# The RxGPS Toolkit:
# Implementation Roadmap & Model Regulation

*The Implementation Roadmap and Model Regulation included here are the two most recent additions to the RxGPS Toolkit of resources for global regulators and supply chain stakeholders. This toolkit provides helpful information and best practices for implementation of serialization and traceability requirements around the world. Please visit [http://www.rxgpsalliance.org/resources/](http://www.rxgpsalliance.org/resources/) to find the full toolkit of resources, including many of the resources referenced here:*

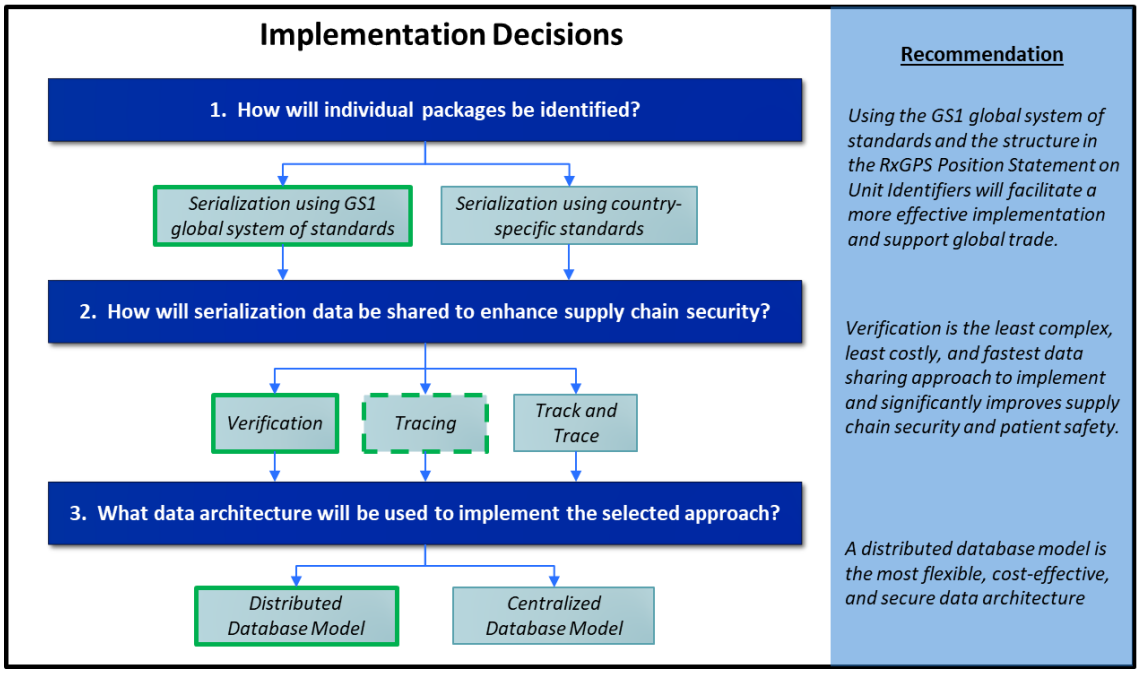
- *Principles for Using Serialization*
- *Serialization Primer*
- *Position Statement on Implementation*
- *Position Statement on Unit Identifier*
- *Position Statement on the Benefits and Complexity of Common Serialization Models*

## *Background*

*Both of these resources are built upon RxGPS's recommended model for implementation. Any country that seeks to implement a serialization model must answer three fundamental, foundational questions:*

1. *How will individual pharmaceutical packages be identified?*
2. *How will serialization data be shared to enhance supply chain security?*
3. *What data architecture will be used to implement the selected approach?*

*These questions, and RxGPS's recommended approaches, are shown in the following chart.*



*As reflected by the green boxes, we strongly support the use of the GS1 global systems of standards for identification of packages. Our specific recommendations for implementation of such identification is described in more detail in the RxGPS Position Statement on **Unit Identifiers**.*

*With regard to the model that will be used to share serialization data for supply chain security, a regulator may choose among three models. These models, and our recommendations, are described in the RxGPS Position Statement on the **Benefits and Complexity of Common Serialization Models**. Each model uses serialization data to answer a different question:*

- ***Verification:** Is this product authentic?*
- ***Tracing:** What distribution path did this product follow?*
- ***Tracking:** Where is the product now, and what path did it take to get there?*

*For the reasons described in our Position Statement on the **Benefits and Complexity of Common Serialization Models**, we strongly support the implementation of verification capabilities first. Once verification has been successfully implemented, an additional assessment can be undertaken to determine whether the additional complexity of tracing or track and trace is valuable in a given country. In assessing the three models, the following considerations should be considered:*

| | Tracing | Tracking | Verification |
|---|---|---|---|
| **Definition** | Ability to identify the origin and characteristics or history of a particular traceable item upstream based on criteria determined at each point of the supply chain by reference to records held about it | Ability to locate or follow the path of a particular traceable item downstream based on criteria determined at each point of the supply chain by reference to records held about it. | Ability to confirm the unique product identifier on a package matches the unique product identifier affixed by the manufacturer of the product. |
| **Objectives Addressed** | • Secure the legitimate supply chain<br>• Determine the history of a product's movement through the legitimate supply chain | • Secure the legitimate supply chain<br>• Determine the history of a product's movement through the legitimate supply chain<br>• Visibility to the specific (current) location of product within the supply chain<br>• Monitor supply chain volumes or velocity | • Secure the legitimate supply chain<br>• Confirm authenticity of packaging |
| **Ease of Implementation and Maintenance** | • Requires all companies through the full supply chain to create and maintain event data<br>• Requires all companies and user connection to the system | • Requires all companies through the full supply chain to create and maintain event data<br>• Requires all companies and user connection to the system | • Requires the manufacturer to create and maintain event data<br>• Requires manufacturer and user connection to the system |

| | | | |
|---|---|---|---|
| **Cost Effectiveness** | • Exponentially more data created and maintained than for verification<br>• Exponentially more connections than for verification | • Exponentially more data created and maintained than for verification<br>• Exponentially more connections than for verification | • Least data created and maintained compared to tracing and tracking<br>• Fewest connections compared to tracing and tracking |
| **Aggregation and Inference** | • Aggregation and inference generally necessary for efficient product distribution | • Aggregation and inference generally necessary for efficient product distribution | • Aggregation and inference not required |
| **Interoperability** | • Requires all companies through the full supply chain to follow event creation and connectivity standards<br>• Exponentially more connections than verification | • Requires all companies through the full supply chain to follow event creation and connectivity standards<br>• Exponentially more connections than verification | • Requires manufacturers to follow event creation and connectivity standards<br>• Fewest connections compared to tracing and tracking |
| **Connectivity** | • Connectivity and immediacy of posting events is important | • Greatest importance of connectivity and immediacy of posting events | • Connectivity is important<br>• Possible batch verification |
| **Information Available** | • Information about events that previously occurred | • Information about events that previously occurred<br>• Information about current location/status of product | • Manufacturer information about the status of the product |
| **Proprietary Business Information** | • Makes use of business information such as identification of specific trade relationships and locations of volumes | • Makes use of business information such as identification of specific trade relationships and locations of volumes | • Limits use and disclosure of business information such as identification of specific trade relationships and locations of volumes |

*Finally, once a model has been selected, a data architecture must be selected. At a basic level, there are two main types of architectures:*

- ***Centralized Database Model:*** *All data is accessed from one central storage repository. All data is mapped to the central location, and all supply chain participants replicate their data to the location for storage and query.*
- ***Distributed Database Model:*** *Each company owns and maintains its own data in separate repositories, and the repositories could be queried to obtain the data, as appropriate.*

*As explained in the RxGPS Position Statement on the* ***Benefits and Complexity of Common Serialization Models****, we believe a distributed database model is the most flexible, cost-effective, and secure data architecture. This view is based on the following comparison of the two models.*

| | Centralized Database Model | Distributed Database Model |
|---|---|---|
| **Definition** | • All data is accessed from one central storage repository. All data is mapped to the central location, and all supply chain participants replicate their data to the location for storage and query | • Each company owns and maintains its own data in separate repositories, and the repositories could be queried to obtain the data, as appropriate |
| **Data Integrity** | • Data is duplicated and held in two locations | • Single, initial source of data |
| **Security** | • Data transmitted to central database<br>• Single layer of security<br>• Single point of potential breach for *all* data | • Data remains in control of initial source<br>• Multiple layers of security<br>• No single breach point for *all* data |
| **Cost Effectiveness** | • Requires development and maintenance of enormous databases to store duplicate data | • Leverages existing data and blueprint for communication gateway |
| **Flexibility** | • Requires development of database with single method of connection | • Leverages existing data and<br>• Allows multiple methods of connecting and continued use of existing service providers |
| **Data Mapping** | • All data is mapped to a single known location | • Data must be mapped among multiple networks |
| **Ease of Implementation and Maintenance** | • Requires development and maintenance of enormous databases<br>• Requires single method of connection | • Leverages existing data and blueprint for communication gateway<br>• Allows multiple methods of connecting and continued use of existing service providers |

### *RxGPS*

*RxGPS is a group of multinational pharmaceutical supply chain stakeholders who have a common interest in developing consensus strategies, policy principles, and policy recommendations that advance global alignment of drug serialization and tracing requirements in order to enhance patient safety, supply chain security, and drug availability around the world.*

*RxGPS brings together senior supply chain and policy leaders who have the strategic insights, technical expertise, real world experience, regulatory knowledge, and public policy expertise. RxGPS includes representation from multiple supply chain sectors (e.g., innovator and generic manufacturers, wholesalers, logistics providers, and dispensers) to provide the broadest possible perspective.*

*RxGPS is a trusted partner and source of expertise for regulators looking to collaborate in the effective development and implementation of serialization and traceability.*

# Serialization Implementation Roadmap

## Introduction

Implementation of serialization and traceability to enhance security of the pharmaceutical supply chain is a significant endeavor. RxGPS has previously detailed the stages of implementation of the serialization process by industry (see: RxGPS Position Statement on Implementation).[1] This Implementation Roadmap ("The Roadmap") adds detail to the implementation process, particularly the regulatory process for markets that have not yet begun that process. It also includes a suggested timeline for phase-in of regulatory requirements over time.

The implementation processes and timelines may differ depending on the amount of experience of the supply chain members in a particular market (*e.g.*, manufacturers' prior experience serializing product, existing infrastructure for scanning/verification on the part of a dispensing entity). Therefore, the Roadmap delineates two separate timelines: one for an "Advanced Market" and one for a "High-Import Market," to acknowledge that prior experience and existing infrastructure may shorten the implementation timeframe.

- ***Advanced Market*** – In this context, an "Advanced Market" is a market that has: (1) a clearly defined and robust regulatory structure; and (2) a significant amount of in-country pharmaceutical manufacturing. The majority of countries currently implementing serialization (*e.g.*, the European Union, the United States, Korea, India) would be considered advanced markets.

- ***High-Import Market*** – A "High-Import Market" is a market that, in short, relies so heavily on imported product that in-country manufacturing upgrades and related regulatory requirements are not directly limiting factors. Therefore, the timeline for implementation of serialization in a high-import market could be shorter than that of an advanced market. For purposes of this document, a High-Import Country is identified based on the following principles (none of which are necessarily dispositive):
    - The country has a minimal number of local manufacturers, and therefore, a high reliance on import from multi-national manufacturers.
    - Limited regulatory capacity for development of a sophisticated track and trace system, but a strong commitment by the applicable regulatory body to improve supply chain security.
    - An environment with a significant risk of illegitimate, falsified, or otherwise high-risk product.
    - The country has significant ties to the international community (*e.g.*, participation in global regulatory forums, significant amount of donated product).

[1] http://www.rxgpsalliance.org/wp-content/uploads/2016/05/RxGPS_Position-Statement-on-Implementation_082216.pdf

## Assumptions

It is important to clarify that the Implementation Roadmap, and the timelines that are detailed within it, is predicated on critical assumptions about the serialization and the traceability model the market chooses to deploy. These include:

1. ***System/Model*** – The Implementation Roadmap assumes that any market moving forward under the Roadmap possesses the technical infrastructure for verification of serial numbers encoded in a product barcode. At the most basic level, this can be accomplished using a mobile application; at the more sophisticated level, this may include computer-based scanners at the point of dispense (*e.g.*, pharmacy).

   The Roadmap timeline also assumes that markets are seeking to accomplish a point-of-dispense verification model through the use of distributed databases. For additional information on this please see the RxGPS position statement on the benefits and complexity of common serialization models.[2]

   Finally, the Implementation Roadmap assumes the availability of an "off-the-shelf" verification solution. The proof of concept for one such solution has been demonstrated by the ABAC Pilot Working Group. Further work, including some piloting, would be needed to scale that solution; however, the Roadmap assumes such work has been successfully completed.

2. ***Serialization*** – The Implementation Roadmap assumes the markets utilizing the Roadmap will follow global standards and norms for serialization. This includes use of a GS1 standard barcode and labelling of the smallest unit intended to be sold to the dispensing entity (*i.e.*, the saleable unit, not the primary packaging). Specifically, it assumes complete alignment with the RxGPS Position Statement on Unit Identifier.[3]

   The Roadmap is also predicated on the assumption that serialization will be implemented for prescription drugs only (*i.e.*, not over-the-counter medications).

3. ***Pharmacy*** – The Implementation Roadmap assumes that a critical mass of pharmacies or other authorized dispensers in the market is capable of establishing the necessary verification technology (*e.g.*, smartphone connectivity) within the timelines set forth in the Roadmap.

4. ***Regulation*** – The Implementation Roadmap assumes that the appropriate regulator in any market has a published document that either states an intent to use a system of serialization to improve supply chain security, or lays out the expectations for regulated entities with regard to a future system of serialization and traceability. Absent stated intent by a regulator to utilize serialization, it may be difficult to achieve the stated industry implementation timeline, as this will require a firm commitment of resources by supply chain entities.

Deviation from any of these assumption would increase the proposed timeline.

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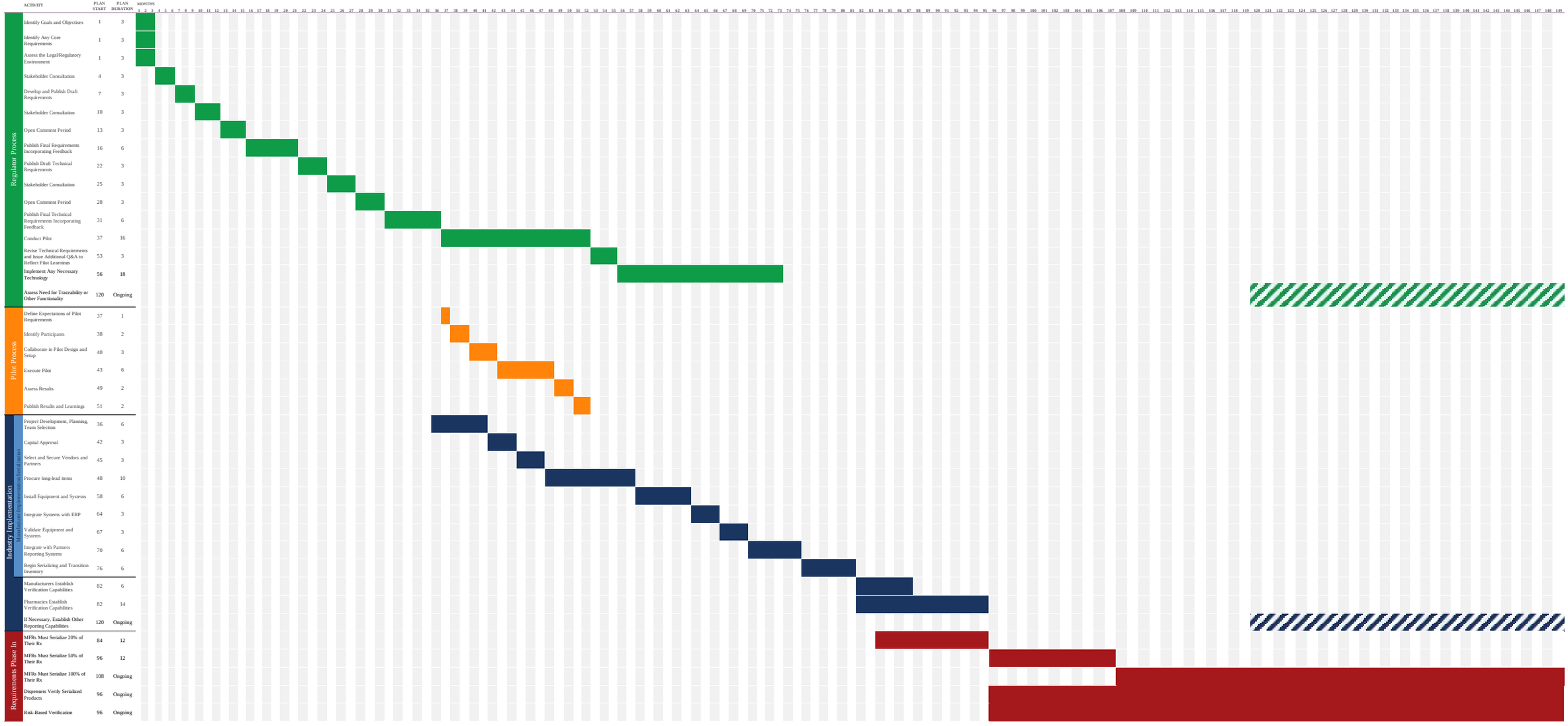
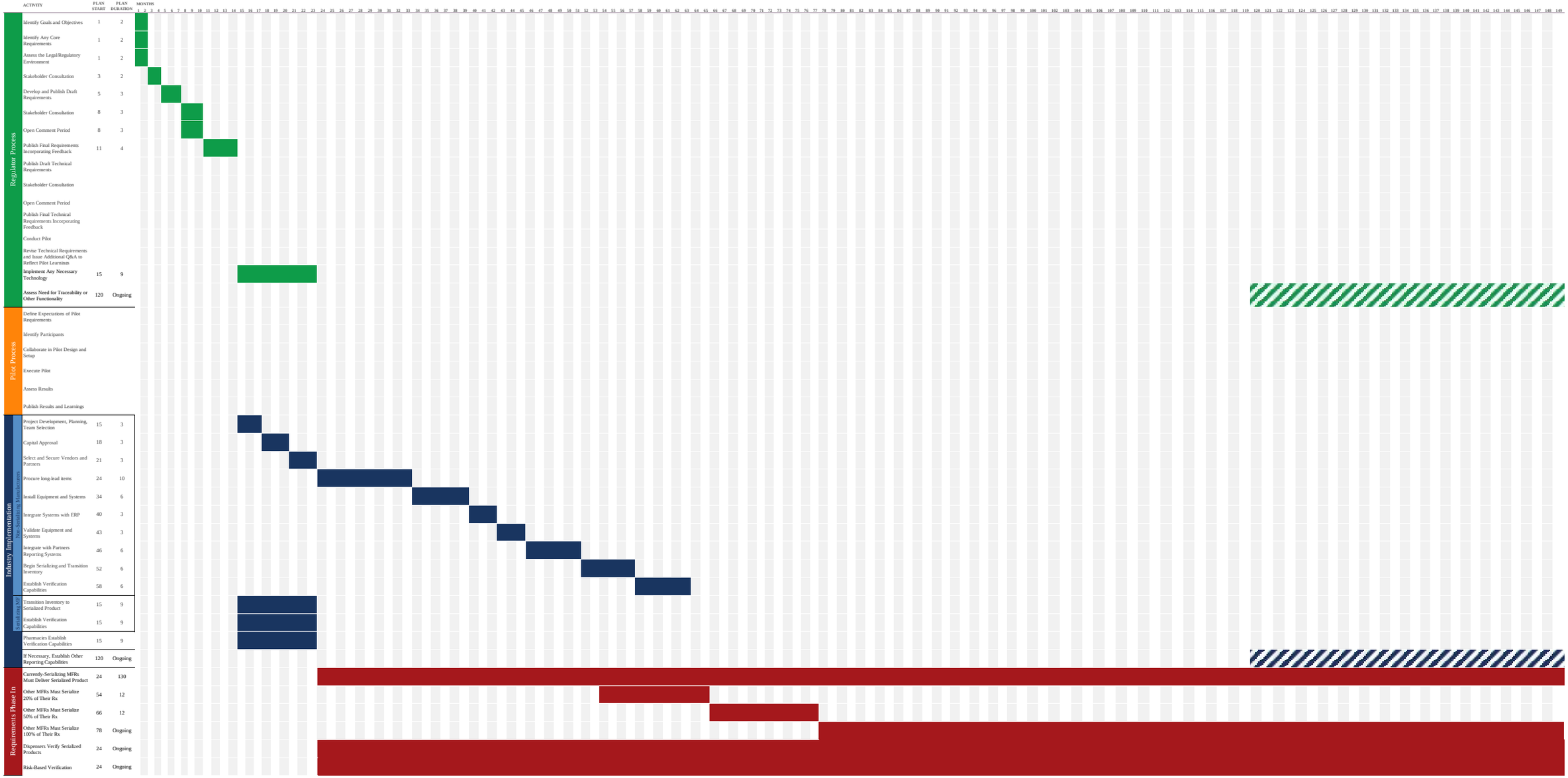
[2] http://www.rxgpsalliance.org/wp-content/uploads/2017/06/RxGPS_Serialization-Models-Position-Statement-010917.pdf

[3] http://www.rxgpsalliance.org/wp-content/uploads/2016/07/Position-Statement-Unit-Identifier-072816.pdf

# RxGPS - Implementation Roadmap



# RxGPS - Implementation Roadmap



# Model Regulation

**July 27, 2018**

*This Model Regulation is intended for use by global regulators in development and implementation of pharmaceutical serialization requirements to advance supply chain security. Implementation of serialization and traceability to enhance security of the pharmaceutical supply chain is a significant endeavor. In doing so, every regulator must assess and account for local market dynamics, including local legal requirements (e.g., whether serialization will be implemented by statute, regulation, or other guidance), technological sophistication (e.g., internet connectivity in various geographic regions), trade practices (e.g., whether unit-of-use, unit-dose, or bulk packaging is used; the variety of distribution channels used), and other similar dynamics. This Model Regulation should be amended to account for such market dynamics.*

### *Summary*

*As written, this Model Regulation requires serialization of prescription pharmaceuticals by manufacturers and repackagers and requires dispensers to verify the serialized packaging prior to use/dispensing. Risk-based verification by other entities is also required. The Model Regulation also provides a method by which regulators can assess supply chain security after successful implementation of these verification capabilities and add traceability capabilities if necessary. For more information on the differences between verification and traceability and the reasons RxGPS supports a phased approach that focuses on implementing verification capabilities first, see* Position Statement: Benefits and Complexity of Common Serialization Models*.*

### *Assumptions*

*The Model Regulation is based on several important assumptions. Adoption of the Model Regulation may not be appropriate if these assumptions cannot be met.*

1. ***Manufacturer Capabilities—****The Model Regulation assumes manufacturers in the relevant market have the technical capability to implement serialization within the timelines set forth in the Model Regulation.*
2. ***Pharmacy and Other Users—****The Model Regulation assumes that pharmacies or other authorized dispensers in the market are capable of establishing the necessary verification technology (e.g., internet or smartphone connectivity) within the timelines set forth in the Model Regulation.*
3. ***Domestic Supply Chain—****The scope of the Model Regulation is limited to the domestic supply chain (i.e., domestic distribution and dispense) and does not regulate exported product.*
4. ***Prescription Drugs—****The scope of Model Regulation is limited to prescription drugs for human use (i.e., those drugs that will be verified by a pharmacist or health professional) and does not apply to other products, such as over-the-counter drugs, animal drugs, or food products.*
5. ***Distributed Database Architecture****—The Model Regulation assumes that each manufacturer will maintain a mechanism for the verification of product (i.e., a distributed*

*database architecture), rather than reporting duplicate data to a centralized government database for storage. More information on the benefits of a distributed database architecture are described in* Position Statement: Benefits and Complexity of Common Serialization Models*.*

*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. Complementary tools not addressed in this Model Regulation may be valuable in securing a country supply chain. For example, a requirement that all supply chain entities be authorized (e.g., licensed, registered) can significantly improve the security of the legitimate supply chain.*

***Using the Model Regulation***

*The Model Regulation includes numerous provisions that must be tailored to the regulatory system of the implementing market. These provisions are noted in [blue brackets]. The Model Regulation also includes several explanatory notes. These notes are offset in italicized text. Explanatory notes are not intended to be included in the adopted regulation; instead, they are intended to provide context to the user of the document.*

*RxGPS welcomes the opportunity to discuss this Model Regulation and any issues related to pharmaceutical serialization. For additional information, please contact RxGPS by email at RxGPS@LeavittPartners.com.*

**Section 1. Purpose.**
The purpose of this [Act] is to enhance the security of the domestic pharmaceutical supply chain by establishing the ability to authenticate prescription pharmaceutical packages in commerce.

**Section 2. Definitions.**

(a) DISPENSER.—The term "dispenser" means any entity or person authorized by the [drug regulatory authority] to dispense a prescription drug to a patient or consumer.

(b) DRUG DISTRIBUTOR.—The term "drug distributor" means any entity or person, other than a manufacturer, repackager, or dispenser that takes ownership of a prescription drug for further sale to a repackager, dispenser, or another drug distributor.

(c) INVALID PACKAGE.—The term "invalid package" means a package for which the manufacturer or the repackager, as applicable, has determined in response to a verification request the unique identifier affixed to, or imprinted upon, the package does not corresponds to a unique identifier assigned by the manufacturer or the repackager.

(d) MANUFACTURER.—The term "manufacturer" means the entity or person authorized by the [drug regulatory authority] to produce and market a prescription drug.

(e) PACKAGE.—The term "package" means the smallest container of a prescription drug designated by the manufacturer or repackager, and [registered/authorized], for sale to a supply chain entity.

(f) PRESCRIPTION DRUG.—The term "prescription drug" means a drug in finished dosage form for human use that is subject to an [approval/authorization] under [cross-reference marketing authorization law], but for purposes of this section does not include [exceptions].

(g) REPACKAGER.—The term "repackager" means an entity or person authorized by the [drug regulatory authority] to repack or relabel a prescription drug or package for further sale or distribution.

(h) SUPPLY CHAIN ENTITY.—The term "supply chain entity" means a manufacturer, repackager, drug distributor, or dispenser. An entity or person that provides warehousing, logistics, transportation, or other services on behalf of a supply chain entity but does not take ownership of a prescription drug is not a supply chain entity.

(i) SUSPICIOUS PRODUCT.—The term "suspicious product" means a prescription drug package for which, due to circumstances to be defined by [regulatory body], a supply chain entity has reason to believe the package is (1) counterfeit, diverted, stolen, or otherwise falsified; (2) intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; or (3) appears otherwise unfit for distribution such that the

**Commented [A1]:** *Explanatory Note: This definition is intended to include all entities in the distribution chain that take ownership of a prescription drug and are not manufacturers, repackagers, or dispensers.*

**Commented [A2]:** *Explanatory Note: This definition should be aligned to other existing regulatory definitions that may exist in your market. Together, the terms 'manufacturer' and 'repackager' should include all entities that package prescription drugs.*

**Commented [A3]:** *Explanatory Note: This term defines the specific level of packaging that must be serialized. Related terminology has created significant confusion in other markets. This definition is intended to allow the manufacturer to identify and serialize the smallest package it intends for sale to a dispenser (often this is referred to as the 'saleable unit'). Final verification activities are carried out by the dispenser, so this will allow the dispenser to conduct such verification. For example, if a manufacturer sells ten-packs of vials to dispensers, the ten-pack would be serialized. The dispenser then verifies the ten-pack prior to opening and using the individual vials. Serialization of the individual vials is unnecessary and would add significant complexity to the verification process.*

*In some contexts, packaging is often referred to as 'primary,' 'secondary,' or 'tertiary.' The primary, secondary, and tertiary package terminology is distinct from the terminology commonly used to refer to trade items. These two sets of terms do not always align. In practice, the saleable unit could be a pill bottle (which is a primary package), a carton containing a blister strip (which is a secondary package), or even a ten-pack of individual vials that could be dispensed to a patient.*

**Commented [A4]:** *Explanatory Note: Nearly every country that has implemented serialization and verification has limited its requirements to prescription drugs. Non-prescription drugs ("over-the-counter" drugs) do not typically present the same level of risk for diversion and counterfeiting, and Inclusion of them would add unnecessary complexity. For example, depending where non-prescription drugs may be sold, inclusion of non-prescription drugs would drastically expand the number of "dispensers" that must engage in verification activities and include many entities that are not typically regulated by health authorities.*

**Commented [A5]:** *Explanatory Note: It may be appropriate to excluded specific types of prescription drugs based on the local market. For example, blood for transfusion is generally considered to be a "prescription drug" in the United States, but it is exempted under the Drug Supply Chain Security Act (DSCSA) because a different system for tracking blood already existed.*

**Commented [A6]:** *Explanatory Note: Obligations are limited to entities that take ownership of a prescription drug. An entity that owns a prescription drug is responsible for that drug for the duration of the time it owns the drug. If the owner chooses to use other service providers (such as a trucking company), the owner retains responsibility for the drug and establishes a contractual relationship with the service provider.*

product would be reasonably likely to result in serious adverse health consequences or death to humans.

(j) TRACING.—The term "tracing" means the ability to identify the origin and characteristics or history of a particular package upstream based on criteria determined at each point of the supply chain by reference to records held about it.

(k) UNIQUE IDENTIFIER.—The term "unique identifier" means a standardized graphic that includes the following information, in both human readable form and encoded in a 2D DataMatrix that conforms to relevant standards developed by GS1 Global:

(1) the Global Trade Item Number (GTIN) of the prescription drug;

(2) the expiration date of the prescription drug, expressed in the format "YYMMDD" where "YY" represents the two-digit year, "MM" represents the two-digit month, and "DD" represents the two-digit day;

(3) the batch or lot number of the prescription drug, expressed as a variable alphanumeric code up to 20-digits in length; and

(4) the serial number of the package, expressed as up to 20 alphanumeric digits or characters unique for that GTIN, variable with degree of randomness at the discretion of the manufacturer or repackager.

The unique identifier enables identification of an individual pack of a medicinal product and verification its authenticity.

(l) VERIFICATION OR VERIFY.—The term "verification" or "verify" means determining whether the unique identifier affixed to, or imprinted upon, a package corresponds to a unique identifier assigned by the manufacturer or the repackager, as applicable.

**Section 3. Serialization.**

(a) IN GENERAL.—Beginning not later than 4 years after the date of enactment of the [Act], the manufacturer or repackager of a prescription drug shall affix or imprint a unique identifier to each package of such prescription drug prior to introducing such package into commerce in [name of adopting country] by sale to a supply chain entity.

(1) Compliance with the requirement in subsection (a) shall be based upon the date on which such prescription drug is packaged by the manufacturer or repackaged by the repackager in its ordinary course of business.

(2) Prescription drugs packaged by the manufacturer or repackaged by the repackager prior to the date that is 4 years after the date of enactment of the [Act] may continue to be sold by the manufacturer, repackager, and other supply chain entity on and after such date

**Commented [A7]:** *Explanatory Note: The WHO uses the term "falsified" to mean Medical products that deliberately/fraudulently misrepresent their identity, composition or source. This definition is intended to align to the WHO definition of "falsified" but provide more detail. This definition could be replaced with the WHO definition.*

**Commented [A8]:** *Explanatory Note: These four data elements are aligned with standard practice in other markets that have implemented serialization. This definition is critical to ensure global harmonization and facilitate global trade.*

*Additional data elements (such as national drug codes) are not necessary and should not be added. Additional information can be included in the master data and other data associated with a package by tying that information to the Global Trade Item Number (GTIN). By including such information in related data files, the same practical results are achieved, and the unique identifier remains harmonized for trade by limiting the printed unique identifier to the four standard elements.*

**Commented [A9]:** *It is not necessary to include or encode a national drug code. If a national code is needed, separate rules can be established to incorporate or convert a national drug code into a GTIN.*

**Commented [A10]:** *Explanatory Note: This timeline assumes timely release of any additional regulations or guidelines that are needed in the market.*

**Commented [A11]:** *Explanatory Note: Manufacturers and repackagers often maintain many months'—or longer—of inventory. This provision allows a manufacturer or repackager to continue the sale of such inventory even if it is not serialized. For example, if 4 years after the date of enactment is January 1, 2023, then a manufacturer must serialize any products that it packages on or after January 1, 2023. Non-serialized product that was packaged in December 2022 and remains in the manufacturer's inventory may continue to be sold on and after January 1, 2023 without being serialized. Paragraph (2) allows subsequent entities to engage in sales of non-serialized product as well.*

*These provisions are commonly referred to as "grandfathering."*

without a unique identifier until the expiry date of such product.

(b) MAINTENANCE OF DATA.—The manufacturer described in subsection (a) shall maintain information about each such unique identifier until the date that is 2 years after the expiry of the prescription drug to which the unique identifier is affixed or imprinted.

**Section 4. Verification.**

(a) MANUFACTURERS AND REPACKAGERS.—Beginning not later than 4 years after the date of enactment of the [Act], each manufacturer and repackager shall have systems in place to enable the manufacturer or repackager to verify the unique identifier affixed to, or imprinted on, a package of its prescription drug upon request by a supply chain entity or the [drug regulatory authority].

(b) DISPENSERS.—Beginning not later than 4 years after the date of enactment of the [Act], each dispenser shall verify the unique identifier affixed to, or imprinted on, any package of prescription drug prior to dispensing or otherwise providing such prescription drug to a patient or consumer.

(c) SUSPICIOUS PRODUCT.—Beginning not later than 4 years after the date of enactment of the [Act], each supply chain entity shall have reasonable systems and processes in place to identify suspicious products in its possession. Upon identification of a suspicious product, the supply chain entity shall quarantine the suspicious product and verify the unique identifier affixed to, or imprinted on, each package of it.

(d) INVALID PACKAGE.—A supply chain entity that possesses an invalid package shall:

(1) Quarantine the invalid package until the manufacturer or [drug regulatory authority] can properly dispose of it.

(2) Promptly notify the [drug regulatory authority] of the invalid package and and coordinate with the [drug regulatory authority] in any related investigation.

(e) VERIFICATION SYSTEMS.—The verification systems described in subsections (a), (b), and (c) shall—

(1) be interoperable electronic systems and shall be developed with, and account for, the input of stakeholders.

(2) Include a method by which a dispenser indicates that a verification request it initiates pursuant to subsection (b) is expected to be the final verification request initiated with regard to that unique identifier.

(3) include a method by which a verification request described in paragraph (2) causes the manufacturer to update the status of the unique identifier such that future requests for verification with regard to that unique identifier will result in a response that the package is invalid.

**Commented [A12]:** *Explanatory Note: As stated in the Purpose (Section 1), serialization is intended to secure the distribution chain—from manufacturer to dispenser. In other words, it is intended to ensure the prescription drug that is dispensed is valid. This Act does not include verification by individual patients. Although some stakeholder support verification by patients, that activity raises very significant challenges and should only be pursued much later after dispenser verification has been implemented. For example, patient-level verification opens the system to exponentially more users, which raises significant questions about how those users are authenticated and increases the risk of improper access (which undermines the entire system). It also complicates the decommissioning process (below). From a practical perspective, simply maintaining the customer service system for a system with millions of patient-users would be expensive and complicated. Finally, as discussed above, serialized packages may include multiple patient-units, in which case the patient would not even have access to the unique identifier.*

**Commented [A13]:** *Explanatory Note: This provision requires each dispenser to check the validity of the package before dispensing it to a patient. It also provides the pharmacy with flexibility to check the validity at the point in its process that is most efficient for them. For some dispensers/types of drugs, this may be at the point of sale/dispensing. For others, this may be at the time the drug is received and put into the dispenser's inventory.*

*Explanatory Note: This Act does not include requirements for tamper-evident packaging. Some markets do require tamper-evident packaging, and depending on your local market considerations, it may or may not be appropriate. Tamper-evident package helps to reduce the risk that legitimate packaging will be reused to introduce counterfeits and increases the likelihood that the product contained in the valid package is legitimate. Conversely, the complexity and cost of adding tamper-evident features could jeopardize the availability of certain low-volume drugs.*

**Commented [A14]:** *Explanatory Note: This should include both virtual quarantining and/or physical quarantining, at the entity's discretion.*

**Commented [A15]:** *Explanatory Note: The requirements in paragraphs (2) and (3) are commonly referred to as "decommissioning." This process effectively invalidates the unique identifier once it has been dispensed. If, for example, the package were then used to introduce a counterfeit product into the distribution chain, the subsequent verification of the counterfeit would be returned as "invalid."*

**Section 5. Tracing.**

(a) ADDITIONAL STUDY.—Not earlier than 6 years after the date of enactment of the [Act], the [drug regulatory authority] may, if necessary and appropriate, undertake a study to—

(1) identify remaining risks to the security of the domestic pharmaceutical supply chain that have not been, and cannot be expected to be, minimized by the full implementation of systems for verification described in Section 4 of this [Act], and

(2) whether additional systems for the tracing of prescription drug packages would be likely to minimize such remaining risks.

(b) TRACING REQUIREMENTS.—If the study described in subsection (a) identifies remaining risks to supply chain security that cannot be expected to be minimized by the full implementation of system for verification and would likely be minimized through additional systems for tracing, the [drug regulatory authority] may establish additional requirements necessary to implement systems for the tracing of pharmaceutical packages through the domestic pharmaceutical supply chain.

**Section 6. Exemptions and Waivers.**

(a) PROCESS TO BE ESTABLISHED.—Not later than 1 year after the date of enactment of the [Act], the [drug regulatory authority] shall establish a process by which—

(1) a manufacturer or repackager may request an exemption or waiver from the requirements described in Sections 3 and 4, with respect to one or more of the prescription drugs it manufacturers or repackages, because—

(A) the unique attributes of the prescription drug package, such as the size of the container, make compliance with Sections 3 and 4 impossible or unreasonable,

(B) compliance with Sections 3 and 4 would result in an undue economic hardship for the manufacturer or repackager, or

(C) compliance with Sections 3 and 4 would otherwise create unreasonable risks to the availability of a prescription drug to patients.

(2) a supply chain entity may request an exemption or waiver from the requirements described in Sections 3 and 4 because—

(A) compliance with Sections 3 and 4 would result in an undue economic hardship for the supply chain entity, or

(B) compliance with Sections 3 and 4 would otherwise create unreasonable risks to the availability of a prescription drug to patients.

**Commented [A16]:** *Explanatory Note: For numerous reasons articulated in other RxGPS materials, verification can provide significant public health benefit with significantly less complexity than tracing. In some limited circumstances, the incremental benefits of tracing may be appropriate. This provision is intended to provide the regulatory authority with the statutory authority to implement tracing if needed. If statutory authority is not needed to implement tracing, this Section 5 may be removed.*

(b) PROCESS TO BE ESTABLISHED.—The [drug regulatory authority] shall approve or deny—

(1) A request submitted pursuant to subparagraph (1)(A) within 90 days, and

(2) All other requests within 180 days.