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How traceability is disrupting the Pharma industry

Alcimed, an innovation and new business consulting firm, assesses the impact of the Pharma supply chain transformation resulting from the Drug Supply Chain Security Act.

June 6, 2016. The FDA's Drug Supply Chain Security Act will enforce drug traceability at the saleable unit level. The FDA's Drug Supply Chain Security Act (DSCSA), in full force throughout the entire pharmaceutical supply chain in 2023, aims to enable the verification of drugs at the saleable unit-level, the detection and notification of counterfeits, and increased efficiency in recall management.

DSCSA compliance will eventually require the total serialization of the Pharma supply chain, an enormous and complex task. Serialization assigns a serial number to each product, enabling scanning, tracking, and the storing of information in a database throughout different stages. Pharma manufacturers, impacted first by the DSCSA in 2017, are spending hundreds of millions of dollars on their serialization programs, undertaking a cumbersome process to integrate new hardware and software enterprise-wide. For example, it took Pfizer an unexpected added 9 months to cleanse their master data just to begin the race.

While the Pharma industry faces grave difficulties in executing the task of compliance, the new technology for drug traceability also presents opportunities for strategic and commercial development.

The DSCSA is not something just for the FDA to conduct investigations more easily. Three ways in which the Pharma industry can immediately reap the benefits from DSCSA-required data and scanning are: 1) understanding demand for products better, 2) helping to avoid shortage and wastage, and 3) facilitating communication for monitoring, recalls, and warnings, not only throughout the supply chain, but down to the patients. This is complemented by the existing OpenFDA public-access data, which automatically augments adverse even reports with full drug datasets.

Industry-wide traceability technology is requiring moves toward standardization. The result is a more common language and platforms that foster the culture of sharing, which had been foreign to the Pharma industry. Standardization can facilitate and advance budding initiatives to relay clinical trial data for R&D optimization.

As already intended by the European Union's Falsified Medicines Directive, data from drug scanning can also make an impact on health economics and pharmacoepidemiology, through more effective cost-monitoring and the study of target diseases in specific populations in defined areas. Such data presents further opportunity not only to the Pharma industry, but to entire health systems, to execute more-informed strategies. For example, in Europe, drug data can contain the national healthcare reimbursement number for tracking.

Alcimed views increasing data availability to be met with advanced analytics and growing patient demand for more information. The Pharma industry will continue to develop their traceability software and hardware to continue to capture data most efficiently and to harness the most robust and powerful analytics. With data monetization on the rise, who owns and can access data will be a key issue. Government regulation will continue to be an important driver. Patient consumers, especially with their smartphones, will expect more access to information and interaction. Patients may eventually demand full transparency to be able to track a drug him- or her- self at every step from the time it leaves the manufacturer.

About Alcimed

ALCIMED (www.alcimed.com) is an innovation & new business consulting firm, specialized in life sciences (healthcare, biotech, agri-food), chemicals, materials, energy; as well as aeronautics, space & defence. ALCIMED relies on a team of 180 highly-skilled individuals to help its clients with exploring and developing their uncharted territories, covering four key areas: New Technologies, Market Innovation, High-Growth Geographies, and Strategic Foresight. ALCIMED is headquartered in Paris and has offices in Lyon & Toulouse in France, in Germany, Belgium, Switzerland, the UK, the USA and in Singapore.