Is Pharma Ready For Serialization? The Answer Lies In Digital Technology

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New legislation requiring pharmaceutical companies to implement 'serialization' is now coming into force. This means that no counterfeit product should enter the supply chain and no legitimate product is diverted from its intended destination. To work effectively, serialization requires a comprehensive system to track and trace the passage of prescription drugs through the entire supply chain. The application of track and trace principles can help to avoid counterfeit medicines from entering the supply chain. To be effective, digital technologies such as blockchain and RFID-enabled tag and trace systems need to be embraced.

Pharmaceutical product serialization is being introduced throughout the world, and there is a consensus between regulatory agencies about the importance of the control and tracking of pharmaceutical products. Some drug regulators, like the U.S. Food and Drug Administration (FDA), are relatively advanced with serialization requirements whereas other parts of the world are at earlier stages. Where legislation is in force, a failure to meet serialization requirements means that drug products cannot be sold into the particular marketplace.

For the U.S., from November 27, 2019 pharmaceutical wholesalers must buy and sell only serialized drugs. In addition, repackagers must also serialize drugs. By November 27, 2020 all dispensers of medicines must buy and sell only serialized drugs. Finally, by November 27, 2023 a full enhanced drug distribution security comes into effect. For this, unit-level traceability mandated (this means every individual container of a pharmaceutical or healthcare product).

The core purpose of serialization is to prevent fraud (through reducing opportunities for counterfeit medicines to enter the supply chain) and to enhance patient safety.

For pharmaceutical manufacturers to meet the requirements of serialization, this involves careful planning and considerable cost. To achieve serialization, every drug product pack needs to be uniquely identified with digital information - a machine-readable code, and for the product to be registered in an external database to permit each individual item to be traceable.

Under U.S. law (the U.S. Drug Supply Chain Security Act, 2017), the machine-readable form must be a 2D Datamatrix barcode (a barcode consisting of black and white "cells" or modules arranged in either a

square or rectangular pattern) that contains the following:

- National Drug Code,
- Serial number,
- Batch number,
- Expiration date.

The idea is that this information can be accurately decoded using common scanning equipment before the medicine is dispensed to the patient. This means that the nurse or clinician can have a high level of certainty that the medicine is the one produced by the manufacturer and that a fake medicine has not been switched or that the medicine has not been tampered with.

Further with the Act, the legislation outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the U.S. and to have this in place by 2023. This timeline has proved challenging for many within the pharmaceutical sector.

Two technologies are helping pharmaceutical companies with serialization requirements: tag technology and blockchain.

Tag and trace technology

Track-and-trace products can be deployed from the point of packaging to the pharmacy. These technologies help to determine the current and past locations (and other information) of a unique item. While this technology does not provide a complete solution, it helps to minimize attempts to interfere with the supply chain. Radio-frequency identification (RFID) and barcodes are two common technology methods used to deliver traceability. The tags contain electronically stored information. There are two forms – passive and active RFID devices. Passive tags collect energy from a nearby RFID reader's interrogating radio waves; whereas active tags have a local power source (such as a battery) and may operate hundreds of meters from the RFID reader.

A second benefit is the secure transmission of correct information between the users of the supply chain network. The cryptographic nature of this builds insecurity into the information exchange. A third example is with a bridge to the Internet of Things and devices like radio-frequency identification(RFID) transmitters. This is a technology whereby digital data encoded in RFID tags or smart labels are securely and digitally captured by a reader via radio waves. To support RFID is ‘middleware’, a service-oriented software layer that allows software developers the possibility to communicate with heterogeneous devices like sensors, actuators or RFID tags.

Blockchain

Once the product enters the supply chain, the database needs to be updated with different stages of movement and any changes to ownership. The difficulty in achieving this is with limitations to current technology. The more advanced technology is found with packaging lines, and where technology is less advanced is with shipping. This is beginning to change as pharmaceuticals start to embrace blockchain.

A blockchain is a time-stamped series of immutable records of data that is managed by a cluster of computers not owned by any single entity (this means it is ‘decentralized’). Each of these blocks of data (a ‘block’) are secured and bound to each other using cryptographic principles (the ‘chain’). This makes the blockchain an incorruptible digital ledger of transactions that can be programmed to record anything of value, such as time, temperature, vibration, costs and so on.

A blockchain provides a digital ledger system for records and log transactions, by grouping them into chronologically ordered blocks. This makes it ideal for tracking supplies and ensuring that required storage conditions have been achieved and that goods have not been tampered with. The “blocks” on the blockchain are made up of digital pieces of information, which store information about transactions, say the date, time, and transaction price. A verified piece of data forms a block which then has to be added to the chain. To do this, blockchain users have to use their respective keys and powerful computing systems to run algorithms that solve very complex mathematical problems. When a problem is solved, the block is added to the chain and the data it contains exists on the network forever, meaning that it cannot be altered or removed. Blocks also store information about who is participating in transactions, and information that distinguishes the block from other blocks. The system is designed to provide transparency and security.

Although blockchain is not yet permitted to be used in the pharmaceutical industry to label actual drug products, digital ledger technology is being implemented as a two-dimensional barcoding system. The technology is then used to authenticate containers throughout the supply chain. Many pharmaceutical manufacturers hope that gradually blockchain will be accepted as the primary tool to enable full serialization.

Whichever technologies are being adopted now or in the near future, serialization will generate massive amounts of data for global companies that will need to be retained for many years to meet compliance requirements. This places additional strain on information management systems and will itself drive further investment into digital technologies.