# Position Statement: Principles for Using Serialization

## Introduction

Serialization is the process by which products are marked with a unique identifier—typically a unique number or alphanumeric code—and is being leveraged around the world to enhance the security of the legitimate pharmaceutical supply chain. The unique serial number, along with other related information, is typically encoded in a barcode that can be read electronically. That serialized data is then utilized in some manner to enhance supply chain security—a process referred to as traceability[1]. While serialization alone (*i.e.*, simply applying a unique identifier) provides virtually no benefit to the supply chain, RxGPS supports the adoption and implementation of effective serialization requirements, and the use of the associated data, as a part of a comprehensive strategy to enhance pharmaceutical supply chain security in a given market.

As pharmaceutical serialization gains momentum globally, regulators and other stakeholders around the world are assessing potential uses for pharmaceutical serialization and serialized data that go beyond supply chain security (*e.g.*, monitoring availability, shortage, and stock; reimbursement and pricing logistics; identification of trading partners; brand, quality, and image processes; etc.). This Position Statement provides RxGPS's recommendations for assessing the challenges and benefits associated with serialization uses beyond supply chain security (referred to in this document as "additional functionalities").

In particular, we seek to distinguish those goals or additional functionalities that necessitate serialization, from those that may only require the identification of general products (*i.e.*, without distinguishing individual units of that general product). Further, some of these proposed or contemplated uses of serialization can be accomplished through other means, or would significantly complicate or impede supply chain security efforts and should therefore not be pursued. It is important to understand how serialization data can, and should, be leveraged across the supply chain.

## Principles for Utilizing Pharmaceutical Serialization beyond Supply Chain Security

This statement outlines several recommendations and principles for countries implementing a serialization system with an interest beyond securing the legitimate supply chain.

### 1. Additional functionalities should not undermine the security and/or reliability of the legitimate supply chain.

First and foremost, serialization requirements should be limited to those requirements necessary to enhance and promote pharmaceutical supply chain security and increase patient safety and should provide flexibility that allows for the addition of voluntary complementary

[1] For more information, see RxGPS' Serialization Primer at http://www.rxgpsalliance.org/wp-content/uploads/2016/03/Serialization-Primer-032916.pdf.

functionalities. Therefore, any additional functionalities of serialization that would somehow impede the ability to secure the legitimate supply chain should not be considered.

In practice, some additional functionalities and/or conflicting requirements have led to significant logistical challenges, such as the placement of multiple barcodes on a single product. Further, some additional functionalities of serialization would require product barcodes to be expanded beyond the globally standard four data elements (see RxGPS' Position Statement on Unit Identifier's here: http://www.rxgpsalliance.org/wp-content/uploads/2016/07/Position-Statement-Unit-Identifier-072816.pdf). The addition of data elements results in scanning confusion, threatens data accuracy, and therefore has the potential to delay product transport and sale. In several markets we have seen additional changes and/or requirements to serialization processes actually increase the threat to security rather than minimize them. For example, the proposed use of aggregated data files at hospitals within the EU would increase security risk, threaten privacy of proprietary data, and unnecessarily duplicate serial numbers outside of the NMVS because the EMVO system cannot accommodate aggregation information, and thus would require data files to be sent to hospitals outside of the secure system for data transmission. Therefore, markets considering additional uses of serialization data should carefully assess the processes and requirements necessary to achieve these goals to ensure that they do not introduce additional risk to the system.

2. **Any additional functionalities of serialization should have clearly identified goals and purposes.**

It is necessary to understand the goal of additional functionalities in order to identify the best way to achieve that goal. We believe the most appropriate use of serialization data is to secure the legitimate supply chain, as noted above. However, additional serialization uses that go beyond securing the legitimate supply chain may be appropriate and valid and the most efficient set of tools should be used to achieve the goals and purposes of these additional functionalities. Thus, clearly identifying the goals and purposes of additional functionalities of serialization is important to ensure the right tools are used to achieve the goal.

3. **Additional functionalities of serialization should support, not impede global trade.**

Serialization is a tool that, if leveraged appropriately, can have great benefits to supply chain security and patient safety. Because product often moves between and among multiple markets, serialization requirements should be consistent and align with global data standards. Harmonization to global standards streamlines processes and reduces unnecessary implementation costs for manufacturers, which facilitates international trade in a global market. Alternatively, inconsistent global requirements have been shown to cause confusion and impede the ability to get patients necessary medications. Therefore, any additional functionalities of serialization beyond securing the supply chain should also align with and support global data standards and avoid any potential barriers to cross-border trade.

4. **Regulators should allow individual companies to develop uses for commercial business practices rather than mandating them.**

Serialization presents significant opportunity for the development of valuable additional services, such as inventory management and improved dispensing accuracy. Companies have their own unique operations and processes in place and know what additional uses of serialization would be complementary and best suited for them. Thus, a one-size-fits all policy or mandating commercial business practices could slow operations and potentially undermine the reliability of the legitimate supply chain. Therefore, companies should have the flexibility to implement uses of serialization for their own benefit, and legislative/regulatory requirements should not prevent or impede the development of such additional practices.

5. **Any additional necessary data required for an additional functionality of serialization should be transmitted through back-end processes such as master data and should not require modification of the encoded or human readable product identifier.**

Standardized identifiers, specifically the structure and elements contained in the unit identifier, streamlines processes and reduces unnecessary implementation costs for manufacturers.[2] Additional functionalities of serialization may require additional product data to be exchanged between supply chain trading partners. It is imperative that any additional data be communicated in a way that does not interfere with the interoperable exchange of data necessary for product verification and traceability. Thus, any additional product data necessary to achieve desired functionalities should not modify or change the encoded or human readable product identifier. For example, the addition of data elements, such as national identifier codes, can increase the size of the 2D datamatrix past practical feasibility. The addition of multiple datamatrices would result in scanning confusion, threaten data accuracy, and therefore potentially delay product transport and sale. Rather, this data should be linked to encoded product information within master data systems and utilize existing means of back-end communication. In addition, additional functionalities of serialization should not significantly expand the amount of, or access to, serialization data. Significant amounts of additional data would necessitate larger and more complex databases and system connections, and opening access to data outside of the supply chain (*e.g.,* to patients) could undermine supply chain security and patient safety.

6. **Voluntary complementary functionalities should be phased in following the implementation of those requirements necessary to secure the supply chain and/or increase patient safety.**

Any additional functionalities of serialization should only be added after supply chain security systems are fully and successfully implemented. If limited initially to those requirements necessary to establish sufficient supply chain security (e.g., addressing counterfeiting or diversion), serialization then presents significant opportunity for the development of valuable additional services (e.g., inventory management, improved dispensing accuracy). However, because additional functionalities often increase the complexity and time for implementation, they should only be pursued once a baseline level of supply chain security and patient safety has been established.

[2] For more information, see RxGPS' Position Statement on Unit Identifiers at http://www.rxgpsalliance.org/wp-content/uploads/2016/07/Position-Statement-Unit-Identifier-072816.pdf.

**7. Serialization and reporting should be tied to the smallest unit intended to be sold to a dispenser.**

Industry consensus is that products should not be serialized at the primary level for cost, security, and logistical reasons. Thus, any additional functionalities of serialization should not require or force primary level serialization. Many manufacturers estimate that the addition of primary package serialization (when the secondary package is the serialized salable unit) would cost up to $1 million per packaging line, and most manufacturers use many lines to package products. In some instances, serialization of the primary package may not even be technically feasible because of the size or material of the product. Therefore, the unit identifier should be affixed to the smallest salable unit (as determined by a product manufacturer) and that serialization of the primary package should not be required.

**8. Utilize serialization for in-country product.**

Serialization requirements should be tailored to the identified goals and purposes of a country's mandate, and therefore should only be set by the country where the product will be dispensed (see RxGPS principles at http://www.rxgpsalliance.org/wp-content/uploads/2016/12/RxGPS-Principles-One-Pager-122216.pdf). Further, serialization, data reporting, and traceability requirements should be limited to product dispensed in the market implementing such requirements. Serialization requirements applicable to exported product have significant potential to create confusion in, or conflict with, the requirements of other markets, and also to create security risks. For example, the unnecessary use of serialization data in a country other than the country of dispensation (*e.g.*, an exporting country where product is manufactured) makes the serialization data susceptible to fraudulent use in the country of distribution. As a result, the requirements of one country jeopardize patient safety in another country. Utilizing serialization for in-country product avoids duplicate labeling and logistical concerns. For example, such duplicate labeling (*i.e.*, applying a domestic serial number and a foreign serial number) can create logistical problems by interfering with the ability to scan products. Therefore, serialization should be used solely for products within country, and only the requirements of the country where the product will be dispensed should apply.

**9. Minimize the use of serialized data for purposes that could be accomplished using lot and/or GTIN-level data.**

A GTIN (Global Trade Item Number) is a globally unique number used to identify trade items and/or products. Once a GTIN is assigned to a product, this information is uploaded to a live database where all of a company's entities and trading partners should be able to recognize the GTIN. A serial number is a code assigned to an individual item for its lifetime. To identify a unique individual item, serial numbers must be augmented with encoded product identifiers. These encoded identifiers must be affixed to all products as they enter the supply chain. Though a straightforward concept, the process of serialization is much more complex than setting up packing lines with bar code printers and scanners. RxGPS supports valid uses of serialization and encourages using lot level and/or GTIN-level data rather than uniquely identifying packages through serialization. Using lot level and/or GTIN-level data is simpler and time saving compared to using unit-level data. Lot level and/or GTIN-level data allows for the use of existing

systems and processes that companies have in place today for business purposes, requires the use of less data, and therefore there is less room for error. However, some valid uses of serialization may be necessary at the unit level and RxGPS may support them as long as they are phased in after requirements for supply chain security have been met.

*Analysis of Additional Functionalities of Serialization*

Serialization of pharmaceuticals can have various applications in the marketplace. However, there are also some supply chain functionalities for which serialization may not be the appropriate solution (e.g., the implementation of serialization in order to identify trading partners that operate in the market is unnecessary; such identification is better achieved through licensure). The best and most appropriate use of serialization is to secure the legitimate supply chain. However, RxGPS has identified numerous uses beyond securing the supply chain that are valid and can be accomplished through lot level traceability rather than unit level data. Some valid uses of serialization do utilize unit level data and RxGPS may support them as long as they are appropriately phased in after requirements for the safety and security of the supply chain have been established. We have identified how stakeholders can leverage serialization data for various uses at the lot or unit level in the chart below.

| **Uses of Serialization** | **Accomplished at the Lot Level** | **Accomplished at the Unit Level** |
|---|---|---|
| Monitoring availability/ shortage and stock/ volumes | X | |
| Tracing current product ownership | | X |
| Loss prevention by expiration date | X | |
| Supply chain efficiencies | X | |
| Reimbursement and pricing logistics | X | |
| Identifying and preventing reimbursement fraud | | X |
| Identification of trading partners | X | |
| Production and total imports | X | |
| Brand, quality, and image processes | | X |
| Advanced analytics (*e.g.*, consumption patterns, geographical penetration, sale and marketing) | X | |
| Track regimen compliance | | X |

**Conclusion**

Serialization is a tool that, if leveraged appropriately, can have great benefits to supply chain security and patient safety. However, additional serialization uses that go beyond securing the legitimate supply chain may be appropriate, as long as the principles outlined above are followed. Particularly, there are numerous uses beyond securing the supply chain that are valid and necessitate serialized units of product, while others may only require tracing product at the lot level. Some uses significantly complicate or impede supply chain security goals and efforts and should therefore not be pursed.