Principles for Using Serialization

RX GPS
THE ALLIANCE FOR GLOBAL PHARMACEUTICAL SERIALIZATION

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

- It is necessary to understand each country's goal in order to identify the best way to achieve that goal.
  - A point of dispense model may be most appropriate if the goal is to ensure that patients receive authentic medication.
  - A full track and trace model may be appropriate if the goal is to monitor supply chain velocity or to have visibility to the specific location of product within the supply chain.
- We believe the most appropriate use of serialization data is to secure the legitimate supply chain through authentication of serialized packages entered into commerce.
- Many tools are necessary to secure a country's drug supply.
  - Serialization is one important tool that we recommend to advance the security of the legitimate supply chain and to reduce fraud. Tools other than serialization may be more appropriate to solve other problems.
  - For example, a requirement that all trading partners be authorized (*e.g.*, licensed, registered) can significantly improve the security of the legitimate supply chain.
- All tools come at a cost, and the most efficient set of tools should be used to achieve the goals and purposes.

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

- Requirements should be specifically tailored to achieve the country's goals.
  - The implementation of a serialization and traceability system is very expensive and burdensome. Overbroad and unnecessary requirements add to that burden and slow implementation of the system.
  - Inappropriate or unnecessary use and sharing of serialized data can actually enable the use of that data for fraudulent practices and decrease the security of the supply chain.
- Serialization presents significant opportunity for the development of valuable additional services, such as inventory management and improved dispensing accuracy. Legal requirements should not prevent or impede the develop of such additional practices.

3 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.

- In our experience, the most cost-effective and efficient way to achieve supply chain security is through the ability to authenticate pharmaceutical packages in commerce.
- The risk that product will be diverted or illegitimate product will be introduced occurs while product is moving through the supply chain.
  - Therefore, security can be achieved by ensuring that product that exits the supply chain and is delivered to patients is authentic. To do so, serialization is necessary for the smallest unit intended to be sold to a dispenser.
  - It is not necessary to serialize primary packages for this purpose.

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

- Implementation of serialization and traceability requirements is expensive, time consuming, and technologically challenging.
  - Stakeholders must be given sufficient time for implementation.
  - Phasing new requirements in on an incremental basis helps ensure that each piece of the system is working properly before moving to implementation of the next piece.
- Without authentication and decommissioning of saleable units prior to dispensing to patients, safety of the supply chain may be compromised. More elaborate requirements provide modest additional value, increase the complexity and time for implementation, and should not be considered until the benefit of authentication and decommissioning have been realized.

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

- Product data and purchase and sale data is valuable and sensitive.
  - Ownership of, and rights to, that data should be carefully protected and should not have anti-competitive effects.
- Each trading partner should only be responsible for the accuracy of the data it generates; a trading partner should not be responsible for the accuracy of data generated by others.

6 The manufacturer and other parties responsible for the product need timely information about authentication attempts to best detect supply chain security concerns.

- Access to authentication data must be balanced against privacy interests of stakeholders and patient safety.
- Appropriate regulator access to authentication information is also important to supply chain security.
- Unauthorized access to data can undermine supply chain security.

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

- The use of standards is critical to developing a working, interoperable system for sharing information.
  - This is especially true in the global market.
- The use of global data standards can speed and ease implementation.
- Global data standards should be used for the identification and serialization of pharmaceutical products and the capture and sharing of data related to such products.
- Global data standards facilitate international commerce through interoperability and promote competition and expansion.

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

- New serialization and data sharing should be consistent with the requirements of other markets.
  - Several countries have made substantial progress toward serialization and traceability, and the experiences of those countries should inform the development of systems in future countries.
  - Leveraging experiences in other countries can speed and ease implementation.
- Requirements should be aligned with common practices used by the supply chain.

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

- Serialization requirements should be consistent and aligned with global data standards because product often moves between and among multiple markets.
- Only the requirements of the country where the product will be dispensed should apply.
  - Requirements applicable to exports have significant potential to create confusion in, or conflict with, the requirements of other markets.
  - Traceability requirements should be tailored to the identified goals and purposes of a country's mandate, and therefore should only be set by the country where the product will be dispensed.
- Serialization requirements should provide the flexibility for manufacturers to serialize product before or after importation.
  - Product is often packaged in one country and distributed to multiple other countries.
  - Serialization prior to the first in-country sale, by the manufacturer to another supply chain participant, sufficiently facilitates verification and traceability.
- Shared packs (*i.e.*, the use of the same pack across multiple countries) are common in many regions and are critical to patient access. The use of global standards (particularly the use of GTINs as the product identifier) is essential to the use of shared packs.

10 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.

- All sectors of the supply chain are critical to achieving supply chain security and improving patient safety.
- The pharmaceutical supply chain is a highly complex, interconnected web of companies, and the perspectives of all parts of the supply chain are critical.
- Stakeholders should be consulted frequently in advance of adoption to support transparency and collaboration.
  - The organizations that make up the supply chain are best positioned to understand operational needs and challenges, and their input should be carefully considered when developing serialization and traceability requirements.
- Each sector should bear an equitable share of the responsibility.