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

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

*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**.*

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|  | **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.**1. 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.
2. 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.
3. 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.
4. MANUFACTURER.—The term “manufacturer” means the entity or person authorized by the [drug regulatory authority] to produce and market a prescription drug.
5. 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.
6. 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].
7. 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.
8. 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.
9. 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 product would be reasonably likely to result in serious adverse health consequences or death to humans.
10. 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.
11. 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.1. 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.**1. 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 without a unique identifier until the expiry date of such product.
2. 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.** 1. 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].
2. 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.
3. 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.
4. 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.
5. 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.

**Section 5. Tracing.** 1. 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.
2. 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.** 1. 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—
		1. 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,
		2. compliance with Sections 3 and 4 would result in an undue economic hardship for the manufacturer or repackager, or
		3. 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—
		1. compliance with Sections 3 and 4 would result in an undue economic hardship for the supply chain entity, or
		2. compliance with Sections 3 and 4 would otherwise create unreasonable risks to the availability of a prescription drug to patients.
2. 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.
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