Complying with the Authorized Trading Partner Requirements of the DQSA

By Eric Marshall

The Drug Quality and Security Act (the DQSA), enacted on November 27, 2013, enhances the security of the pharmaceutical supply chain by establishing a national system for the traceability and serialization of certain pharmaceutical products and for establishing national licensing standards for wholesale distributors and third-party logistics providers. While a great deal of attention has been paid to the information-sharing obligations that commence on January 1, 2015, the serialization obligations that begin in 2017, and the federal licensing standards that will be developed and implemented over the next few years, significantly less dialogue has occurred with respect to the small, but equally important, provision that requires all of an industry participant's trading partners to be "authorized trading partners." The traceability provisions will be immensely valuable in identifying illegitimate drug products and establishing where those products came from and how they entered the supply chain. It is the authorized trading partner provisions, however, that provide a key legal enforcement mechanism to help prevent illegitimate products from entering the supply

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chain by closing the supply chain to disreputable companies.

This article explains the authorized trading partner provisions in the DQSA, identifies challenges related to those provisions, and offers recommendations for complying with the related obligations.

The Authorized Trading Partner Provisions

The DQSA established numerous obligations for prescription drug manufacturers, wholesale distributors, dispensers (*e.g.*, retail and hospital pharmacies), and repackagers intended to secure the pharmaceutical distribution supply chain. The bulk of the requirements relate to the sharing of information among supply chain participants and the development of systems and processes for identifying and investigating suspect drug products.[1] A provision in the subsection of the DQSA applicable to each of those sectors provides, "Beginning not later than January 1, 2015, the trading partners of a [manufacturer, wholesale distributor, dispenser, or repackager] may be only authorized trading partners."[2] In essence, this provision requires that supply chain participants only accept drug products from and transfer drug products to persons that are properly licensed or registered to engage in the relevant supply chain activities.

Many within industry have colloquially described the authorized trading partner provision as a requirement that companies only work with authorized trading partners. That statement technically overstates the requirement. Instead, the DQSA requires that each of an entity's trading partners must be an authorized trading partner. Therefore, the DQSA leaves open the possibility of working with non-trading partners that are not authorized.

The DQSA defines a "trading partner" as:

> a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.[3]

It is important to note that although third-party logistics providers generally are not subject to most of the traceability requirements because they do not take ownership of the products they handle, they are considered trading partners and must be authorized.

The way in which a trading partner becomes "authorized" varies by sector.

- A **manufacturer** or **repackager** is authorized if it is validly registered with the FDA under section 510 of the Food, Drug, and Cosmetic Act (FDCA).
- A **wholesale distributor** is authorized if it is validly licensed under the new licensing scheme established by the DQSA and complies with the reporting obligations established by the DQSA.
- A **third-party logistics provider** is authorized if it is validly licensed under the new licensing scheme established by the DQSA and complies with the reporting obligations established by the DQSA.
- A **dispenser** is authorized if it is validly licensed under state law.[4]

Accepting product from or transferring product to a trading partner that is not authorized constitutes a prohibited act under the FDCA. A prohibited act carries potential penalties of imprisonment for not more than one year and a fine of not more than $1,000 with penalties for subsequent or intentional violations of up to three years imprisonment and up to a $10,000 fine. Each violation is separately subject to these penalties, and the Federal Criminal Code also authorizes a general fine of up to $250,000 for individuals and $500,000 for entities. Equitable remedies, such as restitution, disgorgement of profits, and product seizure are also available.[5]

Authorized Distributors of Record Distinguished

It is important to distinguish an authorized trading partner from an authorized distributor of record (ADR). The Prescription Drug Marketing Act (PDMA) currently requires that certain distributors be designated as ADRs by a manufacturer. Drug samples may only be distributed by an ADR (or the manufacturer itself), and ADRs are exempt from passing the federal pedigree information currently required under PDMA. The DQSA will eliminate the federal pedigree requirement under PDMA on January 1, 2015, but ADR status will continue to be relevant for purposes of sample distribution.[6]

An authorized trading partner differs from an ADR in several important ways. First, ADR status attaches only to distributors, but the authorized trading partner requirements under the DQSA apply to trading partners from all sectors of the supply chain. Second, ADR status requires designation by a manufacturer and an "established [and]

ongoing relationship to distribute such manufacturer's products."[7] The DQSA requirement that all trading partners be authorized applies to all transactions,[8] regardless of whether the trading partners have an ongoing relationship and regardless of any designation by the other party to the transaction. Finally, unlike an ADR with respect to the federal pedigree requirements of PDMA, authorized trading partner status does not impact the information that must be shared by trading partners in a transaction under the DQSA's traceability provisions.[9] The DQSA requires all manufacturers, wholesale distributors, dispensers, and repackagers to share specific information for each transaction regardless of ADR status.

Identifying Authorized Trading Partners

While the DQSA makes clear that each trading partner of a manufacturer, wholesale distributor, dispenser, or repackager must be authorized, it is less clear how a company will determine that its trading partners are authorized. That determination will vary by sector.

Manufacturers and Repackagers

Manufacturers and repackagers will likely be the easiest entities for which to determine authorized status. The FDA maintains a public database of drug establishments registered under section 510 of the FDCA.[10] However, even with that database, there is potential for uncertainty. Specifically, in order to be an authorized trading partner, the DQSA requires that a manufacturer's registration be "valid." It is unclear at this time how the phrase "valid registration" will be interpreted and applied, but potentially it could require companies to monitor trading partners' authorized status on an ongoing basis and could potentially open the door to cascading liability in the event a manufacturer or repackager's registration is revoked.

Dispensers

Interestingly, dispensers are the only entities for which authorized status is entirely dependent on state regulation. A dispenser is authorized if it is validly licensed under state law, and those licensure requirements will vary from state to state. Many states maintain a public database that can be used to confirm a pharmacy's licensure,[11] but again, the phrase "valid license" presents some uncertainty.

Wholesale Distributors

Authorized status for wholesale distributors is tied to the licensure scheme established by the DQSA. The DQSA requires FDA to establish, by regulation, uniform federal licensing standards for wholesale distributors that cover seven topics identified in the DQSA. States will continue to license wholesale distributors, but they must utilize the federal standards. The FDA will issue a federal license to wholesale distributors in states that do not implement a licensing program that uses the federal standards.[12]

The FDA is not required to publish the federal licensing standards until November 27, 2015,[13] and the standards will not be effective until two years after publication. Therefore, the federal licensing standards are unlikely to be effective until late 2017. However, the DQSA immediately preempted all state "standards, requirements, or regulations with respect to wholesale prescription drug distributor . . . licensure that are inconsistent with, less stringent than, directly related to, or covered by" the federal standards.[14] The licensure requirements for wholesale distributors that apply until the federal standards are effective are, therefore, unclear. It appears that states will continue to license wholesale distributors until that time, just as they do now, but it remains to be seen if or how states will be permitted to revise their licensure requirements during that interim period.

The DQSA also requires wholesale distributors to report the following information to the FDA on an annual basis beginning January 1, 2015:

- Each state by which the wholesale distributor is licensed and the relevant license number.
- The name, trade name, address, and contact information of each facility.

Wholesale distributors must also report any significant disciplinary actions within a reasonable period of time. The FDA has not announced the system or process that will be used for annual reporting, but it is required to establish a public database of authorized wholesale distributors by January 1, 2015.

A wholesale distributor is considered authorized if it is validly licensed under the DQSA licensure scheme and complies with the DQSA reporting requirements. However, until the effective date of the federal licensing standards, a wholesale distributor is considered "authorized" if it has a valid license under state law. Once the federal standards are effective, authorized status will continue to depend on state licensure in those states that align their licensing standards with the federal standards. It appears that most states will revise their licensure requirements to do so. Most states maintain a public database of licensed wholesale distributors,[15] and the FDA database will also provide relevant licensure information.

The DQSA requires a wholesale distributor to be licensed in each state in which it is engaged in wholesale distribution. It is unclear how licensure in a state

unrelated to a company's relationship with a wholesale distributor will affect authorized status. For example, if an Ohio pharmacy works with a national wholesale distributor only in Ohio, it is unclear how the wholesale distributor's licensure status in other states will impact its status as an authorized trading partner when interacting with the Ohio pharmacy. It is similarly unclear whether the Ohio pharmacy would have any obligation, or even the ability, to verify that the distributor is licensed in all the states in which it distributes drugs.

Verifying that a wholesale distributor has complied with the DQSA reporting requirements will also be difficult. The FDA database will likely provide much of the information needed to determine compliance with reporting obligations, but it will be particularly difficult to determine whether a wholesale distributor has reported disciplinary actions as required.

Third-Party Logistics Providers

Third-party logistics providers themselves are not obligated to work only with trading partners that are authorized, but manufacturers, wholesale distributors, dispensers, and repackagers are required to work only with third-party logistics providers that are authorized beginning January 1, 2015. Authorized status is tied to the DQSA licensing and reporting requirements for third-party logistics providers.

Like wholesale distributors, the DQSA requires the FDA to establish federal licensing standards for third-party logistics providers. States will be able to license third-party logistics providers using the federal standards, but a federal license will be available in states that do not establish a licensure program. The regulations establishing the federal licensing standards are not required to be issued until November 27, 2015 and will not be effective until one year after publication. Therefore, the federal licensing standards are unlikely to be effective until late 2016.[16]

Beginning January 1, 2015, third-party logistics providers must annually report to the FDA the state by which each facility is licensed, the relevant license number, and the name and address of the facility, including all trade names. Unlike with wholesale distributors, the FDA is not required to establish a public database of third-party logistics providers.

A third-party logistics provider is considered authorized if it is validly licensed under the DQSA licensure scheme and complies with the DQSA reporting requirements. However, until the federal licensing standards are effective, a third-party logistics provider is considered "licensed" unless the FDA determines that it "does not utilize good handling and distribution practices and publishes notice thereof." Therefore, until the effective date of the federal licensing standards, a third-party logistics provider will be considered an authorized trading partner if (i) it complies with the DQSA reporting requirements, and (ii) the FDA has not affirmatively revoked its "deemed licensed" status. Determining whether a third-party logistics provider has complied with its reporting obligation will be especially difficult if the FDA does not develop a database of the reported information.

Confirming the authorized status of a third-party logistics provider after the federal licensing standards are effective will be more complicated. The DQSA requires third-party logistics providers to be licensed in each state where it has a facility. If that state does not have a licensure program, the third-party logistics provider must obtain a federal license. Third-party logistics providers that do not have a federal license must also be licensed in each state into which it delivers drug products. There is some ambiguity around whether a third-party logistics provider that has a federal license must obtain an available state license in states in which it does not have a facility. Resolution of this issue will be important to determining whether a third-party logistics provider is authorized. In addition, since Florida was previously the only state with a licensure program for third-party logistics providers, it remains to be seen how easy or difficult it will be to verify whether a third-party logistics provider is licensed or authorized.

Recommendations

As explained in this article, a number of factors will create potential challenges in ensuring compliance with the DQSA requirement that all trading partners be authorized trading partners. The following practices will help to reduce the risk of violating the authorized trading partner provisions of the DQSA:

- Secure strong representations and warranties from each trading partner that it is an authorized trading partner under the DQSA, will take all actions necessary to remain authorized, and will provide prompt notification of any changes in its authorized status. Representations and warranties by wholesale distributors and third-party logistics providers should specifically require compliance with the DQSA reporting requirements and include attestations that the wholesale distributor or third-party logistics provider has complied with its licensure obligations in all states in which it does business.
- Secure strong representations and warranties from each trading

partner that it will comply with its full scope of obligations under the DQSA and will cooperate with you in carrying out your obligations under the DQSA (*e.g.*, by assisting in the investigation of suspect products).

- Establish a documented process that takes reasonable steps to verify that all trading partners are authorized, for example, by reviewing public databases of relevant state and federal licensing and registering authorities. Verification should occur prior to the first transaction with the trading partner and on a reasonable periodic basis thereafter.
- With respect to trading partners that are third-party logistics providers, until the effective date of the federal licensing standards, monitor for the revocation of the third-party logistics provider's deemed licensure by the FDA.
- Monitor the development of licensing requirements and programs for wholesale distributors and third-party logistics providers to understand licensing obligations and identify opportunities for verifying authorized status.

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1. The obligations are set out in section 582 of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360eee-1. I will refer to these provisions of the DQSA as the "traceability" provisions. For a detailed overview of the DQSA, *see* Ventimiglia, V. & Marshall, E., *What are the Key Implementation Challenges in the Supply Chain Security Provisions of the Drug Quality and Security Act?* in FDLI's Food and Drug Policy Forum (Dec. 20, 2013).
2. 21 U.S.C. §§ 360eee-1(b)(3), (c)(3), (d)(3), and (e)(3). I will refer to these provisions as the "authorized trading partner provisions" or the "authorized trading partner requirements."
3. 21 U.S.C. § 360eee(23)
4. 21 U.S.C. § 360eee(2).
5. 18 U.S.C. §§ 3551, 3571; 21 U.S.C. §§ 331(t), 333.
6. In negotiating distribution agreements, manufacturers should consider the "value" of ADR status under the DQSA model.
7. 21 U.S.C. § 353.
8. This article uses the term "transaction" as defined in the DQSA. Subject to numerous exemptions, a transaction is the transfer of a prescription drug product in which a change of ownership occurs. 21 U.S.C. § 360eee(24).
9. Primary wholesale distributors are exempt from providing certain types of transaction information, but that exemption is not tied to ADR status or authorized trading partner status.
10. The FDA database is available at http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm.
11. Indiana (https://mylicense.in.gov/everification/Search.aspx?facility=Y), New York (http://www.op.nysed.gov/opsearches.htm#rx), and Utah (https://secure.utah.gov/llv/search/index.html) are among the many states that maintain public databases.
12. 21 U.S.C. § 360eee-2.
13. Presumably, these will be final regulations and proposed regulations will be released sooner.
14. 21 U.S.C. § 360eee-4(b).
15. A list of the state databases is available at http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm.
16. 21 U.S.C. § 360eee-3.