Colombia

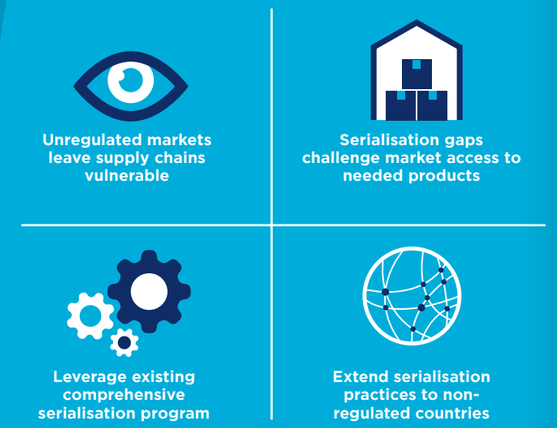
Embracing serialisation by driving adoption beyond compliance mandates

Challenge

Despite serialisation being mandated in approximately 52 countries, many of the countries most at risk remain unregulated. In the absence of regulation, pharmaceuticals may be more vulnerable to product counterfeiting, diversion or adulteration.

Approach

As countries consider enacting serialisation mandates and recognising the positive impact of serialisation, Johnson & Johnson is leveraging its integrated, comprehensive and seasoned serialisation program, developed based on GS1 standards, to benefit susceptible global markets and products.



Introduction

Counterfeit drugs, drug adulteration and other illicit trade have challenged the healthcare industry for decades. Given the complexity of supply chains, each step is potentially vulnerable, making the impact of product counterfeiting and diversion a worldwide concern. At Johnson & Johnson, we are committed to ensuring the integrity and safety of our supply chain through a robust product identification and verification platform. This includes our comprehensive and seasoned serialisation and traceability program.

Serialisation, the process of assigning unique identifiers to individual product units and creating unique identifying information that is automatically verified and recorded at all levels of production and at various points throughout the supply chain, is a powerful tool in the fight against counterfeit medicines. It enables the tracking of a product as it travels through the supply chain.

Serialisation is primarily driven by health authorities in many regions worldwide; however, some countries have no or limited regulations. By voluntarily extending serialisation practices to products in select countries where implementation is feasible, Johnson & Johnson can enhance product integrity, traceability and verification. This proactive approach not only strengthens the supply chain against counterfeiting but also reinforces the company's commitment to patient safety.

Identifying vulnerable products

Illicit trade affects many countries worldwide, but some regions and products are particularly susceptible as they face regulatory system challenges, economic instability and high market demand. For example, in 2020, Johnson & Johnson learned counterfeited and diverted products were making their way into the Columbian market via unauthorised distribution channels. "In Colombia, we observed an increase in incident reports involving certain products. There were several issues including products that did not have the proper commercialisation licenses or packaging materials," says Regina Zamith, Director Global Brand Protection, Latin America.

Various options were considered to tackle the issue, and it was determined that serialisation would be one of the most effective solutions to help protect these products. Johnson & Johnson was able to leverage established processes and best practices based on GS1 standards while using existing equipment and systems. Annette Santiago, Senior Manager Digital Identification & Traceability adds, "While Colombia is a country that has considered serialisation legislation, they have not enacted any specific mandates. However, because we already had serialisation capabilities integrated into our production lines, activating it for high-risk products is a straightforward process and it provides greater visibility to them throughout the supply chain."

Serialisation enabled Johnson & Johnson to gather information, such as to whom the product was sold, or if it had been diverted from another country or facility. This capability allowed Johnson & Johnson to provide accurate and timely information to the Colombian authorities. Since serialisation deters counterfeiters' attempts at labelling, use of replicated serialisation numbers is easy to detect and helps authorities promptly spot and stop counterfeit products.

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Expanding to additional markets

Supply chain flexibility in smaller markets can be effectively achieved utilising multi-market packs. In the Middle East-West Africa (MEWA) region, product packaging is typically designed for multiple markets by including information in several languages and adhering to the regulations and standards of various countries within the region. MEWA packs allow companies to streamline their supply chain by utilising a single packaging format that meets the requirements of several markets, thus simplifying distribution across these countries.

The adaptability provided by multi-market packs has been particularly beneficial as countries in the MEWA region gradually introduce serialisation regulations. Anticipating these changes, Johnson & Johnson incorporated all MEWA packs, as well as other country-specific packs for the entire region, into their serialisation strategy. Accordingly, when new countries in the region introduced serialisation requirements, the necessary standards and processes were already in place. There was no need to launch new projects, which allowed Johnson & Johnson to maintain compliance and supply chain efficiency. There were also no additional costs or investments needed as the capabilities were already in place.

The Traceability & Verification System project

Proactively serialising medicines enables Johnson & Johnson to pursue meaningful partnerships and collaborate with others to address critical global challenges and introduce technologies to countries where it's vitally needed. To aid resource-limited regions, Johnson & Johnson joined forces with UNICEF, GAVI, USAID and other multi-national agencies, to address global counterfeiting. Together, they designed the Traceability and Verification System (TRVST) that allows countries to verify the authenticity of health products and track and trace them through their supply chain.

The mechanics of TRVST are purposely simple. UNICEF operates a central repository where drug manufacturers like Johnson & Johnson send product information – serial number, global trade item number, batch number, production and expiration date and other GS1-standardised data – for medicines they are selling in resource-limited countries. When distributors, custom agents, central medicine stores or health care workers in these countries receive the product, they verify authenticity by scanning the 2D barcode on the package using a TRVST verification app on their smart phone. "Putting the scanning capability on people's smart phones makes this tool accessible to everyone with no need for complicated

or costly systems infrastructure," says Jo Tierens, Senior Director, Global Health Equity Supply Chain.

The app connects back to TRVST's centralised system and immediately indicates if the product is good, expired, under recall or doesn't match the serial number in the repository, which could indicate counterfeiting. Every time a product is scanned, Johnson & Johnson receives a notification showing where and when. Any scans that indicate potential problems trigger an alert to investigate the issue.

TRVST went live in September 2023 in three African countries – Nigeria, Rwanda and Liberia – and just one month later, Johnson & Johnson was receiving more than 6,000 scan verifications and one alert a day. Johnson & Johnson has since proactively serialised all products in their Global Health Equity portfolio and TRVST is used to track them. The portfolio includes drugs to fight Tuberculosis, intestinal worm infections and mental illness.

When you consider that potentially an estimated 700,000 people die each year from fake tuberculosis and malaria medicines[1] and that Africa accounts for more than 40% of all counterfeiting cases[2], the value and urgency behind proactively serialising products and expanding global health efforts with TRVST becomes clear.

Why serialise products without country mandates

Where appropriate, proactively serialising products without health authority mandates offers numerous benefits to patients, health authorities and manufacturers with little to no additional cost or investment. It enhances global operations, protects the brand and ensures organisations are ready for future regulatory changes, all while improving patient safety and supply chain visibility.

- **Patient Safety through counterfeit protection:** Even in countries without serialisation requirements, implementing serialisation helps protect against counterfeit medicines, enhancing product integrity and safety. Ensuring that patients receive authentic and unadulterated medications, especially when facing life-threatening conditions, is critical. Serialisation delivers another level of security in the ability to prevent the introduction of counterfeit products.
- **Regulatory readiness:** By serialising products ahead of potential or future mandates, companies can quickly adapt to new regulations. It reduces rushed implementations and business disruptions when mandates are introduced.
- **Cost savings:** Manufacturers can avoid the need to develop custom hardware and software, leading to more streamlined and cost-effective solutions. Often there are no additional costs or investments needed as the capabilities are already in place.
- **Global supply chain operational efficiency:** Serialisation can streamline various processes including distribution, returns and reverse logistics. It can facilitate automated data collection and analysis.
- **Global supply chain visibility:** Serialisation allows for more precise tracking of products throughout the supply chain. This visibility helps identify and address issues. Transparency, accuracy and responsiveness are improved as products are tracked in real-time.
- **Support for Global Standards:** Implementing serialisation can help companies align with global standards making it easier to operate in multiple markets, even without mandates. Standards help simplify processes to speak "one business language" in a multinational environment and as regulations evolve across the globe. Companies can more easily and quickly report serialised product data to regulatory authorities.

It takes teamwork

Through a highly effective collaborative approach, Johnson & Johnson leverages the internal capabilities of several teams and subject matter experts to pinpoint markets where serialisation can significantly benefit the most vulnerable products. They implement targeted strategies to enhance the security and traceability of these products and apply best practices. Key areas working together include:

Digital Identification & Traceability oversees the entire serialisation program, guiding the organisation through necessary regulatory changes and ensuring all compliance milestones are achieved and maintained. Additionally, they proactively investigate opportunities to implement serialisation in markets that lack formal regulations.

Global Brand Protection focuses on safeguarding patients and products by combating the risks posed by illicit trade – product counterfeiting, tampering and illegal diversion. Part of their strategy involves assessing markets and products to determine where implementing serialisation would offer the most significant impact, thereby enhancing security and traceability.

Regulatory Affairs manages the compliance and notification process, and if necessary, the approval process with health authorities. If product artwork changes are involved, they submit the mock-ups or final versions, depending on the market requirements.

Planning ensures the right products are produced for the appropriate markets. They confirm the stock keeping units (SKUs) in scope and determine which products or markets should be prioritised based on market forecast and demand. Planning assures production is aligned.

Manufacturing at each site determines available production lines and confirms their capabilities for specific products. They may shift products between lines to meet market requirements, with most lines being capable but occasionally needing minor enhancements.

Global Health Equity brings together proven capabilities in public health and social impact in collaboration with Johnson & Johnson's Innovative Medicine and MedTech sectors to deploy programs that advance equitable access to quality care in resource-limited settings.

Next steps and conclusion

Proactively serialising products before it becomes a regulatory requirement helps protect patients and safeguards our brands, thus ensuring the organisation is prepared for future mandates. Johnson & Johnson is dedicated to advancing this initiative by exploring opportunities to extend serialisation to more products and across broader portfolios. "What started with a single product has now grown to include several others," says Santiago. "This effort improves our product tracking capabilities and supports our ongoing commitment to product safety and quality."

About the author

Annette Santiago
Senior Manager, Digital Identification & Traceability, Johnson & Johnson

Annette Santiago is a seasoned professional leading the initial phase of program management for serialisation and traceability, as well as digital labelling. She performs cross functional impact assessments for new regulations and large complex projects all while playing a key role in financial planning. Since joining Johnson & Johnson in 2005, Annette has held various roles in enterprise data management and new product planning. She is an active member of the GS1 Healthcare Public Policy work team and the Rx GPS Industry forum. Annette is green belt certified and holds a bachelor's degree in industrial engineering.

About the organisation

Johnson&Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.

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[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4064812/
[2] https://enact-africa.s3.amazonaws.com/site/uploads/2018-11-12-counterfeit-medicines-policy-brief.pdf