Update July 2026

The Evolving World of Counterfeit Drugs... Where Does Serialization Fit?

Background

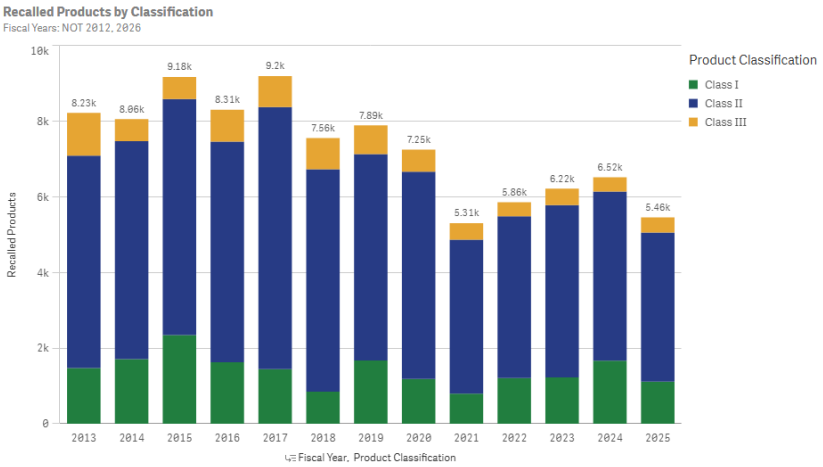
For 13 years, the Drug Supply Chain Security Act (DSCSA) has enacted requirements and deadlines throughout manufacturing, logistics and supply networks to support and enhance the FDA's vision to protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. Across this timeline, pharma and healthcare companies have invested significant resources in implementing enterprise-level IT infrastructures to manage anti-counterfeiting efforts through serialization.

Now, with DSCSA fully enacted, and the extended stabilization period, designated through 2024 with compliance mandatory and enforcement firm, it stands to reason that recall incidents due to counterfeit products should fall. It will likely take several years of data to bear this out.

How Much Do Product Recalls, Withdrawals and Safety Alerts Affect the Industry?

The latest data published by the U.S. Food & Drug Administration regarding recalled products by Classification is shown below. Class I involved high risk, serious adverse consequences where death is likely due to undeclared allergens or tainted product. Class II refers to moderate risk of temporary or reversible adverse health consequences due to contaminated food or defective devices. Class III is defined as low-risk situations unlikely to cause adverse health consequences due to minor labeling or packaging violations. This chart lists total number of recalled products by year between 2013 and 2025.

From DSCSA's inception in 2013 through 2025, a pattern has emerged indicating that recall events showed mild fluctuation through 2020 followed by a roughly 25% decline in the post-Covid era through 2025. This could be attributable to the effects of serialization efforts; however, one might assume the supply chain and inventory management issues that followed the Covid pandemic may have played a role in these numbers, as well.



Source: FDA.gov data dashboard

In addition to these observations, it's interesting to note that Class III recalls relating to infractions with secondary packaging such as cartons, product labels, and informational inserts comprise the smallest category of product recall data, according to the above graph (see yellow bars). Beyond serialization itself, this data aligns with the evolution of new technology that has emerged during this time period — the utilization of vision inspection systems to ensure the quality and accuracy of the printed material and the scanning of serialized codes.

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Vision inspection is a crucial component of quality systems supporting serialization. As depicted in the graph, Class III recalls specifically, have seen a significant decline since the 2013 enactment of DSCSA. The data depicted signals that the advancements in vision inspection have had a profound impact on serialization and product safety and have aided in curbing Class III product recalls.

Serialization as Part of a Broader System

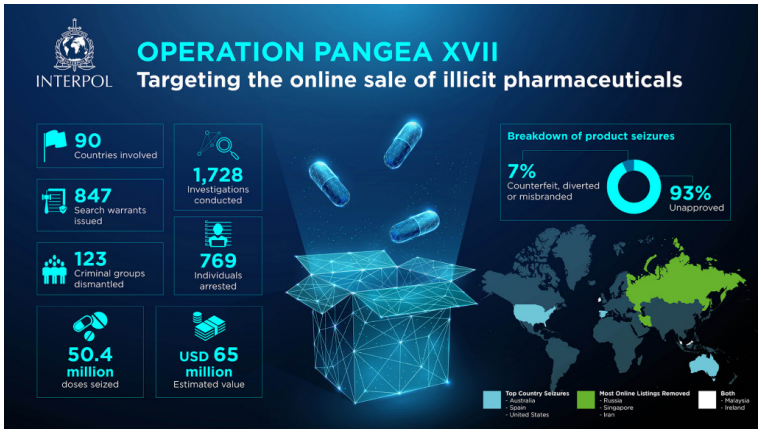
Since 2024, across the pharma and healthcare industries, companies are moving toward standardized data models and robust master data governance to combat the pain points involved in data volume, interoperability and cybersecurity. They are learning that serialization can be implemented as a strategic asset by integrating it into ERP, WMS and quality systems to realize benefits beyond compliance reporting.

Though the United States and Europe have established maturing methodologies, many global markets are still defining and revising serialization rules and criteria resulting in an amalgam of requirements that global organizations must balance.

Much like the concept of serialization is evolving, so too, is the evolution of counterfeiting itself. Despite serialization being developed as an anti-counterfeit measure, counterfeit medicines, biologics and devices remained an issue through 2025.

In January 2026, Jyrki Berg of True Med lists current counterfeit trends stating, "Counterfeit medicines are not only moving through back channels anymore. Many are organized, technology driven operations. Investigations continue to uncover large cross border networks and illegal online pharmacy ecosystems, along with major global enforcement campaigns targeting distribution at scale."[1]

[1]Source: https://truemedinc.com/2026/01/27/



[2]Source: https://www.interpol.int/Crimes/Illicit-goods/Pharmaceutical-crime-operations

Interpol's Operation Pangea[2] reveals the results of its endeavor to target online sales of illicit pharmaceuticals (see above infographic). The rise of GLP-1 drugs since 2024 has become a major focus for counterfeiters and illegal distributors. Particularly in pill form, these drugs are easier to distribute, provide in bulk, and have misled consumers to view them as trustworthy through online channels.

A New Serialization Strategy

Though serialization is critical and necessary in combatting counterfeit products, it must be viewed going forward as one piece of the product protection puzzle. Today, it is essential to reframe serialization as more than merely a compliance task and move to a more holistic strategy that combines it with diversion detection, recall optimization, and a focus on patient services. The optimal plan will include both digital and physical anti-counterfeit and security measures by maintaining current overt and covert features paired with digital authentication, AI anomaly detection and blockchain traceability, where applicable.

The Enhanced Anti-Counterfeit and Security Eco-System

NEW TECHNOLOGY

SMART LABELS/ SENSORS
Monitor temperature, shock and tampering in real time

CONNECTED PATIENT EXPERIENCE
QR codes link to critical info and authenticity checks support patient engagement

IoT-ENABLED TRACEABILITY
Supply chain visibility through continually captured data streaming to cloud-based platforms

CONNECTED PACKAGING

DIGITAL AUTHENTICATION
Scan and verify apps for pharmacists and patients

BLOCKCHAIN DATA SHARING
Verification of serialized data enables trust between trading partners, globally

AI-DRIVEN DETECTION
Uses big data to identify anomalies or suspicious activity in supply chain

TRENDS IN SECONDARY PACKAGING

ENHANCED SUPPLIER CAPABILITIES
100% vision inspection, color quality technology, anti-counterfeit techniques, and 'clean' packaging

REIMAGINED DESIGN
Kitting, combination packaging, complex packaging and insert engineering

SUPPLIER COLLABORATION
Customized designs, country of origin and custom coding, offline imprinting, and sustainability initiatives

SUSTAINABILITY
Plastics reduction, lightweighting, and recyclability that supports security and smart features

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