



## **Recommended Guidelines for Pharmaceutical Distribution System Integrity**

### **Preamble**

Prescription drug wholesalers, like all nongovernmental entities, do not have the investigative powers and resources to guarantee that certain products are not counterfeit. But they are uniquely situated to perform due diligence in order to protect the integrity of the pharmaceutical distribution system. Even with due diligence, in today's fast paced, just-in-time market, it is not always possible to determine the authenticity of specific prescription drugs being offered for sale. But rigorous due diligence can establish whether the sources of those prescription drugs meet certain criteria which provide a greater level of assurance that those sources are legitimate and present no reasonable probability of distributing counterfeit prescription drugs.

Experience with counterfeit drug distributors indicates that they are distinctly different from legitimate prescription drug wholesalers. Therefore, the first step in defining due diligence criteria is to identify the pertinent characteristics shared by legitimate prescription drug wholesalers. Once identified, these pertinent characteristics are the basis for the due diligence requirements contained herein. The logical nexus between the characteristics of legitimate prescription drug wholesaler and the due diligence criteria is an important safeguard to help assure the integrity of the prescription drug distribution system without disadvantaging law abiding wholesalers.

Legitimate prescription drug wholesalers share the following pertinent characteristics:

1. Their business is structured as a "going concern"
2. They demonstrate appropriate financial responsibility
3. They have robust operational standards
4. They have rigorous compliance systems
5. They can demonstrate their corporate and compliance history

An entity that does not display these characteristics may be identified as a suspect source of prescription drugs, or a source that may present an unreasonable risk to the integrity of the pharmaceutical distribution system and the public health.

The due diligence criteria and due diligence best practices in this guideline have been designed to identify facts and information about an entity that would demonstrate whether that entity displays the characteristics of a legitimate prescription drug wholesaler or, in the alternative, is reasonably likely to be a suspect source of prescription drugs. It is recommended that a prescription drug wholesaler:

1. Independently apply these Guidelines when evaluating proposed purchases from prescription drug wholesaler;
2. Use the due diligence best practices to determine whether the source of the prescription drugs meets the due diligence criteria; and
3. Purchase prescription drugs from sources that substantially demonstrate the characteristics of a legitimate prescription drug wholesaler in accordance with 2, above.

These Guidelines, therefore, outline best practices for the exercise of due diligence by prescription drug wholesalers to enhance the detection and elimination of illegitimate sources which market counterfeit products.

The public interest in drug product safety and efficacy is well served by this industry effort to detect and prevent counterfeit products from entering the prescription drug distribution pipeline in the United States.

## **I. Initial Information Request**

When a prescription drug wholesaler is considering making purchases from another prescription drug wholesaler for the first time, it is recommended that a completed information request be obtained from the prospective selling wholesaler prior to the purchase. The information request should include the following information and it is recommended that this information request be updated annually:

1. A listing of states the company is domiciled in and shipping into and copies of all current state/federal regulatory licenses/registrations including license/registration number(s). (Note: purchaser is advised to check to ensure expiration dates have not passed);
2. The company's most recent site inspection(s) dates and inspection reports or resolutions (both state and federal inspections);
3. The minimum liability insurance limits the company maintains including general as well as product liability insurance;
4. All other "doing business as" (d/b/a's) names, and formerly known as (f/k/a's), including all affiliated businesses;
5. A complete list of all corporate officers;
6. A complete list of all owners of greater than 10 percent of the business unless it is a publicly-held company;
7. A list of all disciplinary actions by state/federal agencies against the company as well as principals, owners or officers over the last ten years, or since the company was first licensed, or any of the listed individuals were first in the prescription drug wholesale business;
8. The number of employees at the facility and screening procedures for hiring;
9. A full description of each facility/warehouse. Include all locations utilized for drug storage and/or distribution), including:
  - a. Square footage;
  - b. Security and alarm system description;
  - c. Terms of lease/own;
  - d. Address; and
  - e. Temperature and humidity controls.
10. A description of prescription drug import/export activities, including:
  - a. A listing of all countries importing from and exporting to;
  - b. A listing of what products are being imported/exported from each country identified in 10a;
  - c. The nature of the company's import/export activities pertaining to prescription drugs (i.e., repackaging, re-labeling, etc.); and
  - d. How are products designated for import/export separated from domestic inventory?
11. A description of the process the company uses to validate and certify its suppliers and purchases including the supplier's ADR status, (particularly if the process differs from the Recommended Guidelines for Pharmaceutical Distribution System Integrity).

12. A list of the classes of trade (e.g., manufacturer, wholesale, retail, hospital, institutional, clinics, etc.) the seller is purchasing from or selling his/her product from or to.
13. Available financial statements or SEC filings.
14. Systems and procedures in place for prompt reporting of any suspected counterfeit, stolen or otherwise unlawful prescription drug products or buyers or sellers of same to the appropriate state and federal authorities and manufacturer(s) of the product(s).

## **II. Certification of ADR Status**

If the selling prescription drug wholesaler selling the product claims to be an ADR, it is recommended that the prescription drug wholesaler purchasing the product obtain a written statement from the seller stating that it is an ADR and on what basis. It is also recommended that the purchaser independently verify the seller's ADR status on the initial purchase and then at least annually thereafter.

## **III. Background Check**

It is recommended that the purchaser conduct a background check of any prescription drug wholesaler it conducts business with prior to the initial transaction. This background check should include:

1. Subject to the requirements of the Fair Credit Reporting Act:
  - a. A criminal background and criminal and civil litigation check of all company officers, key management, principals and owners with 10 percent or greater interest in the company (the latter applying to non-publicly held companies only);
  - b. A driver's license and social security verification of all company officers, key management and owners;
  - c. Before completing a background check on the referenced individuals in 1a and 1b above, the purchaser must obtain the written consent of each such individual, clearly indicating how the information will be used. If the purchaser decides not to purchase from the prescription drug wholesaler based on the background information obtained, the purchaser must notify the individual (orally or in writing) in accordance with the notice requirements of the Fair Credit Reporting Act, 15 U.S.C. §1681(a);
2. A credit history maintained by an independent third party credit evaluation organization;
3. A check of the national database of licensed prescription drug wholesalers (if such a database is created);
4. A check to determine if civil/criminal litigation exists against the company; and
5. Verification of the date of incorporation and years in business, place of incorporation and form of entity.

## **IV. Physical Site Inspection**

It is recommended, prior to an initial purchase, that a purchaser conduct a physical site inspection(s) of any prescription drug wholesaler seller it intends to do business with to ensure that the company's facility (ies) is/are in compliance with appropriate storage and operational conditions and practices. These inspections should be conducted on a biannual basis. A third party, so long as not a prescription drug wholesaler, may be used to conduct the inspections on behalf of the purchaser. A standard checklist for site inspections should be utilized and incorporate the following:

### Administrative/Management

It is recommended that the purchaser:

1. Establish the authority, training, and experience of each individual providing the required information to them on behalf of the seller and each individual who controls and is responsible for the direct supervision of all persons who inspect, handle or have access to prescription drug products;
2. Request and examine the seller's organizational chart to identify key management and structure of the company; and
3. Verify the number of employees at the facility.

### Building (size, physical conditions, etc.)

It is recommended that the purchaser check the

1. Structural appearance and general integrity based on a visual inspection;
2. Square footage;
3. Year of construction;
4. General security and alarm system;
5. Climate control; and
6. Surrounding area (e.g., zoning)

### Operations

It is recommended that the purchaser examine the following:

1. Documentation of PDMA compliance status including receipt and provision of "identifying statements," ADR status, requirements for PDMA compliance guarantees, recordkeeping and compliance with state and federal laws relating to the purchase and sale of prescription drugs.
2. Procedures for stock rotation;
3. Policies and procedures for conducting inspections of samples of product purchases;
4. Visually inspect a sample of the seller's product;
5. Temperature monitoring program and documentation;
6. Systems/procedures for detecting adulterated/misbranded product, including systems and procedures to verify that manufacturer-identified anti-tampering devices are intact;
7. Systems/procedures for validating Identifying Statements;
8. Condition of medical product inventory in the warehouse;
9. Compliance with 21 CFR 1304.22 DEA recordkeeping requirements; and
10. Form of payment the seller uses to purchase product.

## **V. Seller Qualification**

Once the site inspection has been completed, the results should be discussed with those employees or representatives of purchaser who are responsible for approving new suppliers. If the seller's background check, the completed information request, and the site inspection are determined to be satisfactory and the purchaser obtains the appropriate internal approval of the new supplier, the seller should execute signed agreements or contract provisions with language specific to PDMA compliance and compliance with all state and federal laws relating to the purchase and sale of pharmaceuticals and that the purchaser will be notified if the seller receives information that the integrity or legal status of prescription drugs sold to purchaser has been called into question by the manufacturer, retailers, wholesalers, or state or federal authorities. The signed agreements should include language stating that the seller agrees to notify the purchaser of any changes in its information request within 30 days.

## **VI. Ongoing PDMA Compliance Review**

It is recommended that the purchaser conduct ongoing compliance reviews and document all findings. These reviews should include:

1. Verifying that the seller is meeting the requirements for obtaining an “Identifying Statement”, and that the “Identifying Statements” contain the required information;
2. Verifying that the seller has an effective process in place to authenticate the accuracy and integrity of the “Identifying Statement.”
3. Performing appropriate supplemental review actions when:
  - a. The “Identifying Statement” has more than three entities on it; or
  - b. The price of the product being sold is substantially less than the prevailing market prices.

## **VII. Additional Purchaser Responsibilities**

In addition to all the previous steps, it is also recommended that the purchaser:

1. Maintain an internal company list of non-complying/at risk companies that are not reputable, or otherwise suspect, whose products prescription drug wholesaler would not purchase, based upon prior experience or other criteria;
2. Maintain an internal list of non-complying/at risk products (i.e. biologics, previously counterfeited drugs) that the prescription drug wholesaler would not purchase from a non-manufacturing vendor (NMV) or non-ADR;
3. Have systems and procedures in place for prompt reporting of any suspected counterfeit, stolen or otherwise unlawful prescription drug products or buyers or sellers of same to the appropriate state and federal authorities and manufacturer(s) of the product(s).
4. Cooperate with state and federal regulatory authorities by promptly providing copies of requested records and other information relevant to administrative, civil and criminal investigations related to prescription drug products.

**Definitions for the  
Recommended Guidelines for  
Pharmaceutical Distribution System Integrity**

1. ADR means Authorized Distributor of Record as defined in
  - A. 21 CFR 203.3 or as defined under appropriate FDA guidances (e.g., FDA *Letter to Industry and Other Interested Persons*, Aug. 1, 1988) in the absence of final regulatory specification;  
OR
  - B. state laws;  
OR
  - C. The HDMA recommended guideline for the definition of the Authorized Distributor of Record<sup>1</sup> which is as follows
    - must be on the manufacturer's list
      - list to be updated monthly  
OR
    - have a written agreement currently in effect with the manufacturer  
OR
    - have a verifiable account<sup>2</sup> with the manufacturer and minimal transactional or volume requirement thresholds as follows :
      - 5000 sales units<sup>3</sup> per company within 12 months  
OR
      - 12 purchases (invoices) from manufacturer within 12 months

**whichever is more stringent.**

**(Note: It is recommended that your legal counsel be consulted to ensure that the most stringent definition is being applied)**

2. Identifying Statement is defined as specified in 21 CFR 203.50 or as defined under appropriate FDA guidances (e.g., FDA *Letter to Industry and Other Interested Persons*, Aug.1,1988) in the absence of final regulatory specification. In addition, any state laws that may include additional qualifications are included in this definition of Identifying Statement when doing business in or with entities located in those states.
3. Prescription Drug Wholesaler means state licensed Non-Manufacturer Vendors including both ADRs and non-ADR.

---

<sup>1</sup> There is a consensus that the definition of Authorized Distributor of Record should be enhanced from the 1988 Food and Drug Administration PDMA Guidance to incorporate elements of the Food and Drug Administration's 1999 regulation and objective criteria that can be met based on transactions with the pharmaceutical manufacturer. Usage of the HDMA definition is optional.

<sup>2</sup> "Verifiable account" means 1) an account which the manufacturer confirms (in written or oral form) is assigned to the customer in question or 2) copies of manufacturers' invoices containing a printed account number and the name and address of the customer are obtained.

<sup>3</sup> A sales unit is the unit of measure the manufacturer uses to invoice its customer for the particular product.