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Partnership for DSCSA Governance

PDG Point of View on Waivers, Exceptions, and Exemptions

The requirements of the Drug Supply Chain Security Act (DSCSA) generally apply to all transactions of a finished prescription drug for human use, including the trading partners who are engaged in those transactions. Some or all of DSCSA requirements are inapplicable, however, in four instances.

1. **Statutory Exemptions:** The definition of a "product" (FD&C Act § 581(13)) exempts certain prescription drugs from DSCSA requirements, such as blood or blood components intended for transfusion, and radioactive drugs. Similarly, the definition of a "transaction" (FD&C § 581(24)) exempt certain types of transactions from DSCSA requirements, such as distribution of a product for emergency medical reasons and the distribution of samples in certain instances.
2. **FDA-Issued Exemptions:** Section 582(a)(3)(iii) authorizes FDA to issue (upon stakeholder request or of its own initiative) additional exemptions for specific *products or transactions.* Such exemptions are subject to a biennial review and renewal by FDA.
3. **Waivers:** Section 582(a)(3)(i) authorizes FDA to waive DSCSA requirements, upon request, for an authorized manufacturer, repackager, wholesale distributor, or dispenser if FDA determines that such requirements "would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration . . .." Unlike exemptions—most of which apply to types of products or transactions across *all* trading partners—a waiver applies to one specific, individual trading partner.
4. **Exceptions:** Section 582(a)(3)(ii) authorizes FDA to issue an exception to the DSCSA requirements relating to product identifiers, upon request by a manufacturer or repackager, "if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance."

The applicability (or inapplicability) of statutory exemptions is determined by each individual trading partner. At least regarding statutory "product" exemptions, that determination is most often made by the manufacturer and relied upon by downstream trading partners. Conversely, FDA-issued exemptions, waivers, and exceptions are issued by FDA. In those determinations, FDA commonly indicates how the trading partner should communicate the existence of the exemption, waiver, or exception.

Impact

Generally, transaction information is not required when an exemption, waiver, or exception applies, which creates deviations from the typical flow of transaction information. Unfortunately, there is no single repository or other single source of truth that can be referenced to determine when an exemption, waiver, or exception applies. This has the potential to create significant disruption in the supply chain.

In practice, the purchaser of a product will receive physical product without accompanying transaction information. Absent systems and processes to recognize the applicability of an exemption, waiver, or exception, the purchasers' systems and processes should identify this as

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a misalignment exception (*i.e.*, a misalignment between the product and data), preventing the product from further transaction until the two trading partners communicate and identify the applicability of the exemption, waiver, or exception. This process will slow the movement of good product and require both parties to dedicate time and resources to identify the perceived misalignment.

Solution Challenge

The existence of a single source of truth that identifies all products, transactions, and parties subject to an exemption, waiver, or exception would—in theory—avoid many of the challenges noted above and enable product to continue to move efficiently. The establishment such a single source of truth is simply infeasible, however, for many reasons. Among those reasons:

1. Each manufacturer is responsible for determining whether a statutory exemption applies to its products, and different manufacturers may reach different conclusions with regard to the same or similar products.
2. Waivers, exceptions, and non-statutory exemptions are issued by FDA, and FDA has not expressed a willingness to publish those decisions broadly. In fact, making those decisions widely known would identify potential gaps that could be exploited by bad actors.
3. It is likely infeasible to convince a critical mass of trading partners to self-disclose waivers, exceptions, and statutory exemptions upon which they rely. In fact, there may be commercial or other reasons a trading partner affirmatively desires not to make them widely known.
4. A comprehensive list of all exemptions, waivers, and exceptions would be continually evolving, and it would be extremely difficult to keep such a list current.

For these reasons and others, PDG does not anticipate the existence of a single source of truth for even a significant portion of the exemptions, waivers, and exceptions that exist.

Recommendation

It is important that trading partners actively plan for the management of exemptions, waivers, and exceptions. Specifically, PDG recommends:

1. Trading partners that determine a statutory exemption is applicable or obtain a waiver, exemption, or exception from FDA should be proactive in communicating that exemption, waiver, or exception to its direct trading partners.
2. Trading partners should proactively determine how their systems and processes will manage both known and unanticipated exemptions, waivers, and exceptions.
3. FDA should evaluate and identify steps it can appropriately take to help trading partners better anticipate exemptions, waivers, and exceptions and avoid supply chain disruption.