

## Balancing Cybersecurity with Data Sharing in the Pharmaceutical and Biotech World

(Source: An article by Tess McCarthy & Brian Stewart of Thermo Fisher Scientific for TechnologyNetworks.com)

With the growing threat imposed by cybercriminals, pharmaceutical and biotech companies are forced to bear the burden of intellectual property (IP) theft, according to a study published by Deloitte. Even the biggest names in the industry are not immune to these security breaches and the penalties they carry – hefty fines from regulators, a decline in brand trust, and potential years of wasted investment if the proprietary information falls into the hands of competitors.

Additionally, there is a growing concern that these breaches will not only affect the bottom line but will compromise individual privacies and safety. Large scale clinical trials and individualized therapies hold vast amounts of patient data that is highly susceptible to these cybersecurity attacks. Most companies in the sector are now focusing on these potential attacks, making data security a top priority. Fundamental in these efforts are robust data management platforms aimed at minimizing potential risks posed by cybercrime. Outsourcing to contract research organizations (CROs) as well as collaboration with academic institutions has become increasingly important in the process of drug discovery and development. These platforms must ensure the safety and efficacy of the data, while also readily sharable with key external partners.

Increasingly, pharma and biotech companies are turning to the latest cloud-based information platforms to protect and manage their data. These solutions allow them to increase their information pipelines while also adding capabilities as they grow. These capabilities include laboratory information management systems, electronic laboratory notebooks, scientific data management systems and other applications, as required.

These systems are deployed using some of the most versatile informatics platforms with maximum flexibility. These state-of-the-art solutions can be deployed on an organization’s in-house data center as well as on secure third-party cloud housing platforms and managed by their own IT team or a third-party source. These third-party solutions are becoming increasingly attractive since most breaches are linked to poorly maintained servers and inadequate security software.

With many businesses spread out across multiple locations and countries, seamless access to information is vital to accelerate research efforts. This is where cloud-based platforms become even more enticing as a solution since they allow for efficient data sharing between authorized users no matter where they are located.

Another key factor is how these cloud-based platforms store and manage information in a central location. This creates a single standardized repository for a company’s data. Since approved users access the data through secured data gateways, this circumvents the usability challenges often encountered when working with

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## In Brief...

- ◆ U.S. drug manufacturer **Pfizer** has announced that it is acquiring **Array Biopharma**, a commercial stage biopharmaceutical company that focuses on discovery, development and commercialization of targeted small molecule medicines used in the treatment of cancer and other diseases with a high level of need. Pfizer will pay US\$11.4 billion (US\$48 per share) in cash for the company. The acquisition will make Pfizer a leader in the treatment of colon cancer.

- ◆ The **U.S. Food and Drug Administration** handed drug manufacturer **Merck Inc.** a key approval for *Keytruda* (*pembrolizumab*) for use in patients with metastatic small cell lung cancer who show disease progression after previous treatment. The accelerated approval is based on tumor response rate and durability of response in studies, giving the FDA the ability to require further confirmatory data at a later date. *Keytruda* is already used in the treatment of non-small cell lung cancer and other conditions ranging from melanoma to lymphoma.

- ◆ **Sanofi** announced that it will create a virtual lab with **Google** in order to enable precision health care as well as optimize research and development, and commercial operations. The French pharmaceutical manufacturer is undertaking the big data collaboration just months ahead of incoming CEO *Paul Hudson’s* start. Details of the partnership are limited, but it is known that the alliance is not between Sanofi and Google’s healthcare spinoff Verily Life Sciences LLC. Sanofi has also

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## UK Government Holds Brexit Select Committee Hearing Regarding Impact on Pharmaceutical Industry

(Source: An Article by Baker McKenzie for Lexology)

In the continuing story of the potential threat of a “no-deal” Brexit and its negative impact, a Select Committee Hearing was held on June 19th addressing the tremendous uncertainty and concern amongst the pharmaceutical industry.

A number of salient and key points were brought to light, including:

- Government preparations to prepare for such a scenario have been inconsistent in nature, particularly in relation to the pharmaceutical industry. While industry representatives noted that the department of Health and the NHS have done their best by way of setting up a shortages team within NHS, productivity has been limited as a direct result of uncertainty and inconsistent information around the present Brexit situation.

- Businesses (including pharmaceutical companies) will face: (1) continuous prices increases; (2) associated costs; and, (3) supply chain disruptions and inefficiencies. This includes challenge of getting needed medicines in and out of the United Kingdom, impacting the timing on the supply of these products.

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## Balancing Cybersecurity (cont.)...

spreadsheets and databases stored on different networks that often become out of date. With a cloud-based solution, data from instruments, sensors and monitoring equipment are stored in the platform as it is collected. This gives users real-time access and insight, allowing for faster decision and more productivity. This collaborative working effort also assists in the full accountability of actions—from measurement to reporting to auditing. User interactions are automatically recorded with the system. Because every interaction can be traced to an individual's password-protected account, it is much easier to determine who is accountable.

With cybercriminals going to increasingly sophisticated lengths to steal valuable IP from pharma and biotech companies are evermore aware that the data tools employed must also offer the highest levels of protection. Cloud-based informatics provide a solution that is both flexible and effective in meeting this challenge. This is proof that data integrity does not need to come at the expense of operation efficiency.

## Brexit (cont.)...

- There is not only a substantial real risk of medicine shortages, but there will be significant price increases for the NHS, as well as shortages of in-demand and necessary drugs in the majority of constituencies within the U.K.

- Wholesale distributors can only stockpile up to two weeks work of product before they need to be delivered to pharmacies and hospitals. Over-stockpiling would not only be a waste of product resources, but money, and would result in costly inefficiencies within the entire distribution network. Additionally, some products cannot be stockpiled due to issues such as product lifecycle and must be delivered direct to pharmacies and/or hospitals. If there is a disruption in the cold supply chain, it would render these products unusable.

- Since manufacturers aim to keep the supply chain as fluid as possible (in order to keep down costs associated with stockpiling) complications caused by Brexit would require the sourcing of additional space to hold products within the United Kingdom, which could become increasingly problematic and costly.

Martin Sawyer, Director of the U.K.'s Healthcare Distribution Association, pointed out that there is a potential risk of a rise in the amount of counterfeit medicine entering the U.K. following Brexit. The new Falsified Medicines Directive (effective February of 2019) aims to protect and enhance the security and distribution of medicinal products within a distributor's supply chain. At present, this regulation will cease to apply in the U.K. as of October 31, 2019. As a result, counterfeit products could more easily be disseminated throughout a distributor's supply chain, making hospitals and pharmacies more susceptible to these counterfeit products. Currently, every legitimate product must be scanned to verify the product's efficacy. After Brexit, this would no longer be the case since the U.K. would be treated as a "third country". The end result would potentially be risk of harm to patients in the U.K.

The threat posed by a no-deal Brexit is clear and poses a threat to the stability of the U.K. pharmaceutical sector. Once the U.K. government provides more clarity and consistency in its handling of the Brexit situation, it will enable the pharma industry to better prepare and adjust for potential challenges.

## In Brief (cont.)...

inked artificial intelligence partnership with IBM Life Science, Schrodinger Inc. and Exscientia Ltd., all with a focus on drug discovery efforts.

- ♦ **AbbVie Inc.** has announced its intended acquisition for **Allergan** at a price of US\$53 billion. This comes after shareholder worries regarding Abbvie's future beyond its top-selling drug *Humira*. The merger would rank as one of the pharma industry's largest companies by revenue. The cash and stock agreement comes less than four years after Pfizer's attempt to merge with Allergan at a price tag of US\$160 billion. That deal was called off after changes in the U.S. tax rules.

- ♦ The pharmaceutical industry in Mexico has notified the Mexican government that it will not take responsibility for medication shortages created by its new model for purchasing and distributing medications. Industry leaders took advantage of the attendance of the president's chief-of-staff, *Alfonso Romo*, and Health Secretary *Jorge Alcocer* at an industry meeting. The Mexican government announced a new centralized and consolidated purchasing model last month that will allow medicines to be obtained at a cheaper price. These medicines will be purchased from a wide variety of suppliers. The process will be overseen by the Mexican Social Security Institute and is aimed at stamping out perceived corruption in the purchase and distribution of medicines.

- ♦ **Walmart**, consulting firm **KPMG**, and pharmaceutical manufacturer **Merck** have been chosen by the **U.S. Food and Drug Administration** to be included in a program to support the U.S. Drug Supply Chain Security Act. The pilot program is intended to assist drug supply chain stakeholders, including the FDA, in developing an electronic interoperable system that will identify and trace prescription drugs as they are distributed within the country, and will create a shared permissioned blockchain network that allows for real-time monitoring of products while reducing the time needed to track and trace inventory.

- ♦ Worldwide logistics company **DHL Supply Chain** will expand its U.S. pharmaceutical and medical device network by 40 percent this year with an investment of US\$150 million in new facilities, technology and other enhancements. The company said it will build nine new sites by the end of 2019, bringing its total number of sites devoted to compliant pharmaceutical and medical device distribution to 30 nationwide. The investment also covers an expansion of its existing operations. Target cities for the new facilities include North Carolina, Tennessee, Pennsylvania, California and Virginia.

- ♦ China's **Jo-Jo Drugstores Inc.**, a leading online and offline retailer and wholesale distributor of pharmaceutical and healthcare products announced that it has entered into an agreement with **Zhejiang Medical Insurance Bureau**. With the establishment of this agreement, the company joins the first batch of third-party distribution service partners that officially undertake the provincial medical insurance project. The company expects to improve its negotiation position for drug procurement, expand its retail coverage, and highlight its corporate brand and influence which will provide a strong foundation for the rapid expansion of the Jo-Jo franchising operations.

Sources: *BioPharma Dive, Drug Store News, European Pharmaceutical Review, Investor's Business Daily, Mexico News Daily, Scrip, Supply Chain Brain, and Yahoo Finance*