using techniques to protect the environment, animal welfare, human communities, and public health.

The study shows that the pharmaceutical industry must work harder to earn consumer confidence and loyalty. Overwhelmingly, patients agree government/regulatory agencies and pharmaceutical companies need to work better together to protect patients and ensure the medications they receive are safe and effective. Patients also believe pharmaceutical industry decision-makers, regulators, pharmaceutical companies and manufacturers are most responsible for combating counterfeit, stolen and contaminated medications.

Pharmaceutical industry decision-makers feel they are prepared to comply with traceability and transparency mandates and confirm they have already deployed location services technology or plan to in the next year, a move which would improve production workflows and drug tracking, reduce shrink and tampering, and give patients the visibility and information they want. The biggest challenge these leaders are facing is being able to make – and move – enough medications to meet patients'

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In Brief...

- **Walgreens Boots Alliance (WBA)** and **McKesson Corporation** reached an agreement for WBA to acquire the remaining 30% share of their **GEHE Pharma Handel (GEHE)** and **Alliance Healthcare Deutschland (AHD)** joint venture. Following this transaction, WBA will become the 100% owner of the combined GEHE and Alliance Healthcare businesses in Germany. GEHE and AHD successfully combined their operations in the German pharmaceutical market on November 1, 2020. In that transaction WBA became the 70% owner of the joint venture with McKesson holding the remaining 30%. Today's announcement follows McKesson's announcement in July 2021 of the sale of certain European businesses and its intention to exit the European region fully.
- **The European Healthcare Distribution Association (GIRP)** celebrated its 60th anniversary of its founding in 1960. The event brought together key pillars and actors of GIRP's community and network for an evening of reflection, remembrance, and celebration. For over six decades, GIRP and its members, as the full-service distribution sector, have been regarded a key pillar in the healthcare systems. GIRP is proud to celebrate this grand milestone and IFPW offers its sincere congratulations to GIRP on its 60th anniversary.
- A new variant of the COVID-19 virus, named Omicron (also known as B.1.1.529), has emerged in South Africa and other surrounding countries on the African continent. While much is still unknown about this specific variant, 32 mutations have been discovered. It is reported that the variant is more

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Japan Sees 'Drug Lag' as Foreign Pharmas Pass Up the Market Amid Pricing Pressure

(Source: An article by Angus Liu for FiercePharma)

Japan has been leveraging different policy tools to rein in drug expenditures, and that is a cause for concern for some foreign pharmaceutical companies. The country is seeing "trends of a drug lag," as approvals decrease, Yasushi Okada, president of the Japan Pharmaceutical Manufacturers Association and Eisai's chief operating officer, said in a recent interview, as quoted by local news agency Jiji Press.

Altogether, 176 new drugs that were approved in the U.S. and Europe between 2016 and 2020 didn't enter Japan, up from 117 in the five years leading up to 2016, according to the industry group.

"An industry will not prosper unless technological innovation is rewarded," Okada said, as quoted by Jiji. "We barely feel any advantage from being based in Japan."

Okada's comment comes as Japan this year reportedly

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New Study (cont.)...

needs. In addition to regulatory delays, industry decision-makers say they are also dealing with production limits, distribution and storage problems, shipping capacity constraints and transportation delays.

Over three-quarters of patients surveyed say they have experienced issues either purchasing or taking medication in the past. And 70% of all patients confirmed they have either changed prescribing providers, pharmacies, or medications in the past due to a poor experience. Among patients experiencing problems, a severe side effect was among the top five issues.

Patients' lingering concerns center on medication affordability and shortages. Additionally, patients say all pharmacies need to monitor the medications dispensed, including mail-order pharmacies.

Other key regional findings include:

Asia Pacific (APAC) - Over three-quarters of patients say more regulation of pharmaceuticals is needed, and nearly all (95%) decision-makers say better cooperation between government/regulatory agencies and pharmaceutical industry companies is needed to protect patients, the highest of any region.

Europe - Only 64% of patients and 74% of industry decision-makers agree that direct-to-patient delivery of medications by mail is a convenient and consistently safe way to receive medications—the lowest agreement level among regions.

Latin America - Latin American patients are the least tolerant of issues with their medications when compared to other regions, with 87% reporting a change in pharmacy, provider or medication due to a poor experience.

North America - Patients in North America are the least knowledgeable about pharmaceutical traceability, with only 33% saying they are somewhat or very familiar with the concept.

Japan (cont.)...

implemented its first "off-year" price cut outside of its planned biennial drug price revisions. Japan adjusts drug prices biennially mainly to close the gap between the reimbursement price and the actual purchase price on the market.

Okada, in particular, took issue with how Japan slashes drug prices simply when sales exceed certain thresholds. The country maintains a system of repricing for market expansion, which pares back prices when annual sales vastly exceed a drug's original estimated figure.

In extreme cases, authorities may cut a maximum of 25% off a drug's price if its annual sales rise to between 100 billion yen and 150 billion yen and are at least 1.5 times the original expected sales or 50% off when sales exceed 150 billion yen. The most well-known case that experienced a price cut under this scheme was perhaps Ono Pharmaceutical's Opdivo, which was licensed to Bristol Myers Squibb outside of Japan. Opdivo originally launched in Japan in 2014 in the small indication of melanoma. But its sales growth from label expansions to such areas as non-small cell lung cancer spooked Japanese authorities, which singled out the drug in a special repricing with a hefty 50% discount, which took effect in 2017. The PD-1 inhibitor went on to take several more rounds of price cuts in the following years.

The repricing for market expansion rule is just one of several tools the Japanese government has resorted to for cutting drug prices. This year, Japan started officially applying a cost-effectiveness assessment (CEA) system to drug prices, two years after its introduction in April 2019. Novartis' CAR-T therapy Kymriah and GlaxoSmithKline's three-in-one COPD inhaler Trelegy became the first two treatments to undergo an assessment under the program. Starting in July, those drugs will see a 4.3% and 0.5% price cut, respectively.

Gilead Sciences' rival CAR-T drug, Yescarta, which is managed by Daiichi Sankyo in Japan, got the same 4.3% downward adjustment from the get-go because its original reimbursement price was benchmarked against Kymriah. Back in 2019, Kymriah won Japanese coverage at a price of 33.5 million yen, whereas Yescarta secured approval earlier this year.

The CEA system, which uses an incremental cost-effectiveness ratio for its calculations, targets highly innovative but pricey drugs. Okada also opposes a proposal to tie the maximum increase in drug prices to the growth rate of Japan's nominal GDP, according to Jiji. "The pharmaceutical industry has the potential to make money," he said. "It must lead GDP growth instead."

In Brief (cont.)...

contagious but reported cases have been milder than the Delta variant. Agencies such as the **U.S. Centers for Disease Control** and the **World Health Organization** are urging countries not to panic until more information is gathered, which should take approximately two weeks. So far, the Omicron variant has been reported in more than 20 countries, including Australia, EU countries, Africa, Asia, U.S. and Canada.

- Both **Pfizer** and **Moderna** have received expanded emergency use authorization from the **U.S. Food and Drug Administration** for their COVID-19 boosters in all adults 18 and older. The dose can be administered no sooner than six months after completion of the primary vaccine series. Those who received the single-dose **Johnson & Johnson** vaccine are also eligible for a booster of the vaccines after two months. Likewise, **Japan's Ministry of Health** has granted special emergency approval for Pfizer's COVID-19 vaccine, *Comirnaty*, for use as a booster shot in individuals 18 and older. The approval comes a day after the vaccine cleared Japan's Pharmaceutical Affairs and Food Sanitation Council's Second Committee on Drugs. The third dose will be given at least six months after the second shot.
- **Pfizer** and the UN-backed **Medicines Patent Pool (MPP)** (a public health organization working to increase access to medicines in low-and middle-income countries) announced the signing of a voluntary license agreement for Pfizer's COVID-19 oral antiviral treatment candidate, which is administered in combination with low dose ritonavir (PF-07321332). The agreement will enable the MPP to facilitate additional production and distribution of the drug, pending regulatory authorization or approval, by granting sub-licenses to qualified generic drug manufacturers.

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