

Supply Chain Security – Global Product Serialization



Product serialization, the process used to assign and mark each product with a unique identifier embedded in a 2D barcode, is an important method for combating product falsification or counterfeiting. The value of serialization is in this protection of the integrity of pharmaceutical products in commerce, providing additional assurance that the products that patients consume are genuine. Merck believes that global product serialization should be addressed through a carefully considered, standardized approach to ensure cost effectiveness. We support global regulatory harmonization and cooperation to accelerate adoption and implementation of common requirements and technical solutions for serialization. We are steadfast in our commitment to meet regulatory serialization requirements and to ensure patients around the world have access to safe and effective products.

Background

While serialization provides significant security benefits to markets, it cannot be considered a standalone security feature or sole source of product verification but rather as a useful part of a multi-layered product security platform. Additional details regarding measures Merck takes to ensure supply chain integrity are outlined in our Public Policy Statement on Counterfeit Medicines.

Serialization, by design and definition, generates electronic data as an integral part of the physical batches of medicines and vaccines that we produce. This electronic data travels through the supply chain, and issues of who owns and who should have access to these data are critical. Steps must be taken to ensure security of this information. Manufacturers must retain access to data generated in meeting serialization requirements. We also believe that in order for us to continue to uphold our responsibilities to secure and protect the integrity of Merck products, manufacturers must have access to authentication data (successes and attempts) to fully understand the extent and location of product that could be falsified.

Scope

Serialization should be applied at the secondary pack level, which is the so called “saleable unit” level where saleable unit is what the patient receives. Serialization requirements

below the secondary pack level (which is the primary pack level e.g., a blister, a vial or a syringe) add complexity and cost to packaging materials, packaging operations and information technology systems. Furthermore, there is limited space to accommodate the serialization information required at the primary pack level. There may be uncommon instances where product authentication may be warranted at the primary pack level, and such cases should be evaluated based on the specific need and impact of serialization.

Where serialization at shipper case or pallet level is required and serial numbers are linked in a database, we speak about aggregation and opportunity for inference. Merck is committed to meeting aggregation requirements wherever included in country regulations, however we also acknowledge the benefits of aggregation for purposes of supply chain efficiency and data integrity. We will evaluate based on specific needs where investments to apply aggregation on a voluntary basis are warranted.

Rationale for our position

The implementation of serialization places an additional cost on manufacturers, distributors, wholesalers, retailers, governments, and consumers. These system costs are like any other burden on a country's healthcare system and should be carefully evaluated to ensure that the public is obtaining value for this added burden. Merck is working with industry organizations to advocate that governments requiring product serialization consider carefully how this capability can be implemented most efficiently, particularly with respect to the following:

- **GS1 Global Standards:** Product serialization requirements should be consistent with industry standards published by the Global Standards Organization GS1. Serialization standards from GS1 include the 2D Data Matrix as the barcode data carrier, the Global Trade Item Number (GTIN) as unique product identification number, the Global Location Number (GLN) as the unique trading partner identification number, and the Electronic Product Code Information Services (EPCIS) as the interoperable event data exchange.
- **Product authentication at the point of dispense:** We believe serialization requirements should include product authentication at the point of dispense. This is the best way to ensure patients will obtain benefit from serialization.
- **Product authentication at each supply chain node:** Requirements to authenticate product at each supply chain node is called track & trace, and should be considered in market conditions where a high risk of counterfeit or diversion exists. This will help detect illegitimate product in the supply chain, and eventually prevent it from reaching the patient.

- **Global regulatory harmonization:** Serialization requirements can be very complex and involve multiple parties and complex data structures. Given many markets have implemented serialization requirements in the last decade, it is essential that governments around the world understand how serialization is being implemented elsewhere, and seek to leverage existing data structures, standards, systems, technology and lessons learned versus developing unique requirements for their markets.