Will Serialization Affect Minimum Order Quantity for Rx Products?



Serialization will have a visible impact on prescription drug packaging as new unique identifiers (UIDs), including 2D data matrix barcodes, are added to boxes, bottles, and cartons. But will serialization change how the drugs themselves are packaged for sale? What does the FDA mean when they specify that a unique identifier is required on the “individual saleable unit?”

DSCSA is not expected to change how manufacturers and repackagers package minimum order quantities of drugs for sale to pharmacies, whether it’s a single unit or a homogeneous case of individual units. What will change is the exterior of the packaging itself—and the ability for wholesalers and pharmacies to more easily identify and track the “individual saleable unit.”

What is the “individual saleable unit?”

DSCSA requires that a unique, serialized identifier be applied to the individual saleable unit or a homogeneous case. An individual saleable unit is defined as *“the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.”* A homogeneous case is defined as *“a sealed case containing only product that has a single National Drug Code number belonging to a single lot.”*

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Pharmacies often think in terms of the “lowest unit of measure” or “lowest dispensable unit of measure” when dispensing a product to a patient. But the lowest unit of measure does not always correspond to the individual saleable unit. For example, a homogeneous case of 12 vials might be the individual saleable unit as defined by the manufacturer or repackager, but a single vial is the lowest dispensable unit of measure. The serialized UID is required on the homogeneous case, not the individual vial.

DSCSA compliance “at a glance”

Because an individual saleable unit or homogeneous case can be easily tracked using a unique identifier, pharmacies and hospitals will have a clearer way to be sure that packaging is compliant with DSCSA regulations when they are buying, loaning, or borrowing products. The process of verifying that products are eligible for transactions under DSCSA can be streamlined using optical scanners connected to a shared data platform like the TraceLink network to capture 2D barcode information and verify it against the manufacturer’s data.

The product data available on the TraceLink network also enables healthcare providers to get insights into expiry dates, dispensation trends, product inventory, and more. Every day, thousands of hospital and pharmacy locations rely on the TraceLink network to exchange hundreds of millions of compliance messages and adhere to legal requirements. Contact TraceLink to learn more about our solutions for Healthcare and Pharmacies.

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Learn more about the value of serialized data in pharmacy operations.
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Thank you for contacting us; we’ll be in touch shortly.

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