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Pending Anti-Counterfeiting Legislation Makes Investment in Serialization Technology Imperative

By editor

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The European Parliament and Council are in the process of developing legislative amendments to the Directive 2001/83/EC regarding preventing the entry into the legal supply chain of medicinal products that are falsified in relation to their identity, history, or source. The new legislation, expected to be completed before the end of 2010, strongly emphasizes patient safety.

Thus, the proposed amendments affect all areas within the supply chain—from brokers and distributors to Internet pharmacy. The amendments include securing the individual dispensed packs given to the patient and make safety features that permit the identification, authentication, and traceability of medicines mandatory for prescription medicines. The only technology that supports all three of these initiatives—identification, authentication, and traceability—is serialization.

Once the European Commission passes the legislation, all 27 European member states must implement local legislation within 24 months. Therefore, it is imperative that pharmaceutical manufacturers begin implementing serialization solutions. These solutions must ensure accuracy of serialization data and support serialization at line speeds required to maintain packaging line throughput.

IDENTIFICATION, AUTHENTICATION, AND TRACEABILITY REQUIRE MORE THAN ITEM-LEVEL IDENTIFIERS
Item-level serialized product tracking solutions that assign, encode and record unique identification numbers support serialization initiatives such as authentication and traceability. Authentication is the ability to verify that a drug product genuinely came from the manufacturer or other legalized source within the supply chain. To authenticate a product, the pharmacy reads its serialization code. This code, when linked to a database, can identify an individual pack and determine that it has not been copied, is in date, has not been recalled, and is legally available for sale.

In addition to authentication, serialization coding enables traceability within the supply chain. Traceability allows authorized individuals to verify samples of packs to confirm their authenticity before they are distributed as well as locate and remove the packs from the supply chain if issues are detected. The initiative also helps identify where in the supply chain a counterfeit drug entered. Both authentication and traceability initiatives place sufficient barriers across the supply chain, making it significantly more difficult for counterfeit drugs to enter the chain and reach patients.

Authentication and traceability require a very high quality of serialization data to ensure that every item can be identified before dispensing it to a patient. Therefore, aside from simply placing a unique number on a package, serialization is also a technology that encompasses the following three imperatives:

- Knowing which numbers have been assigned and placed on which products and which batches of products.
- Knowing that the serialized products are in the supply chain or have been consumed.
- Updating the status of specific serialization numbers in the case or recall, illegal importation, or theft.

In order to achieve these three imperatives, companies need excellent quality control procedures that ensure a high quality of data; otherwise, errors will make authentication and traceability impossible. When applying unique serialization coding, the primary errors that are at risk of occurring are:

- Missing information.
- Overlapping ranges of serialization numbers.
- Overlapping ranges of serialization numbers with a range of numbers supplied by another pharmaceutical manufacturer.

Ensuring that the integrity of the data is maintained through its packaging process includes:

- Controlling what numbers are issued to a particular packaging line for a particular process.
- Ensuring the numbers are secure from counterfeiters by strict staff policies.
- Assigning numbers randomly rather than sequentially.
- Accurately accounting for numbers that may have been assigned to packages rejected during packaging both on and off the line.
- Associating serial numbers to the correct lot/batch information.
- Delivering serialization information efficiently to IT systems so they can be managed on an enterprise basis

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and made available for authentication and reporting purposes.

Aligning serialization data with distribution data at the enterprise level is dependant on a serialization solution's ability to enable bi-directional communication between the IT environment and the packaging environment.

Some manufacturers have begun employing a serialization solution that acts as a gateway between enterprise IT systems and packaging line operations. The solution connects with the manufacturer's enterprise repository of serial number data and provides serial number data to the packaging line when it is needed.

At the line level, the solution assigns and verifies unique identification numbers at the item level, tracks items through the packaging process, and if required can establish relevant parent-child relationships between item, case, and pallet. The solution then collects precise item level data from the entire on-line and off-line packaging operation, ensuring the integrity of serialization data before it is delivered back to the enterprise IT systems. Regardless of the speed or availability of enterprise servers, the packaging operation can continue running at maximum speed throughout. This bi-directional capability can become critical even for successful authentication models.

As an example, a manufacturer produces a batch of 10,000 units. Each unit has a unique identifier. The units are packaged into cases of 50 units each for a total of 2000 placed into finished goods inventory. The manufacturer ships 1000 cases to various distribution channels. While in transit, a shipment of 100 cases is stolen.

What information should be available in an authentication database? In addition to containing information about the unique items within the 1000 cases shipped into the supply chain, the authentication database must also be made aware of the unique serialization identifiers of each of the items that were stolen. This ensures that if the stolen items appear in the supply chain, or at the point of dispensing, the authentication would immediately identify these and notify the authorized person.

TAPPING A PES INFRASTRUCTURE FOR AUTHENTICATION AND BEYOND

To ensure that bi-directional communication can occur between IT and packaging when executing serialization, manufacturers need a Packaging Execution System (PES) infrastructure. A PES integrates all packaging line information systems, including vision inspection, line management, and serialization. By managing data between the packaging line and the enterprise, a PES architecture protects data integrity at the enterprise level while ensuring packaging line throughput. Therefore manufacturers achieve serialization while maintaining operational efficiency.

CALL TO ACTION

European requirements for authentication and traceability are fast approaching. To prepare for these mandates, manufacturers need solutions that can quickly and cost-effectively meet both current and future demands. Therefore, they should consider solutions that meet the following criteria:

Productized. As packaged software, a productized serialization solution is ready to be quickly installed when it is bought, thereby increasing efficiency and speed of line set-up. In addition to speedy installation, productized solutions are replicable, making each packaging line consistent. As more countries implement serialization requirements, manufacturers benefit from investing in a serialization solution that is quickly installed and replicable line-to-line or plant-to-plant. This repeatability reduces design, deployment, maintenance, and associated training costs. Moreover, since it does not require new code to be written, productized software is easily upgraded.

Configurable without requiring customization. Configurable serialization software is designed with elements that can be assembled and realigned to quickly accommodate changing demands without requiring code rewrites. This eases handling multiple code schemas to comply with various regulations, enables in-house personnel to easily maintain the solution, and speeds implementation.

Configurable solutions easily plug into any packaging line environment and support a wide variety of packaging line functions without requiring code rewrites or line revalidations. Thus, by investing in configurable serialization software, manufacturers employ an adaptable and flexible solution that addresses current needs and that can also meet changing demands as more complex regulatory requirements surface.

Expandable. An expandable serialization solution easily grows to meet new requirements. Expandable serialization software is modular because it allows manufacturers to increase capabilities as they need it. This allows companies to embrace new capabilities by leveraging existing investments in infrastructure rather than making large, expensive changes to the technology.

Expandable solutions are also scalable, enabling the same solution to manage small or large throughput. Scalability also allows manufacturers to move quickly from pilots to full-scale implementation.

The only technology that supports all three emerging anti-counterfeiting initiatives—identification, authentication and traceability—is serialization. Employing these initiatives on the packaging line and through the supply chain to the pharmacy level requires a very high quality of serialized data.

Therefore, manufacturers need to invest in serialization solutions that maintain the integrity of data throughout the packaging process.

By implementing productized, configurable and expandable serialization solutions that leverage a PES infrastructure, manufacturers can protect data integrity while also quickly and cost-effectively meeting new demands and maintaining operational efficiency.

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