Position Statement: Benefits and Complexity of Common Serialization Models

Introduction

RxGPS supports the adoption and implementation of effective serialization requirements as one tool to secure the legitimate supply chain. We also understand that the adoption and implementation of an interoperable solution for serialization and traceability is a process that requires significant upfront investments given the complexity of the pharmaceutical distribution chain. Therefore, as discussed in our August 2016 Position Statement on Implementation, we believe that a phased approach that starts simple, achieves benefits, and considers additional functionalities over time helps both industry and regulators develop effective systems and processes to realize the benefits of serialization.

Specifically, we recommend that countries implementing a serialization system begin with point-of-dispense verification before considering full traceability system.[1]

1. Serialization without point-of-dispense verification does little to advance patient safety.

The primary purpose of securing the legitimate supply chain is to ensure that patients receive safe, authentic, and effective medications. A point-of-dispense verification model provides for authentication of a product before that product is dispensed, which is essential to realizing the benefits of serialization. This means that adulterated or counterfeit product is significantly more likely to be identified and removed from the supply chain before it is delivered to a patient, after which point it is impossible to ensure that a damaged or ineffective product is not used by a patient. This is a significant improvement to patient safety and supply chain security.

A point-of-dispense verification system is efficient and effective. At the most basic level, a verification model has only two components. First, manufactures must affix a serial number to a product package, commission this event, and maintain a repository of the serial numbers they commission. This is done by manufacturers as part of the serialization process, and those databases established by each manufacturer can be used for verification. Second, a mechanism by which data can be shared in order for dispensers to verify serial numbers against those manufacturer databases is needed. As a result, a verification model limits the number of stakeholders that must integrate their data systems. Other supply chain partners (*i.e.*, wholesale distributors, 3PLs) are not required to scan, upload, transmit, or otherwise connect to a data communication pathway.

[1] In a **verification model**, product serial numbers are authenticated by the end-user (*i.e.*, pharmacy) prior to the dispensing of the product.

In a **full traceability model** each member of the supply chain must capture and maintain information about (1) from whom it bought the product, and (2) the person to whom it sold the product.

While the complexity of serialization and verification should not be underestimated, it is the least complex of the various approaches that can be taken.

2. A traceability system provides modest additional security value but is significantly more complex.

A traceability (*i.e.*, recreating the path of a product from the current entity/owner back to the manufacturer) or track and trace (*i.e.*, identifying the current owner of the product and the pathway the product has taken to get to its current location) provides some added level of security to the supply chain beyond verification. For example, in the event that a counterfeit product enters the supply chain, a verification model is likely to identify that product as counterfeit and prevent it from being dispensed to a patient. The addition of traceability or track and trace will also facilitate an investigation of where that product penetrated the legitimate supply chain. This is a modest benefit to patient safety and supply chain security, but it comes at a significant cost.

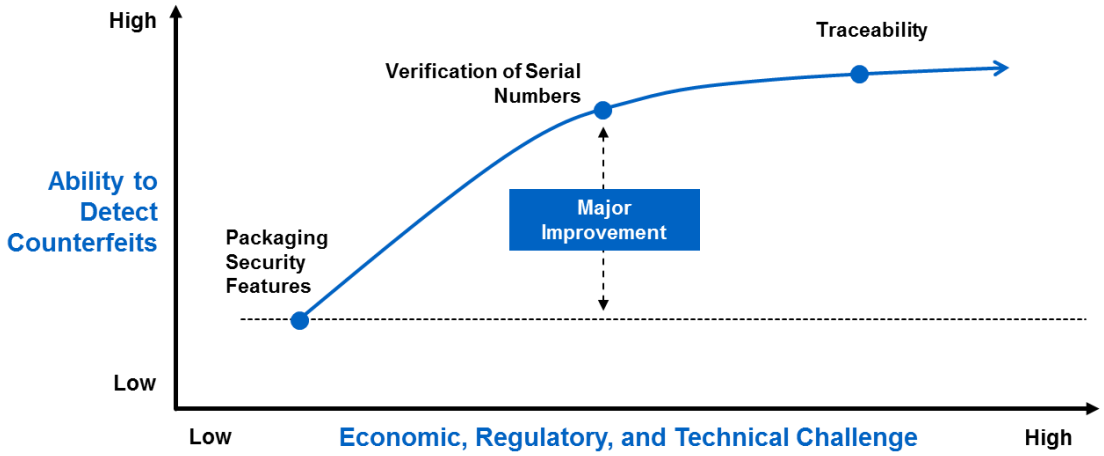
A traceability or track and trace system is significantly more complex to implement than verification. First, traceability or track and trace requires the capture and maintenance of significantly more data. As noted above, a verification model requires only the manufacturer to capture and maintain information about each individual serialized unit—an activity a manufacturer must already do as part of any serialization process. A traceability or track and trace system, however, requires that *every* company that owns a product (manufacturers, wholesalers, and dispensers) capture and maintain[2] data about each serialized unit. This is a significant operational burden to scan and capture the data, and a significant information technology burden to maintain the related data repository.

Second, a traceability or track and trace model significantly increases the number and complexity of data connections that are needed. As noted above, a verification model requires a communication mechanism by which a dispenser may query against manufacturer data sets. This includes the appropriate functionality, specifically for dispensers receiving product from multiple manufacturers, to ensure that verification requests are routed to the appropriate manufacturer's database. Traceability or track and trace, however, requires that every member of the supply chain connect to some type of data exchange, not just manufacturers and dispensers. This adds to an already complex system of communication by drastically increasing the number and type of connections needed.

The drastic increase in data capture obligations, data volumes, and complexity of data connections needed for a traceability or track and trace system means that the minimal benefit of such system is realized only at significant cost. Implementation is significantly more complex, which requires more testing, results in more implementation challenges, and increases the likelihood of failure. All of this adds to the time needed, by all companies that take ownership of a product within the supply chain, to for implementation, and delays realization of the benefits

[2] In the traceability context, data "capture" refers both to the *scanning* of a physical product serial number, as well as the *exchange* of data, often via Electronic Data Interchange (EDI). These data must then be recorded, or "maintained," for future query, such as under a product investigation.

that can be achieved through serialization. It also adds to the regulatory complexity by increasing the number of parties and systems that must be established, maintained, regulated, and enforced.



3. A phased approach achieves significant improvement with the least complexity.

Adoption and implementation of any traceability or track and trace system should be phased in over time, starting simple and achieving benefits before considering additional functionalities. The pharmaceutical supply chain is a complex, interconnected network of manufacturers, wholesale distributors, pharmacies, and other service providers, and a supply chain security system must account for a variety of elements and environments across this diverse array of stakeholders. Phased implementation leverages existing infrastructure and shared learnings across the supply chain to promote efficiencies as industry moves from one implementation phase to the next. A phased approach also allows for assessment of supply chain security at each phase and prior to implementation of a costly and complex traceability system.

The initial phase of traceability or track and trace should be limited to serialization—the process by which manufacturers and repackagers affix and encode serial numbers. The second phase of implementation should be verification of the serial numbers encoded in the barcodes. As described above, this functionality is essential to securing the supply chain and protecting patients, yet is much less complex than full scale traceability or track and trace. Only after the safety and security benefits of verification are realized should traceability or track and trace requirements be considered. Prior implementation of serialization and verification facilitates the successful implementation of traceability or track and trace requirements, yet, as discussed above, the additional security benefits of this more complex system are modest and should therefore be considered in light of the improvements in supply chain security already realized through verification.

Conclusion

Given the complexity of additional traceability requirements and the minimal added benefit that they impart on patient safety and supply chain security, full traceability should not be considered

until the benefit of authentication and decommissioning of serial numbers has been realized. If traceability is ultimately desired, a country must establish an implementation timeline that provides sufficient time to develop, implement, and test the functionalities discussed above.