

Identifier Hierarchies and Encoding Position Statement

Introduction

Pharmaceuticals are identified through a number of standardized identifiers at varying levels to enable addressing different needs in global markets. Each type of identifier can serve distinct purposes. Further, any of those identifiers can be encoded into different types of barcodes or data carriers to support logistical efficiency. As noted in our RxGPS document, “[Principles for Using Serialization](#),” it is necessary to understand each country’s goal in order to identify the best way to achieve that goal, as different identifiers can support different goals.

This document provides an overview of the hierarchy of common identifiers to help regulators understand their role in meeting various policy objectives.

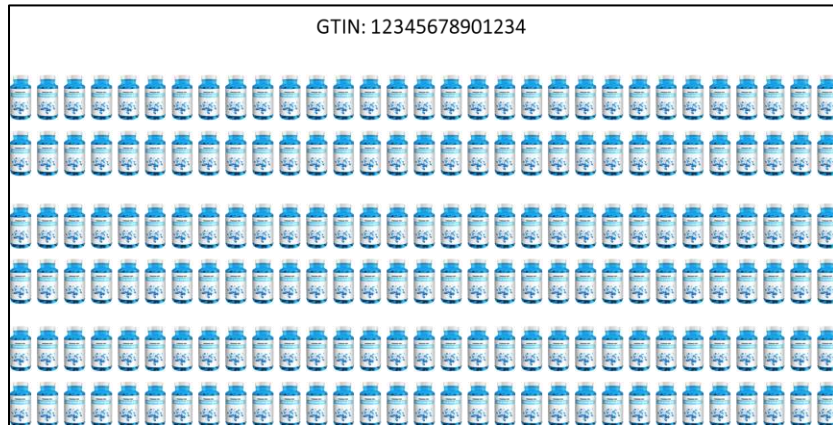
Definition of Identifier Hierarchies

Pharmaceuticals can be identified at multiple levels, including the following key levels.

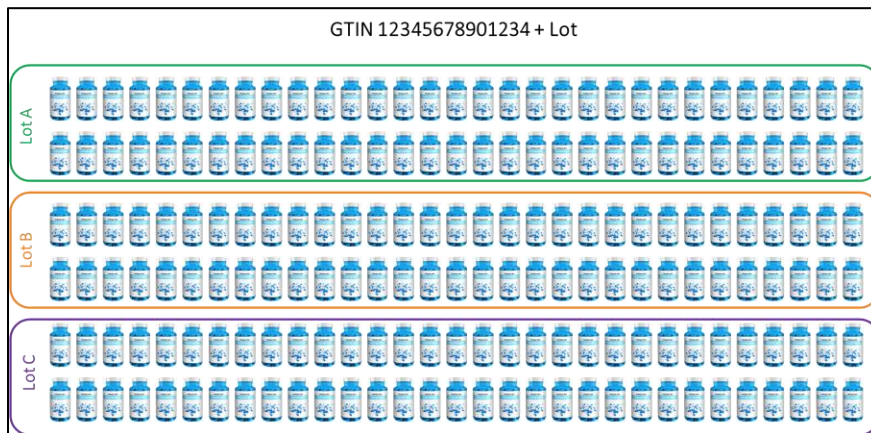
1. **Product Level:** In most markets, an individual product is identified by a unique number. This is generally the least granular level at which pharmaceuticals are identified. For example, 10mg tablets of Atorvastatin Calcium in a 100-tablet package, packaged by a particular manufacturer, is typically identified by a government-issued **national code**. In GS1 standards, this product is typically identified by a **global trade item number (GTIN)** to serve a similar purpose.
2. **Lot/Batch:** An individual production batch or lot is the next level of granularity that can be identified. The combination of a national code/GTIN and a lot/batch number with expiry information identifies a product and correlates it to a unique individual production batch.
3. **Saleable Units:** For many drugs, a batch or lot includes thousands or tens of thousands of individual packages or saleable units. Serialization is used in some markets to uniquely identify and distinguish individual packages of product within a given batch/lot. Serialization is typically applied to the smallest saleable unit that can be sold to a pharmacy, which can be the primary (e.g., a bottle containing tablets) or secondary package (e.g., a carton containing a vial). See RxGPS’ [Packaging Levels Position Statement](#).
4. **Unit Dose:** A saleable unit *may* include multiple unit doses. For example, a pack of vaccine vials sold to a clinic may include ten individual vials (unit doses) of the vaccine.

Each of the product levels above represents the ability to distinguish increasingly granular units of product. This granularity is represented visually in the following.

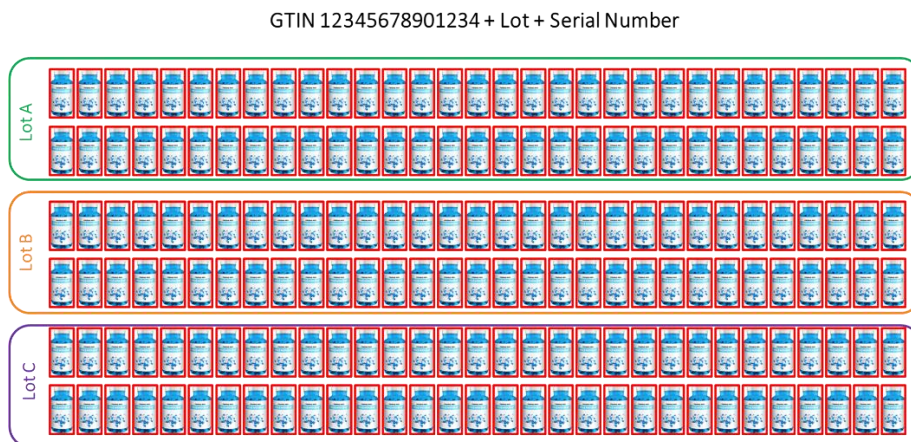
The national code and/or GTIN represents a general product and package type and does not distinguish between lots of individual units, as shown below.



The combination of a GTIN and Batch/Lot number identifies a subset of the product from a common production batch with a common expiration date, as shown by the three distinct lots of the same product below.



The combination of a GTIN, Batch/Lot number, and serial number affixed to each saleable unit allows each package, shown in red below, within a batch/lot to be uniquely identified and distinguished.



Each identified level enables different levels of visibility, which in turn allows different questions to be asked and use cases to be addressed. However, the identification and management of data associated with each level is increasingly complex, costly, and resource intensive as further granularity is established. Therefore, it is important to understand which level of granularity is needed to support the regulatory policy goals of each country.

For example, the monitoring of product inventories to identify shortage risks can be achieved by identifying product at a lot/batch level. In that instance, the relevant data point is that inventory includes 100 bottles of the product with a common expiration date; it does not matter *which* specific 100 bottles from that batch/lot are in inventory, and serialization of saleable units is therefore unnecessary.

On the other hand, if a regulator seeks to verify the authenticity of a specific drug package, saleable unit serialization is necessary because the authentic package must be uniquely distinguished from other packages in the same lot/batch that may or may not be unique. Authenticating a package at the lot/batch level is a meaningless endeavor: for example, if you were to ask a manufacturer to authenticate a specific saleable unit that may be counterfeit, based only on lot/batch, the manufacturer would effectively say, “I produced 20,000 packages in that lot; I have no way of knowing whether the one package you are asking about is authentic; it could be any one of those 20,000 packages.” However, when asked to authenticate the package based on a unique serial number, the manufacturer can effectively say, “I did/did not make a package with that specific serial number within a certain batch because I only made one single package with the given serial number.”

The table below summarizes the various product levels, and why each might be utilized.

	Use Cases/Questions Answered	Global Landscape	Complexity/Cost
GTIN/ National Code	<p>Product Identification: e.g., What product is being imported or domestically manufactured? Is the correct product being dispensed?</p> <p>Product Volumes: e.g., How many units are in inventory? How many units are being imported?</p> <p>Product Location: e.g., Which national stockpiles include the product at what volumes?</p>	Most, if not all, countries require identification of product with a national code. The national code is commonly encoded in a barcode to facilitate efficient and accurate capture.	Lowest cost, lowest complexity. Identified through package artwork that is consistent across all batches. Highest level of accuracy in data management.
Lot/Batch Number	<p>Commonly Produced Products: e.g., Which packages are compromised due to a manufacturing quality issue?</p> <p>Volumes with Common Expiry: e.g., How many units are in</p>	Most, if not all, countries require the assignment of lot/batch numbers. It is somewhat common for the lot/batch number to be encoded into a barcode (typically a 2D data matrix due to length).	Relatively low cost, low complexity. Must be dynamically assigned and printed for each batch. Very high levels of accuracy in data management.

	inventory with more than 6 months of shelf-life?		
Saleable Unit Serialization	Counterfeiting and Diversion: e.g., Is this particular package authentic or counterfeit? Payment Integrity: e.g., Has the government already paid for this particular package?	Approximately 70 markets around the world require or plan to require the serialization of individual saleable units.	Significantly more complex and more costly than identifying product at the lot/batch level. Significantly more risk of errors and discrepancies in data management compared to lot/batch.
Serialization and Aggregation	Saleable Units Associated with Logistical Units: e.g., Which saleable units are in this case or pallet?	Approximately half of the markets requiring saleable unit serialization have adopted data models that necessitate aggregation.	Necessary to support tracking or tracing of product distributed in logistical units or in specific transactions, but significantly more expensive and complex than saleable unit serialization and verification. Significantly more risk of errors and discrepancies in data management compared to serialization and verification. See RxGPS' Serialization Models Position Statement
Unit Dose Serialization	Dose Counterfeiting and Diversion: e.g., Is this particular vial dose authentic? Dose Payment Integrity: e.g., Has the government already paid for this particular dose?	No countries have adopted unit dose serialization due to the immense cost and complexity.	Serialization of each dose would be tremendously complex and costly. Adds another layer of aggregation which dramatically increases data volumes, cost, complexity, and errors. See RxGPS' Packaging Levels Position Statement

Conclusion

Pharmaceuticals can be identified through various product levels which enable different levels of visibility. However, each level is increasingly complex and costly. Therefore, it is important to understand which level of identification best supports the regulatory policy goals of each country.