

IFPW Service Member Spotlight

**Crecon Research and Consulting
Offering Excellence as Japan's Premier Resource
for Pharmaceutical Market Research**



CRECON Research & Consulting Inc. (CRECON), established in 1955, was the first pharmaceutical market research organization in Japan. Since then, the company has continued its business for more than 60 years as an information company while changing its form with the development of drug distribution, based on its mission of contribution to a sustainable health care system through medical and pharmaceutical information. The company is working for pharmaceutical wholesalers, manufacturers, and medical institutions, with the aim of attaining a higher quality and more productive health care industry through improved industrial knowledge and cutting-edge technologies.

CRECON plays a role in three main areas. First, CRECON contributes through its industry support services, which help raise awareness of pharmaceutical distribution as a part of the health care infrastructure, and enhance its value.

More than 10,000 different kinds of medical pharmaceuticals are supplied through a capillary network of pharmaceutical wholesalers to medical institutions and pharmacies in roughly 250,000 locations throughout Japan, with wholesalers also being responsible for price negotiations and credit management. Wholesalers in Japan also conduct marketing activities aimed at prescribers. Because of the comprehensive range of activities they undertake, pharmaceutical wholesalers have an intimate knowledge of regional demand for pharmaceuticals, which enables them to act rapidly and appropriately in times of emergency. CRECON is engaged in activities that make use of various media to bring to the attention of society the value provided by this pharmaceutical wholesaler infrastructure, and the company works continually to strengthen these initiatives.

Second, CRECON contributes through the application of pharmaceutical information & infrastructure and solutions, using information systems to enhance productivity within companies or within the links between companies.

Pharmaceutical wholesalers and other companies affiliated with the pharmaceutical industry have amassed various information during their day-to-day operations. CRECON summarizes that information, and offers it for use, thereby contributing to the increased efficiency of the pharmaceutical industry. As IT has developed over time, the company has moved forward to build and provide information systems that allow customers to focus on their competitive domains.

Third, CRECON contributes by playing an important role in

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- ◆ Government-back **Shanghai Pharmaceuticals Holding Co.** (China) and investment group **FountainVest Partners** have both submitted second round bids for **Cardinal Health's** Chinese distribution unit. The deal, valued at more than US\$1 billion according to sources familiar with the deal, has also garnered interest from Warburg Pincus and PAG Asia Capital. Cardinal Health China's market value is approximately US\$20.8 billion. Advanced negotiations are expected to commence in the next few weeks.

- ◆ **AmerisourceBergen's Lash Group** has unveiled *Fusion*, a new tech ecosystem for patients that is designed to bring both technologies and patient support systems together. The new system offers advanced data models in order to give patients, providers and manufacturers a more personalized experience by streamlining administrative tasks and allowing for quicker access to treatment.

- ◆ Sources reveal that **Amazon** could make an announcement before late November with regard to the company's strategy to enter into the prescription drug market. The prescription drug market valued at US\$560 billion annually, making it a very inviting target for Amazon, who already has a presence in the medical supplies market. In an August report by Goldman Sachs, it speculated that Amazon is looking to improve price

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**Big Pharma Turns to Blockchain to Track
Meds: No more counterfeits?**

(Source: an article prepared by Jeff John Roberts and published by Fortune)

The pharma industry may be on the verge of solving a longtime problem: How to stop a flow of stolen or counterfeit pills entering the supply chain and trickling down to patients. The answer comes in the form of blockchain technology (also known as distributed ledgers), a form of software that runs across multiple computers, and creates a tamper-proof, indelible record of transactions.

Recently, a group of companies announced the MediLedger Project, which is creating blockchain tools to manage pharmaceutical supply chains. The group includes drug giants Genentech and Pfizer, and has already completed a successful pilot program to track medicines. If the project meets its goals, everyone from drugmakers to wholesalers to hospitals will be recording drug deliveries on a blockchain. What this means in practice is that, at each step of the distribution process, a network of computers will vouch for the provenance and authenticity of a drug shipment—making it harder for thieves to unload stolen medications, or for counterfeiters to introduce fake wares.

According to Ryan Orr of Chronicled, the San Francisco-based company creating the blockchain tools for MediLedger,

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proving the value of pharmaceuticals and supporting the proof of correctness of health care expenditures. The company has been involved in pharmacoeconomic analysis since 1993. In August 2014 it established CRECON Medical Assessment Inc. and began offering outsourced services in the field of pharmacoeconomic analysis.

By contributing in these three ways, the company turns its corporate slogan of “Proving and Improving Your Health Care Value” into reality.

Information Database and Solution Service: CRECON provides three groups of services based on the roles it plays in the three above-mentioned areas. One of these groups is offering a database focusing primarily on the sale, distribution, and marketing of pharmaceuticals.

CRECON offers a pharmaceuticals sales database that includes sales values for medical pharmaceutical products in Japan (covering approximately 99% of the domestic distribution market), enabling users to grasp the monetary value sales and shares in a market. It also provides a monthly quick report on pharmaceutical sales trends by region and by pharmaceutical company.

In addition, the company maintains a database of calls made by pharmaceutical wholesaler marketing specialists (MS). One of the largest such databases in Japan, a single year of data represents approximately 160,000 calls. One of the issues in relation to MS activities had been a shortage of third-party evaluation, but by using this database, MS activities can be evaluated properly, contributing to the formation of a strategy in partnership with pharmaceutical company medical representatives (MR).

The company also offers databases for clinical diagnostic reagents, veterinary drugs, and agrichemicals, with primary wholesalers surveyed directly and the resulting data aggregated for analysis at the prefectural and national level in order to show their actual distribution within Japan.

As a second range of services, CRECON is devoting resources to solutions outsourcing, which helps enhance productivity within companies and within the links between companies.

One of the solutions offered consists of a cloud-based platform aimed at improving the efficiency of education at pharmaceutical wholesalers. In addition to general education and guidance that takes place within pharmaceutical wholesalers, some customers turn the needs of pharmaceutical companies into their own business by using it, and provide training support for MS.

On the other hand, one of the services being offered to pharmaceutical companies incorporates cloud-based sales support tools. This is being used by some customers as a solution to focus on various problems resulting from the communication gap between different locations in the field, or between locations in the field and headquarters.

Health Care Economics Evaluation: The third group of services consists of analysis, evaluation, and consulting operations related to proving the value of pharmaceuticals and supporting the proof of correctness of health care expenditures. Through its three main service lines of cost-effectiveness analyses based on pharmacoeconomics, burden of illness analyses, and real-world data analyses, CRECON Medical Assessment Inc. assists the customer in creating evidence that cannot be obtained through clinical testing alone.

Below is the outline for the current state of affairs regarding cost-effectiveness evaluation in Japan.

Trial Introduction of Cost-Effectiveness Evaluation: In April 2016, trial introductions of cost-effectiveness evaluation were begun in Japan. The results of cost-effectiveness evaluations for the designated products were submitted by companies in March 2017. These are currently undergoing appraisal at a Special Committee on Cost-Effectiveness, and will be used to adjust pricing at the April 2018 round of drug price revisions.

The trial introduction of cost-effectiveness evaluations will undoubtedly prove to be one of the most significant developments in the history of Japan's drug pricing system. For pharmaceutical companies aiming to secure high prices, generating cost-effectiveness evidence is an essential process, and it would not be an exaggeration to say that whether they can adapt to the new system or not will become a question of vital importance going forward.

CRECON will continue to take initiatives to improve its business in order to contribute further to resolving the issues faced by medical care today, while the employees and officers of the company maintain a keen sense of appreciation for the trust shown by those in the pharmaceutical industry, and remain committed to giving back.

Big Pharma (cont.)...

the drug industry already uses software to manage supplies, but these consist of a mixture of different databases. The introduction of a blockchain system, in which each participant controls a node on the network, and transactions require a consensus, is thus a significant leap forward.

“The pharma industry consists of large conservative companies, so it takes a lot of confidence to build up a network like this,” said Orr. Drug companies aren't the only ones using a blockchain to tighten up their supply lines. The diamond industry is working with a company called Everledger to verify the origins of precious stones (it has already added over 1.6M gems to a ledger) while food sellers, including Walmart, are using blockchain to track pork and chicken. Meanwhile, the state of Delaware passed a law to help companies place shareholder lists and other corporate records on a blockchain.

For the drug industry, the potential advantages of the blockchain go beyond securing supply chains. According to Orr, the permission-based nature of the node system is a superior way for companies to share information with partners and customers without “leaking key business information.” Genentech, meanwhile, sees blockchain as a logical extension of its efforts to assign unique traceable numbers to pharmaceutical products. “Ensuring the safety of people receiving our medicines is of utmost importance to us. We look forward to exploring the potential benefits that this pilot could provide in protecting our medicines across the entire supply chain,” said the company's SVP of Managed Care and Customer Operations, Marc Watrous, in a revised statement to Fortune.

One further upside to using a blockchain is speed: In the event a shipment is disrupted or goes missing, the data stored on the common ledger provides a rapid way for all parties to trace it, and determine who handled the shipment last. For now, Orr says, the MediLedger Project is working on getting big companies to adopt

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the blockchain technology, and only intends to focus on business models down the road. The initiative is likely to get a boost thanks to the Drug Supply Chain Security Act, a law that requires companies to take a series of steps to create a more uniform drug-tracking system in the U.S..

The MediLedger Project, which is receiving support from supply chain consulting group The LinkLab, has been building its software using Quorum—an enterprise version of the Ethereum protocol backed by J.P. Morgan. This is part of Fortune's new initiative, The Ledger, a trusted news source at the intersection of tech and finance.

The Bellwether of Pharma's Current Concerns

(Source: an article prepared by Tracy Staton and published by FiercePharma)

The Securities and Exchange Commission filings in the U.S. contain a risk disclosure section, where biotech and pharma companies list the pitfalls of investing in their shares. The accounting and advisory firm BDO sifted through those statements to discover just what the top 100 life sciences companies are currently most worried about and though many of the same challenges have caused concern year after year, a few of this year's 25 most stated risks haven't always been top of mind.

One example came in 21st place among the risks cited most often in 2017's annual reports: Natural disasters, war, conflicts and terrorist attacks. Back in 2013, only 47% of biopharma 10-Ks listed one or more of these as investment risks. This year there was a significant increase to 81%.

Another significant worry: The ability to maintain company infrastructure, including IT security and privacy. The increase there was even more marked, from 46% in 2013 to 89% in 2017. And given that Merck & Co.'s cyber breach happened after most companies filed their annual 10-Ks, that number may well take another jump next year. But the biggest leap was workforce-related. Labor concerns—including pension costs, rising healthcare costs, immigration and outsourcing—popped up in 78% of the reports examined, up from just 24% in 2013. Healthcare insurance costs for employers have increased over the past five years and more recently, biopharma companies have flagged immigration shifts as a threat to their ability to attract and keep top scientific (and other) talent.

Litigation is new to the top of the list. Every company examined listed legal proceedings and lawsuits as risks to their operations, up from just 84% in 2013. Take a look at Johnson & Johnson's legal fight against thousands of claims that its talc products caused ovarian cancer, or AbbVie's load of lawsuits over the safety of its testosterone drugs. One bellwether testosterone verdict just last week put AbbVie liable for US\$140 million in damages. AbbVie plans to appeal.

Meanwhile, the perennial worries are of no surprise. Competition and marketing challenges figured in at the top in 2017 filings, along with intellectual property protections (or loss thereof) and the success (or not) of current and future drug launches all tied for first place, and they've been at or near the top for five years running. And then, of course, there's regulation, by FDA and other authorities at the state and federal levels.

FDA and regulation could take the lead, BDO says. "The top risks cited by the largest 100 U.S. publicly-traded life sciences companies have remained relatively consistent over the last several years, with competitive pressures, intellectual property challenges, and the ability to commercialize and market products all tying for first place this year," BDO says. "Nevertheless, new leadership steering the Food and Drug Administration (FDA), paired with political and regulatory uncertainty, could impact how those risks evolve."

New Economic Report on Wholesalers and Distributors Released

(Source: Drug Channels Institute)

Drug Channels Institute has released its new 2017–18 *Economic Report on Pharmaceutical Wholesalers and Specialty Distributors* which analyzes how a deteriorating healthcare business environment culminated in significant profit declines and loss of stock market value within the sector.

Drug Channels Institute CEO Adam J. Fein, Ph.D., the study's author, said, "We project that U.S. drug distribution revenues at the Big Three public wholesalers—AmerisourceBergen, Cardinal Health, and McKesson—will reach US\$425 billion in 2017, a 4.5% increase from the 2016 figure." He added, "This is the slowest revenue growth since 2013. We also estimate that core U.S. drug distribution margins peaked in 2015 and have declined ever since."

In addition, Fein commented, "The pharmacy market's evolution will continue to pressure wholesalers' sell-side margins for brand-name drugs. Wholesalers' profits from generics drugs have tumbled due to generic deflation and pharmacy negotiations. As we predicted, specialty biosimilar drugs have not delivered significant profits for wholesalers."

These findings are among the many insights and trends included in the report, now in its eighth edition, and which includes 117 proprietary charts, exhibits, and data tables.

To review the report's contents, read its overview or to purchase and immediately download it, please visit: http://drugchannelsinstitute.com/products/industry_report/wholesale/

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transparency and out-of-pocket costs for the consumers while gaining a foothold in this very lucrative market. Amazon declined to comment.

- ◆ **The Food and Drug Administration's Drug Shortages Unit** is working with Puerto Rican pharmaceutical manufacturers to determine what is needed to prevent drug shortages of any drugs manufactured on the island. Puerto Rico is the home to 12 of the top 20 global biotech and pharmaceutical companies and manufactures seven of the top 10 drugs sold around the world. In an effort to prevent these critical shortages, the FDA has convened a "hurricane shortages task force" that will go above and beyond the Agency's normal drug shortage responsibilities, including identifying potential issues and determining creative solutions to these challenges.

(Sources: Bloomberg, CNBC, Drug Store News, Forbes, and FiercePharma)