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 many pharmaceutical manufacturers use to assign and mark each product with a unique identifier, has become an increasingly common and favored method for combatting product falsification or counterfeiting. In fact, in many markets around the globe, governments are choosing product serialization in its various forms as a preferred method for securing the pharmaceutical supply chain. Merck is committed to meeting the full extent of these statutory and regulatory requirements and is actively taking steps to implement serialization solutions for these markets.
It is critical for governments considering serialization requirements to realize that 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 contemplating requiring product serialization consider carefully how this tool can be implemented most efficiently, particularly with respect to the following:

- Global standards: Product serialization requirements should be consistent with global standards such as the GS1 DataMatrix as the barcode data carrier, the Electronic Product Code Information Services (EPCIS) as the interoperable event data exchange, the Global Trade Item Number (GTIN) as unique product identification number, and the Global Location Number (GLN) as the unique trading partner identification number.
- Product authentication at the point of dispensing: Any serialization requirement should include product authentication at the point of dispensing. Without such a requirement, little benefit would be obtained 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 flexible requirements: Serialization requirements can be complex and involve multiple parties and complex data structures. Governments considering serialization should strive to simplify these requirements and give supply chain partners as much flexibility as possible for implementing these requirements.
- Global harmonization: Serialization requirements that vary significantly from country to country only serve to add complexity and cost to implementation. It is essential that governments that are evaluating such a program understand how serialization is being implemented elsewhere, and seek to leverage existing data structures, standards, systems, and technology versus developing unique requirements.
- National requirements: Merck believes that, to be effective, there should be a reasonable timeframe allowed for developing regulations and/or standards for the implementation of serialization technologies. We strongly believe these standards should be developed at the national or multinational level, rather than by states, provinces, or other political subdivisions.

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As an example, the United States legislation enacted in late 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.

In addition, from our perspective:

- Data security and access: Serialization, by design and definition, generates a significant amount of data, including information about who made the product and where the product has traveled through the supply chain. The issues of who owns and who should have access to these data are critical. Steps must be taken to ensure security of this information. Merck believes that 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 or “saleable package” level where “saleable package” is what the consumer receives. Serialization requirements below the “saleable package” level add tremendous complexity and cost to packaging materials and packaging operations. Further, there is limited package space to accommodate the serialization information required on a blister or vial, for example. We acknowledge that there may be uncommon instances where product authentication may be warranted below the “saleable package” level, and such cases should be evaluated based on the specific need and impact of serialization.

In summary, Merck believes that 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 consumers around the world have access to safe and effective products.

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