

PUBLIC POLICY STATEMENT

SUPPLY CHAIN SECURITY- GLOBAL PRODUCT SERIALIZATION

Consistent with our longstanding commitment to provide high quality, safe and effective medicines and vaccines to patients who need them, Merck maintains a comprehensive product integrity program. We carefully manage our supply chain through strict policies and procedures designed to keep the Merck drug distribution system safe and secure. Therefore, we have a high degree of confidence in the integrity of our products in the marketplace.

Additional details regarding measures Merck takes to ensure supply chain integrity are outlined in our [Public Policy Statement on Counterfeit Medicines](#). Product serialization, the process used to assign and mark each product with a unique identifier, is an important method for combatting product falsification or counterfeiting. Many governments around the globe have chosen some form of product serialization as the preferred method for securing the pharmaceutical supply chain. Merck is committed to meeting the full extent of these statutory and regulatory requirements as they exist now and will exist in the future.

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:** Any serialization requirement should include product authentication at the point of dispense. Without such a requirement, patients would obtain little benefit from serialization.
- **Product authentication at each supply chain node:** Requirements to authenticate product at each supply chain node should be considered only after the full benefit of point-of-dispense authentication is realized. It is Merck's position that authentication at each supply chain node is an extraordinary measure that would only be warranted in unusually troublesome market conditions.

- **Simplified and phased requirements:** Serialization requirements can be very complex and involve multiple parties and complex data structures. Governments requiring serialization should strive to simplify and phase these requirements as much as possible and give industry ample lead time for implementation.
- **Global harmonization:** Given major markets such as the United States and the European Union have implemented serialization requirements, 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. Merck strongly believes that standards should be developed at the national or multinationals level rather than by states, provinces, or other political subdivisions.

As an example, the United States legislation enacted in 2013 - The Drug Supply Chain Security Act - establishes uniform federal standards to improve the security of the drug supply chain and reduces the impact of the burdensome patchwork of state laws related to pedigree requirements for drug distribution by establishing a national system for tracing pharmaceutical products through the supply chain.

Additionally, the European Union legislation from 2016 - The Falsified Medicines Directive - imposes serialization requirements and standards that are uniform for all European Union member states, and are also followed by non-EU members states in the European Economic Area (EEA)

In addition, from our perspective:

- **Data security and access:** 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.
- **Item level serialization:** Serialization should be at the item level, which is the secondary pack or “saleable unit” level where saleable unit is what the patient receives. Serialization requirements below the secondary pack level add complexity and cost to packaging materials and packaging operations. Further, there is limited space to accommodate the serialization information required on a primary pack (e.g., a blister, a vial or a syringe). 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.
- **Aggregation and inference:** Where serialization at 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 if investments to apply aggregation on a voluntary basis are warranted.

In summary, the true value of serialization is in the protection of the integrity of pharmaceutical products in commerce, providing additional assurance that the products that patients consume are genuine. We believe that global product serialization can be more effectively addressed through a carefully considered, standardized approach. We support global regulatory harmonization and cooperation to accelerate adoption and implementation of common requirements and technical solutions for serialization. We remain steadfast in our commitments to meet global serialization requirements and to ensure patients around the world have access to safe and effective products.