

# Wholesaler Safe Product Practices

To help thwart the counterfeiting and adulteration of pharmaceutical products and to suppress the illicit traffic in such products, [name of company] adopts the following practices:

## 1. Distribution Chain

[Name of company] will not trade any prescription pharmaceutical product that is sold more than three times in the supply chain from the Manufacturer to the Final Dispenser.

- a. Whenever [name of company] purchases any prescription pharmaceutical product from an entity other than a Manufacturer, it will:
  - i. purchase only from an Authorized Distributor of that Manufacturer or a wholesaler that has adopted these Wholesaler Safe Product Practices,
  - ii. if purchasing from an Authorized Distributor that has not adopted these Wholesaler Safe Product Practices, obtain a written certification from that Authorized Distributor that said product was purchased directly from the Manufacturer, and
  - iii. sell that product only to a Final Dispenser.
- b. If [name of company] purchases a prescription pharmaceutical product from a Manufacturer, it will sell that product only to a Final Dispenser or to a wholesaler that has adopted these Wholesaler Safe Product Practices and within the last 12 months certified its compliance as required by paragraph 3.
- c. [Name of company] will provide purchasers with pedigrees or pedigree information when and as required by any federal or state law.

## 2. Compliance

- a. [Name of company] will have compliance measures, subject to audit by its trading partners or third parties, designed to detect and prevent (i) the purchase or sale of any prescription pharmaceutical that will be sold more than three times in the supply chain from the Manufacturer to the Final Dispenser; (ii) diversion of prescription pharmaceuticals, including sales by Closed-Door Pharmacies into the Secondary Market; and (iii) other practices impairing the integrity of the pharmaceutical distribution chain. The compliance measures shall include mechanisms for punishing or terminating employees and excluding trading partners who engage in such practices.
- b. [Name of company] will comply with the PDMA, any regulations in force thereunder, and any other applicable federal and state law governing wholesaling of prescription pharmaceuticals.
- c. [Name of company] will comply with HDMA Recommended Guidelines.

### **3. Certification**

- a. Upon adoption of these Wholesaler Safe Product Practices and at the end of each year thereafter, [name of company] will designate one of its officers who will certify the company's compliance with such Practices in the form annexed.
- b. Upon request, [name of company] will provide the certification, via United States mail, to any federal, state or local governmental entity for retention in that entity's files, and for any use as such entity sees fit.

### **4. Verification**

[Name of company] will include an audit of its compliance provisions under paragraph 2 above in its annual audit plan.

### **5. Exceptions**

- a. If emergency medical needs require in particular instances that a prescription pharmaceutical be purchased from or sold to an entity other than as provided above, such purchase or sale does not violate these Wholesaler Safe Product Practices. Nor does it violate these Wholesaler Safe Product Practices to make de minimis sales to a wholesaler in the event of a manufacturer-recognized product shortage to satisfy legitimate Final Dispensers' needs.
- b. If an agency of the United States government directs that particular prescription pharmaceuticals be purchased from an entity other than as provided above, then such purchase, for distribution only to such agency, does not violate these Wholesaler Safe Product Practices.
- c. Sale of prescription pharmaceutical products to units of federal, state, or local government, for use by such governmental units, including medical facilities owned by governmental or quasi-governmental agencies, instrumentalities, or authorities, or for intragovernmental transfer for such use, does not violate these Wholesaler Safe Product Practices.

### **6. Definitions**

The following definitions apply to terms used in these Wholesaler Safe Product Practices:

- a. "Manufacturer" means an establishment authorized to engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, as reflected in a registration with the United States Food and Drug Administration, or an establishment that submits listing information directly to the Food and Drug Administration and obtains a Labeler Code.
- b. "Authorized distributor" means a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products, as established by a written agreement under which the distributor is authorized to

distribute the manufacturer's products for a period of time or for a number of shipments.

- c. "Final Dispenser" means (i) entities and individuals, such as retail pharmacies, hospitals, physicians, and other authorized prescribers, whose practice with respect to prescription pharmaceuticals is devoted to dispensing or administering such pharmaceuticals to individual patients or patients' agents; (ii) chain pharmacy warehouses that exclusively supply retail pharmacies in their chains and/or individual patients with prescriptions; and (iii) entities that use prescription pharmaceuticals for research and development or clinical trials. Accordingly, an entity is not a Final Dispenser if its business includes the sale of prescription pharmaceuticals to wholesalers.
- d. A prescription pharmaceutical is "sold" each time it is the subject of any sale or transfer, except for transactions in which the purchaser or transferee, rather than subsequently dispensing or reselling the pharmaceutical, subsequently returns it in full compliance with federal and state law.
- e. "PDMA" means the Prescription Drug Marketing Act, Public Law No. 100-293, 102 Stat. 95 (Apr. 22, 1988), as subsequently amended and codified.
- f. "HDMA Recommended Guidelines" means the Healthcare Distribution Management Association's "Recommended Guidelines for Pharmaceutical Distribution Integrity" dated November 6, 2003, and available at [www.healthcaredistribution.org](http://www.healthcaredistribution.org), except that the guidelines shall be deemed to require vendor inspections on an annual basis.

## Certification of Compliance with Wholesaler Safe Product Practices

*Signature of this certification constitutes a representation that your Company complies with the annexed Wholesaler Safe Product Practices, as set forth more fully in the next paragraph. Any violation of those practices will constitute cause for immediate termination of your accounts with any vendors or customers.*

I hereby certify that (i) the [name of company] has adopted these Wholesaler Safe Product Practices and fully complied with them during the past 12 calendar months (or since the firm adopted these Wholesaler Safe Product Practices, if that period is shorter); (ii) that [name of company] will continue to comply with the Wholesale Safe Product Practices; (iii) that [name of company] makes this certification to induce entities to sell and/or to purchase prescription pharmaceutical products to and from it; and (iv) that I have made sufficient inquiry to be able to make the certification truthfully and accurately and without material omissions. I understand that any false statements herein may violate federal or state laws and result in liability thereunder.

Your name:

Title:

Company Name:

Signature: \_\_\_\_\_

Date: \_\_\_\_\_