

U.S. FDA Working with Companies to Test Prescription Blockchain Pilot Program

(Source: An Article by Mark Hamstra for Drug Store News)

In a synchronized statement, four major U.S. companies announced that they were selected by the U.S. Food and Drug Administration to collaborate on the agency's new Blockchain Pilot program. Each of the four companies – IBM, KPMG, Merck and Walmart - bring to the table their technical knowledge and experience with blockchain technology encompassing critical components of the process such as end-to-end capabilities, artificial intelligence, and pharmaceutical supply chain (including security and detection of counterfeit drugs.)

This program builds upon the Drug Supply Chain Security Act (DSCSA) enacted by Congress on November 27, 2013. The DSCSA requires the FDA to create an electronic interoperable system to identify and track prescription drugs distributed within the United States by 2023. In February of 2019, the FDA announced the implementation of pilot projects to help achieve the goals set out by the DSCSA. The announcement also asked pharmaceutical stakeholders to propose pilot projects for review by the FDA that would enhance the safety and security of the distribution supply chain. The results and advancement of these pilot programs offer key information to be shared with all stakeholders.

The Blockchain Pilot's supporters hope to leverage blockchain to create a reliable and verifiable supply chain that helps improve confidence among all stakeholders, especially patients. When employed by the pharmaceutical supply chain, this could potentially allow users to access a platform that tracks a drug from creation all the way through to its delivery to the patient. This "ledger" would be transformational regarding how pharmaceutical data is controlled, managed, and shared throughout the lifecycle of a drug.

The companies will create a shared permissioned blockchain network that allows real-time monitoring of products. The network would seek to reduce the time needed to track and trace inventory, allow timely retrieval of reliable distribution information, increase accuracy of data shared among network members, and help determine the integrity of products in the distribution chain (including whether products are stored at the correct temperature.)

"With successful blockchain pilots in pork, mangoes and leafy greens that provide enhanced traceability, we are looking forward to the same success and transparency in the biopharmaceutical supply chain," said Karim Bennis, Walmart's vice president of strategic planning and implementation in health and wellness. "We believe we have to go further than offering great products that help our customers live better at everyday low prices. Our customers also need to know they can trust us to help ensure products are safe. This pilot and the U.S. Drug Supply Chain Security Act requirements will help us do just that."

The Blockchain Pilot has several challenges to overcome as far as technical limitations. As blockchain grows larger, it operates more slowly and requires more energy to run. Likewise, storage size can become a significant issue. More data equals a larger ledger.

In Brief...

- ◆ Brazilian wholesaler and distributor **Profarma Distribuidora** posted its best second quarter performance in the last two years. Gross revenues rose by 19.1% in the period to US \$5.8 billion, and gross profit rose by 19.9% to US\$27.3 million. Its retail division saw an increase of 5.4% for same store sales while specialties sales rose by 4.6%.

- ◆ Pharmaceutical manufacturer **GlaxoSmithKline** is expected to name *Jonathan Symonds* to the position of Chairman. Symonds previously served as CFO for Novartis and AstraZeneca. He will replace *Philip Hampton*. Hampton announced that he would be stepping down in January of 2019. Symonds is well versed in the life science industry, and his experience with major deals makes him an excellent choice for the chairmanship. GSK is currently in the middle of the creation of a consumer health joint venture with **Pfizer** in preparation for a spinoff.

- ◆ The **U.S. Food and Drug Administration** approved the first generic version of the blockbuster drug *Lyrica*, a key treatment in the management of neuropathic pain associated with diabetic peripheral neuropathy as well as management of postherpetic neuralgia and fibromyalgia. The generic version, *Pregabalin*, has received approval to be manufactured by **Alembic Pharmaceuticals, Alkem Laboratories, Amneal Pharmaceuticals, Dr. Reddy's Laboratories, InvaGen Pharmaceuticals, MSN Laboratories, Rising Pharmaceuticals, Sciegen Pharmaceuticals** and **Teva Pharmaceuticals**.

- ◆ U.S. wholesaler and distributor **Cardinal Health** announced that *Stephen Mason*, currently president of the company's at-Home Solutions business, has been promoted to CEO of Cardinal Health's medical segment. Mason will succeed *Jon Giacomini*, who will be leaving the company mid-August to assume the CEO position of a privately held company. Mason is a 20-year veteran of the company and has successfully led several businesses within both Cardinal's medical and pharmaceutical segments.

- ◆ **MinuteClinic**, **CVS Health's** retail medical clinic, is now offering telehealth in eight additional states, bringing the total number of states with this option to 26. Patients with minor illnesses and injuries, skin conditions and other wellness needs can now seek care through *MinuteClinic Video Visits* in Arkansas, Connecticut, Hawaii, Indiana, Minnesota,

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Since the ledger is copied to and stored on multiple nodes across a network, more storage space on each node will be required.

The current timeline for completion of the Blockchain Pilot is the fourth quarter of 2019. Ideally, it will allow both the FDA and industry leaders to weigh the strengths and weaknesses of the program, its potential as an overall solution, and how best to implement the technology moving forward.

Europe Comes Up Short on Drug Supplies

(Source: An article by Jillian Deutsch for Politico)

France is the latest country to join the group of European countries calling upon European Union officials to find an EU-wide approach to stopping drug shortages, which are at an all-time high due in part to increased dependency on a limited number of suppliers located overseas. Pharmacists and health campaign groups have issued warnings for years of these worsening shortages.

In July, cancer patients in Italy were unable to access necessary treatments, while shortages of neurological drugs plagued Poland. The total number of unavailable drugs in Belgium also reached a new record high. Reports from France state that the number of scarce or unavailable drugs increased by a factor of 20 between 2008 and 2018 and is predicted to rise an additional 60% this year.

In the past, drug shortages were generally limited to smaller countries with less attractive markets like Romania, Bulgaria, and Eastern European countries. Now even the wealthiest countries are experiencing critical drug supply shortages. One explanation for this is that drugs and their ingredients are increasingly manufactured by only a handful of companies, mostly located in Asia. The result is any disruption in the supply chain can cause serious shortages.

“It is true that medicines and the required raw materials are increasingly being produced outside of Europe. This mainly concerns countries such as China and India,” stated Bruno Bruins, Medical Minister for the Netherlands. “If we are dependent on a limited number of countries for the production of raw materials, this makes the chain of drug production vulnerable. I find that undesirable.”

“For years, we’ve been ringing alarm bells because the market is becoming concentrated,” said Adrian van den Hoven, Director General of Medicines for Europe, which represents generic drug manufacturers. He gave an example involving the explosion of a Chinese manufacturing facility that made *piperacillin-tazobactam*, an active antibiotic ingredient, in 2017. The explosion left only one other manufacturer of the drug worldwide.

Pharmacists have also pointed to drug shortages in the U.K. caused by the coming Brexit. As manufacturer confidence in the U.K. market wanes, the industry scrambles to stockpile necessary medicines. In order to alleviate the issue of drug shortages, pharmacists have requested permission to modify a patient’s prescription without having to send people back to the doctor’s office for a new script. Activists are looking towards better transparency as a means of keeping drug prices down. Patient groups have also proposed penalties in the form of fines against pharma companies if they are found to be responsible for a shortage.

EU countries (including Belgium, Poland and Slovakia) have tried to address shortages by limiting parallel trade, a practice through which traders sell drugs purchased in one country in another, for a higher price. And while restricting parallel trade when the issue is parallel trade, it does not help when there are marketing or manufacturing issues.

In a survey of 1,009 individuals, conducted by France Assos Santé before the European Parliament election, 90% of those

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Missouri, Oklahoma and Texas. MinuteClinic Video Visits provide patients with access to care 24 hours a day, seven days a week from their mobile device or computer.

- ◆ **Celltrion Inc.** will set up a joint venture with Hong Kong-based **Nan Fung Group**. The joint venture, **Vcell Healthcare, Ltd.**, will develop and commercialize biosimilars, including *Remsima* (*infliximab*; *CT-P13*), *Truxima* (*rituximab*; *CP-T10*) and *Herzuma* (*trastuzumab*; *CT-P6*). All three have already been approved in the U.S. and EU, and *Remsima* gained IND approval in China in 2017. The two partners will also explore establishing a biologics manufacturing facility in China, although the exact location is yet to be determined.

- ◆ **Takeda Pharmaceuticals** has tapped **J.P. Morgan** to assist in finding a buyer for some of its European consumer and prescription drugs, according to a report from **Reuters**. A source close to the matter said that the company hopes to raise as much as US\$1.7 billion for the products, most of which have lost patent protection. Takeda is working to pay down debt it incurred for its buy of pharmaceutical manufacturer **Shire**.

- ◆ In a likely response to investor concerns, **Biogen** is putting greater emphasis on its ophthalmology and immunology treatments, supported respectively by the recent acquisition of **Nightstar Therapeutics** and Biogen’s two experimental lupus treatments. The company now considers immunology as an area of emerging growth, while ophthalmology falls under its list of core therapeutic areas alongside multiple sclerosis, movement disorders and neurodegenerative diseases.

- ◆ **Gilead** announced that three of its executives will be stepping down as CEO, *Daniel O’Day*, continues to reshape the organization. Among those leaving are *John McHutchison*, chief scientific officer and head of R&D, *Katie Wilson*, President of Human Resources, and Chief Patent Officer *Gregg Alton*. Alton and McHutchison will both serve in advisory roles until the end of the year.

- ◆ **Bayer, Bristol-Myers Squibb and Ono Pharmaceuticals** announced a clinical collaboration agreement to evaluate the combination of Bayer’s kinase inhibitor *Stivarga* (*regorafenib*) and BMS/Ono’s anti-PD-1 immune checkpoint inhibitor *Opdivo* (*nivolumab*) in the treatment of patients with microsatellite stable metastatic colorectal cancer. Full details of the collaboration were not disclosed.

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

individuals surveyed said they want more EU-wide regulation to prevent shortages.

Lieven Zwaenepoel, spokesperson for the Association of Belgian Pharmacists APB, said the European Commission needs to do something about the issue, focusing less on the free movement of goods and more on public health.

“If one country does so you get some attention but no real solution,” said Zwaenepoel. “If the European Union were to do so it would make more of an impression.”