



Pharmaceutical Serialization and Tracing Principles

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Any country mandating serialization or traceability should clearly identify the goals and purposes of the mandate.

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Mandatory requirements should be limited to those requirements necessary to secure the supply chain and should provide flexibility that allows for the addition of voluntary complementary functionalities.

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The value of serialization is the ability to verify the authenticity of packages introduced into commerce. Serialization and reporting should be tied to the smallest unit intended to be sold to a dispenser.

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Mandatory requirements should be phased in over time to allow supply chain participants sufficient time to transition to new operational practices.

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Data ownership rights should be respected and protected across all sectors reporting or sharing data.

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The organizations with responsibility for the product should have access to authentication data.

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To facilitate harmonization across markets, economies considering serialization should adopt global approaches because they promote efficiency, reliability, and effectiveness.

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Markets considering new requirements should leverage successful practices and systems from other markets.

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Serialization and traceability requirements should facilitate, not impede, cross-border trade.

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The implementation and operation of a system for leveraging serialization must be a cross-sector, integrated, and shared effort, and no individual sector should bear an inequitable share of the responsibility.