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Blockchain for Rx Track and Trace?

(Source: Edited excerpts from an article prepared by Matthew Leising, with assistance by Anna Edney, and published by Bloomberg)

The implementation of blockchain has been slow in getting deployed outside the cryptocurrency space where the technology was developed. But a little-noticed U.S. law could change that, bringing the ledger system to the pharmaceutical industry.

The Drug Supply Chain Security Act from 2013 requires drug companies and their supply chain partners to more closely track where their finished products are shipped, making counterfeit medicines harder to sneak into the system and easing drug recalls. By 2020, pharmacies and hospitals must be able to verify that the drugs they're dispensing came from manufacturers or repackagers (which separates huge batches of pharmaceuticals into the actual bottles that get distributed in pharmacies or hospitals.) While pharma giants are still evaluating how to comply, healthcare analysts believe the impeding deadline is leading firms to seriously consider the blockchain, since it's designed to create detailed and immutable databases.

"The best bet going right now appears to be blockchain," in part because of the shortcomings of conventional software, said Chet Stagnaro, a consultant with healthcare advisory firm Freed Associates. "The potential is definitely there."

Blockchain, originally developed as the ledger technology that powers the Bitcoin digital currency, is promising for corporations, if they can figure out how to use it. Proponents predict billions of dollars in savings by handling records more efficiently and rapidly. Yet most corporate efforts are still in early development or testing. Healthcare may counter that trend. The Center for Supply Chain Studies has been conducting studies and trials with drug manufacturers, distributors and pharmacies since 2017 to assess how blockchain can meet the law's requirements, according to Robert Celeste, founder of the organization.

Plugging tens of thousands of American pharmacies into a drug-tracking database is a huge challenge, and a blockchain is an attractive way to simplify that, Celeste said. "From the blockchain point of view, there is still a lot of work to be done, but it's being done in earnest," he said.

The law requires tracking each package of drugs separately, but current industry software can only do it to the lot or batch level, said Arun Ghosh, blockchain leader at KPMG. A blockchain solution won't necessarily displace existing software, but augment it, he said. "With blockchain you can now get to a much lower grain of detail," Ghosh said. For sophisticated drugs used in cancer treatment or biologics, which are expensive to develop, that can lead to huge savings if a bad ingredient leads to a recall because the exact point of failure will be recorded on the blockchain. "The recall on a biologic is hundreds of millions of dollars compared with a generic," he said. Drugmakers will need to prove to the Food and Drug Administration that expired drugs are returned to them, Ghosh said. Here too, the detailed records kept by a blockchain may prove superior. "When all these things come into place, blockchain is being actively entertained," he said.

In Brief...

- **Walgreens Boots Alliance** reported a sales increase of 11.3% for fiscal year 2018, with revenues of US$131.5 billion, and adjusted earnings per share increasing 18% to US$6.02. Fourth quarter sales were US$33.4 billion, with adjusted earnings per share of US$1.48. Adjusted net earnings for the full year rose 23.2% to US$5 billion.
- **Cardinal Health** has appointed *Victor Crawford* as CEO of the Pharmaceutical Segment. He will assume the role effective November 12, 2018. He was previously chief operating officer of Aramak's Healthcare, Education and Business Dining division. Separately, **Telix Pharmaceuticals** (USA) Inc announced that it has entered into a distribution agreement with Cardinal Health. Telix USA is a clinical stage biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or "molecularly-targeted radiation". The agreement covers pharmacy preparation and distribution of the *Ga-HBED-CC-PSMA-11* imaging cold kit *(Ga-PSMA Kit)*, developed by ANMI SA and commercialized for the US market by Telix USA.
- UK pharmaceutical manufacturer **GlaxoSmithKline** will start using wholesalers to distribute its drugs in its home country. **Phoenix UK, AAH** and **Alliance Healthcare** have agreed to distribute GSK's prescription medicines to community pharmacies, hospital and dispensing doctors across the UK, reported *The Pharmaceutical Journal*. This is a departure from GSK's direct-to-pharmacy model. The changes will take effect starting November 1st, although GSK vaccines will still be available online.

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Sustainability of Biosimilars

The following is an edited excerpt of the executive summary from the report, IQVIA Advancing Biosimilar Sustainability in Europe - A Multi-Stakeholder Assessment, prepared by the IQVIA Institute for Human Data Science, written by Murray Aitken, Executive Director, IQVIA Institute for Human Data Science; Isabel Rodríguez, Principal, Consulting Services; Joanna Diamantara, Associate Consultant, Consulting Services; Manuel Vázquez, Manager, Consulting Services.

Biosimilars are now an integral part of the market for biologics, which overall accounted for US$277 (€238) billion in sales globally in 2017 and is projected to reach US$452 (€388) billion by 2022. In ten developed markets alone (U.S., Japan, Germany, France, Italy, U.K., Spain, Canada, South Korea, Australia), US$45 (€38) billion of biotech spending is now estimated to be exposed to biosimilar competition, and another US$52 (€44) billion is expected to go off patent from 2019 to 2022. By 2027, 77% of current biotech spending is expected to be subject to some form of competition. A large and diverse group of manufacturers—numbering 184 globally— are investing in the development and commercialization of biosimilars, bringing with

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Biosimilars (cont.)...

this investment the promise of high-quality biologic therapies at a lower cost.

In Europe, more than 45 biosimilar products (for 15 biologic medicines) are now approved and registered—treating a variety of diseases within oncology, autoimmune disorders, diabetes and fertility. Frameworks to facilitate, and mechanisms to encourage, the use of biosimilars have been established at the European and country level and have consistently emphasized the role biosimilars can play in expanding biologics access for patients while lowering treatment costs. With the potential for biosimilar use to offer savings of more than US$11.8 (€10) billion between 2016 and 2020 in the EU 5 countries alone, payers are likely to experience some relief of budgetary constraints or the ability to reallocate funds, depending on the policy priorities of each country. However, to sustain the market for biosimilars in the long-term, ongoing benefits for all stakeholders must be ensured. A multi-faceted view of sustainability therefore comprises elements including providing patient access, physician prescription choice, a means to manage existing healthcare budgets for payers, the safeguarding of a healthy level of competition and supply, and product safety and quality. Metrics that can gauge trends in these individual elements of sustainability are useful tools to monitor progress and the impact of policy decisions.

In the European market, biosimilars have increased patient access to biologic medicines, raising utilization of the molecule (i.e., all variants of the same biologic medication, including the originator and biosimilar products) across countries. The current regulatory environment and clinical guidelines are positive toward sustainability by creating a neutral or positive climate for biosimilars relative to originator biologics (i.e., the first, branded variant of any biologic medication). Additionally, product-related sustainability elements have been maintained across countries: biosimilars have proven to be safe, quality products, and manufacturers have provided a reliable supply to markets.

Different levels of biosimilar uptake, price erosion and competitor concentration among manufacturers occur based on the setting of care in which biosimilars are prescribed and used, and the payer purchasing mechanisms in place. In the retail setting—where physician incentives to switch patients to biosimilars may formally exist but with lenient implementation, and patients are familiar with the products and may even be attached to them—biosimilar uptake is slower than in the hospital channel, where different payer purchasing mechanisms—which include tendering and contracting—and different types of incentives, provided by or enforced by payers, drive higher levels of uptake. Price competition among manufacturers in response to different payer purchasing mechanisms results in different levels of price erosion, with single-winner tenders exerting maximum pressure on price but negatively affecting sustainability.

Some of the key elements of a sustainable system were found to potentially be at future risk due to payer-driven switch (where a patient's treatment is switched by the treating physician but influenced by payer decisions, incentives and prescribing barriers) and purchasing systems. For physicians, sustainability means being able to consistently deliver the best healthcare for patients and to maintain their freedom to prescribe relevant treatments of choice. However, payer-driven switch reduces physician prescription choice and patient involvement in the treatment decision, limiting or changing product selection for the patient by removing some as possible options for physicians to select without adding significant work-burden. Overall, the impact of these policies is expected to be greater for patients whose disease requires chronic treatment (e.g., diabetes). In addition, payer-driven switch, especially if enforced though negative physician incentives, provides a means to manage healthcare budgets in the short term but jeopardizes sustainability by disrupting market forces and bringing uncertainty to manufacturers of whether they will be locked out from selling product in a market for a duration of time.

Although single-winner tenders were found to achieve greatest price reduction on biologic molecules when biosimilar competition exists, they were also found not to support long-term sustainability as they disrupt market forces and competition by excluding non-winner manufacturers from the market for the duration of the tender contract. Additional evidence suggests single-winner tenders do not always optimize savings, since physicians can still use non-preferred product at a higher price; whereas multi-winner tenders offer price reductions on all contracted products. They also eliminate the incentive for biosimilar manufacturers to innovate in areas to support patients and providers when they select on price only.

An increased focus on a number of areas is necessary for payers and policy makers to help strengthen sustainability in the long-term and ensure biosimilars continue to improve access to safe and high-quality biologic treatments in Europe. Firstly, safeguarding the interest of patients and serving their needs in the best way possible remains a critical consideration for health authorities and will become even more so as a greater number of new biosimilars coming to market will be able to be self-administered. Secondly, while creating incentives that promote biosimilar uptake, it is necessary to ensure that physicians retain prescription freedom to offer the best product selection for a specific patient. Thirdly, careful design of purchasing mechanisms is important, with tenders and contracts designed to have multiple winners and include criteria other than price, as they allow greater prescription and product choice for physicians and patients respectively, as well as sustain healthier levels of competition as compared with single-winner tenders.

Overall, in an environment that fosters sustainability, both originator biologic and biosimilar manufacturers will be incentivized and encouraged to continue innovating in differentiation areas for their products outside price and to continue the development of new biologic products, including biosimilars, thus further supporting the sustainability of the biologics market and finding new ways to assist in the needs of all stakeholders.

In Brief (cont.)...

- Global pharmaceutical manufacturer **Novo Nordisk** said it will introduce 10 new innovative drugs in the Chinese market by 2025-2026. It will continue to invest in China to develop more treatment-related products as well. Novo Nordisk is widely known for its line of diabetes drugs. According to the China Health Economics Association, approximately 114 million people suffer from diabetes in China, making it the world's largest such group in a single country, and a major health concern.

(Sources: China Daily, Drug Store News, Nasdaq.com, Seeking Alpha, and The Pharma Letter)