# Packaging Levels Position Statement

## Introduction

Over the past several years global markets have been exploring serialization and traceability of pharmaceutical products in order to help secure the legitimate pharmaceutical supply chain (among various other purposes described in RxGPS' Position Statement on Potential Uses of Serialization: http://www.rxgpsalliance.org/wp-content/uploads/2019/03/Principles-for-Using-Serialization_Position-Statement_032119-1.pdf). Key to the design of a system for serialization and traceability are the regulatory parameters around which units are to be serialized, verified, and traced.[1]

Frequently, global regulators utilize the terms "primary," "secondary," and "tertiary" to distinguish between common packaging levels and to dictate which packaging level must bear a unique identifier for purposes of verification and/or tracing. [2] However, this terminology (ISO Terminology 21067-1:2016) is not aligned with the standard units of trade across the pharmaceutical industry. A lack of consistent terminology within and across markets has led to significant confusion and has resulted in situations where product barcodes are misplaced, repetitive, etc. This type of confusion impedes compliance with any market's regulations and, rather than promoting supply chain security, can actually introduce additional risks as well as potential product delays, which can be harmful to patients.

This position statement aims to provide clarity around the packaging level terminology that is being utilized in the industry, and provide recommendations around how best to identify on which packaging levels/units a serial number should be applied.

### Examples of Confusing Regulatory Language

Global manufacturers serialize at the level of the salable unit. Used here, and frequently in the industry, **the salable unit means the smallest unit of a finished product intended by the manufacturer for sale to the dispenser**.[3] Given that the definition of the salable unit is at the discretion of the manufacturer, the salable unit is not always a "secondary package" or a

[1] For analysis on the challenges associated with serialization of the primary package, see: https://www.gs1.org/docs/healthcare/position-papers/Discussion-paper-on-medicines-identification-requirements-on-primary-level-packaging-using-GS1-standards-final.pdf

[2] The 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 packaging containing one or more primary packages. 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.

[3] Serialization and the application of the unique identifier should apply to finished product (i.e., not bulk) that is ready for distribution.

"primary package." This is why the regulatory language used in many markets looking to require serialization can be problematic. Examples include:

- A requirement to serialize the secondary package except if the secondary package is the primary package[4] – this type of language can lead to confusion because it conflates the definitions of two distinct packaging levels. More appropriate terminology would create mutually exclusive packaging levels.
- A requirement to serialize the primary package except under certain circumstances[5] – this language, while specific, does not allow for changes in packaging protocols or industry technology. Having a defined list of packaging scenarios included in a regulation would require re-write and re-ratification of a new regulation if a new packaging scenario were introduced to the market.
- A requirement to place an SSCC on the tertiary package[6] – many packaging configurations have multiple levels of packaging above the salable unit. Further, trading partners make individual determinations about which level of package to ship to a downstream entity. This type of language results in confusion around which higher level of packaging is to be considered the tertiary package.

**Commonly Used Packaging Configurations**

The chart below uses specific examples of packaging scenarios to align the "primary," "secondary," and "tertiary" packaging level terminology commonly used in regulatory language to the trade terminology more commonly used across the pharmaceutical supply chain. This chart is not meant to be an exhaustive list of packaging scenarios, but rather provides some illustrative examples that can be extrapolated to related packaging scenarios. The goal of the chart is to illustrate how utilizing trade terminology eliminates unnecessary confusion regarding the appropriate level of packaging on which to apply a serial number. For example the trade terminology of "salable unit" directly maps to the serialized salable unit for every packaging scenario.

The first column in the chart describes, in detail, a potential packaging scenario. The second column depicts the packaging hierarchy described in the scenario. Each level of packaging is then mapped in the third column to the commonly utilized (and often confusing) ISO terminology. The forth column recommends the appropriate trade terminology that should be used for each packaging level to help avoid confusion. Then, using the trade terminology, the chart demonstrates where serialization should occur across three (potential) serialization levels:

1. The serialized salable unit
2. A higher level serialized package (sGTIN) for aggregation purposes
3. The highest level package labeled with an SSCC

[4] For example, India Public Notice No. 52/2015-2020, "Implementation of the Track and Trace system for export of Pharmaceuticals and drug consignments.
[5] For example, Indonesia Regulation Number 33 Year 2018, "Implementation of 2D barcode in supervision of drugs and foods"
[6] For example, Pakistan S.R.O. (I)/2017, "Notification: Drugs (Labelling and Packing) Rules"

| Example Packaging Scenario | Packaging Hierarchy | ISO Terminology 21067-1:2016 | Trade Terminology | Serialized salable unit | Higher level serialized package (sGTIN) for aggregation purposes | Package labeled with SSCC |
|---|---|---|---|---|---|---|
| 24 60-count bottles of tablets are placed in a corrugated cardboard case. 72 cases are put on a pallet. | Pill bottle | Primary | Salable Unit | X | | |
| | Case | Secondary | Shipper \| Case | | Identify with sGTIN OR SSCC depending on market dynamics | |
| | Pallet | Tertiary | Logistical Unit | | | X |
| Four 60-count bottles of tablets are placed in a placed in a logistical inner pack (e.g., plastic wrap). Six such inner packs are placed into a corrugated cardboard case. 72 cases are put on a pallet. | Pill bottle | Primary | Salable Unit | X | | |
| | Inner pack | Secondary | Logistical Unit | | | |
| | Case | Tertiary | Shipper \| Case | | Identify with sGTIN OR SSCC depending on market dynamics | |
| | Pallet | Tertiary | Logistical Unit | | | X |
| One 60-count bottle of capsules is placed in a Regulator-approved and medically labeled carton. Four mono-cartons are placed in a logistical inner pack (e.g., plastic wrap). Six such inner packs are placed into a corrugated cardboard case. 72 cases are put on a pallet | Pill bottle | Primary | Primary pack | | | |
| | Mono-carton | Secondary | Salable Unit | X | | |
| | Inner pack | Tertiary | Logistical unit | | Identify with sGTIN OR SSCC depending on market dynamics | |
| | Case | Tertiary | Shipper \| Case | | Identify with sGTIN OR SSCC depending on market dynamics | |
| | Pallet | Tertiary | Logistical unit | | | X |
| 5 pre-filled syringes are placed in a Regulator-approved and medically labeled carton. Four cartons are placed in a logistical inner pack (e.g., plastic wrap). Six such inner packs are placed into a corrugated cardboard case. 72 cases are put on a pallet. | Pre-filled syringe | **Primary** | **Primary pack** | | | |
| | Carton | Secondary | Saleable unit | X | | |
| | Inner pack | Secondary | Logistical unit | | Identify with sGTIN OR SSCC depending on market dynamics | |
| | Case | Tertiary | Shipper \| Case | | Identify with sGTIN OR SSCC depending on market dynamics | |
| | Pallet | Tertiary | Logistical unit | | | X |
| 5 blister packs of 6 tablets are placed in a labeled carton. 30 cartons are placed in a logistical inner pack (e.g., plastic wrap). Six inner packs are placed into a corrugated cardboard case. 72 cases are put on a pallet. | Blister Pack | Primary | Primary pack | | | |
| | Carton | Secondary | Saleable unit | X | | |
| | Inner pack | Secondary | Logistical unit | | Identify with sGTIN OR SSCC depending on market dynamics | |
| | Case | Tertiary | Shipper \| Case | | Identify with sGTIN OR SSCC depending on market dynamics | |
| | Pallet | Tertiary | Logistical unit | | | X |
| 120 60-count bottles of tablets are placed in a mixed tote. | Pill bottle | Primary | Saleable unit | X | | |
| | Mixed tote/ carton | Tertiary | Logistical unit | | | X |

## Solutions to Confusing Regulatory Language

Demonstrated by the chart above, there are four key principles that, if utilized together in the creation of regulatory requirements for serialization, can provide clarity and consistency for

trading partners, and in particular those trading partners who buy and sell products in multiple markets:[7]

1. **Utilize trade terminology.** As evidenced in the chart above, levels of pharmaceutical packaging containing serialized barcode align much more consistently with trade terminology (*i.e.*, salable unit, shipper/case, logistical unit) rather than ISO terminology (*i.e.*, primary package, secondary package, tertiary package). The salable unit is always serialized as it is the smallest trade unit intended for sale to a dispenser. Further the highest level logistical unit always carries an SSCC. Regulations should therefore reference serialization of the salable unit (defined by the manufacturer and relevant across any packaging scenario) rather than a primary or secondary package since the salable unit could be the primary or the secondary package depending on the packaging scenario. In addition, regulators should make clear that the highest level logistical unit should carry an SSCC, rather than using the more confusing "tertiary package" terminology.
2. **Serialize the smallest salable unit.** The unit identifier should be affixed to each salable unit. Product serialization at the primary level is costly and not harmonized with requirements in other markets around the globe. 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 salable unit is the smallest level of serialization needed for an end point authentication traceability system.
3. **Allow for flexibility in the identification of packaging levels other than the "salable unit" and the highest level "logistical unit."** Several packaging scenarios contain multiple packaging levels that are neither the salable unit nor the highest level logistical unit. For these packaging levels (e.g., shipper/case), serialization for the purposes of aggregation may be useful and applicable for trading partners. Alternatively, different trading partners may trade in different packaging levels, which would require the application of the SSCC on a packaging level below the pallet. For this reason, trading partners should have the flexibility to how to identify a shipper/case, or a lower level logistical unit. However, as noted above, serialization for a primary package that is not the salable unit should not be required.
4. **An SSCC should be applied to the highest level logistical unit.** The highest level logistical unit is typically the pallet in markets like the United States or the European Union. While RxGPS does not recommend requiring serialization for exported product, it is critical that markets requiring serialization of exported products exempt all levels of packaging below the highest level logistical unit to prevent confusion in the importing market. Verification at customs does not require that a unique identifier be affixed to any package level smaller than the highest-level shipping container. Smaller levels should be serialized and labeled according to the importing country's requirements.

[7] For additional detail on how to construct globally-aligned regulatory requirements, see the RxGPS Implementation Roadmap and Model Regulation, available at: http://www.rxgpsalliance.org/wp-content/uploads/2018/08/RxGPS_Implementation-Roadmap-and-Model-Regulation_30Jul2018.pdf

## Conclusion

Pharmaceutical packaging scenarios can be complex and varied across global markets. This complexity can lead to confusion when regulatory requirements requiring serialization and traceability do not clearly distinguish the packaging levels that are required to be identified, verified, and traced. Utilizing trade terminology in global regulations, while providing the flexibility for manufacturers to respond to in-market dynamics, will minimize confusion and promote successful, efficient global trade.