Position Statement on Unit Identifier

Introduction

The use of global standards is critical to the successful implementation of a serialization and traceability system in the global pharmaceutical market. Serialization is the process of uniquely identifying individual packages for purposes of tracing and securing the supply chain. Use of global standards in serialization allows supply chain participants to develop systems and processes that are interoperable across markets. Global standards also facilitate the trade of product across borders, thereby stimulating economic trade, increasing both efficiency and implementation, and promoting patient access.

This statement outlines the serialization and unit identifier specifications that RxGPS recommends be adopted by any country implementing serialization.

Unit Identifier[1]

Product should be serialized and identified by affixing a unit identifier to each saleable unit in accordance with GS1 Global Standards. Specifically, it is the position of RxGPS that the unit identifier should include the following four data elements without additions or modifications.

- *14-digit GTIN.* Use of a GTIN-14 is the preferred method of identification. A GTIN-14 is globally unique, meaning the use of national numbers is both unnecessary and burdensome. RxGPS does not support the inclusion of national numbers on the unit identifier because they do not provide any additional security beyond the GTIN-14 and their inclusion creates significant challenges for product package and sold to multiple markets. It is also important that packaging-level indicators in the GTIN-14 conform to GS1 Global standards.
- *Serial number.* Serial numbers should be 1 to 20 digits, variable with degree of randomness at the discretion of the manufacturer.
- *Expiration date.* A "YYMMDD" date format should be used.
- *Batch number.* The batch number should be a variable number up to 20-digits.

These four elements should be included in human readable form and should also be encoded in a DataMatrix. Specifically, the data elements should be encoded in a two-dimensional (2D) GS1 DataMatrix ECC200 code as shown below. Additional data elements are unnecessary in securing the supply chain, and the inclusion of additional elements significantly impedes harmonization across markets.

[1] We use the term "unit identifier" to refer, collectively, to the data elements and data matrix described in this section. Different markets characterize this collection of data elements in different ways (*e.g.*, "product identifier" in the U.S. and "unique identifier" in the E.U.)

GTIN: (01) 07046261398572
Expiry: (17) 130331
Batch / lot: (10) TEST5632
S/N: (21) 19067811811

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Packaging Level

The unit identifier should be affixed to each secondary package (sometimes also called a saleable unit), meaning the smallest unit that is intended by the manufacturer to be sold **to** a pharmacy or dispensing entity.[3] Product serialization at the primary level is costly and not harmonized with requirements in other markets around the globe. 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. Furthermore, serialization of the secondary package is the smallest level of serialization needed for an end point authentication traceability system. We believe that the unit identifier should be affixed to the secondary package and that serialization of the primary package[4] should not be required.

Harmonization and Shared Packs

To facilitate harmonization across markets, economies considering serialization should adopt global approaches because they promote efficiency, reliability, and effectiveness. (*See* Principle 7 of the RxGPS Principles for Using Serialization, available at: http://www.rxgpsalliance.org/principles/).

Harmonization of data standards is particularly important for markets where shared packs are used. The use of shared packs allows a manufacturer to utilize the same packaging for multiple markets. Per GS1 standards, manufacturers must print a single GS1 product identifier on a package; therefore, all countries where shared packs are leveraged would be required to accept the same GS1 product identifier. 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.

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[2] Image courtesy of GS1 Global. The use of application identifiers (the numbers included in the parentheticals in this graphic) should conform to the GS1 Global general specification.

[3] There are three levels of packaging that are generally addressed in serialization laws and regulations worldwide:

- The *primary package* is the level of packing that is in direct contact with the product (*e.g.*, blister card or vial).
- The *secondary package* is the smallest unit intended by the manufacturer to be sold to the dispenser/pharmacy. In some instances (*e.g.*, a bottle of tablets without an outer carton), the primary package and the secondary package can be the same.
- The *tertiary package* is the logistical unit that is shipped, the shipper, carton, case, pallet, or tote that contains one or more primary/secondary levels of packaging.

[4] Except when the primary package is also the secondary package (*e.g.*, a bottle of tablets without an outer carton).

Harmonization of serialization regulations across countries that use shared packs results in decreased product costs and increased efficiency at the packaging site. Shared packs allow use of a single distribution site to service multiple markets, which decreases distribution expense and increases efficiency. Restrictions on shared packs could impact the availability of products in small markets.

Even for countries that do not use shared packs, prescription drugs are produced by a global supply chain, where individual production and packaging plants produce products to be sold in several markets. Uniformity of serialization markings and methods leverages work being done for other markets and helps for an orderly implementation of requirements and creation of applications for leveraging that data.

Conclusion

Serialization is a tool that, if leveraged appropriately, can have great benefits to supply chain security and patient safety. Harmonization to global standards, specifically the structure and elements contained in the unit identifier, streamlines processes and reduces unnecessary implementation costs for manufacturers, which facilitates international trade in a global market. RxGPS believes that the success of serialization and traceability at the global level is dependent on harmonization to global standards.