

Wholesaler Verification Checklist

When you fill out the PharmacyChecker IPVP application, you can expect to provide the following information:

Basic Information

- ☐ Wholesaler parent company name
- ☐ Wholesaler parent company address
- ☐ Mailing address (which may be different from the company address)
- ☐ Name of Wholesaler
- ☐ Wholesaler's physical address (which might differ from the above)
- ☐ URL of website (if applicable)
- ☐ Copy of wholesale license
- ☐ Wholesale licensing body name
- ☐ Wholesaler license number
- ☐ License expiration date (format: DD/MM/YYYY)
- ☐ URL of website where this wholesale license can be verified
- ☐ Copy of all other required business and pharmacy licenses (e.g., export license)
- ☐ Disclosure of disciplinary sanctions with explanations
- ☐ List of officers, directors, managers, and persons in charge of distribution/storage/handling
- ☐ Description of duties and summary of qualifications for each person listed
- ☐ Valid license for the operations manager
- ☐ URL to verify license of the operations manager
- ☐ Copy of local/state/national regulation permitting wholesale distribution
- ☐ Copy of international export regulations with relevant info to consider (if applicable)

Product Safety & Storage Processes

- ☐ Wholesaler's process to identify/avoid contaminated or unfit drugs
- ☐ Distribution process ensuring no damaged/improperly stored drugs are delivered
- ☐ Process for maintaining sanitary storage facility
- ☐ Storage process to ensure temperature and conditions are appropriate
- ☐ Pictures of temperature and humidity monitors
- ☐ Temperature and humidity logs
- ☐ Process for recording/reporting medication losses or thefts
- ☐ Inventory error correction process
- ☐ Inventory/transaction record-keeping system (receipt, distribution, disposition, etc.)

Wholesaler Verification Checklist Contd.

Cold Chain & Refrigerated Medications

- ☐ Does the wholesaler supply refrigerated medications?
 - ☐ Cold storage process to maintain proper conditions
 - ☐ Cold chain transportation/delivery/shipping process
 - ☐ List of refrigerated medications sold
 - ☐ List of accredited dispensing pharmacies receiving refrigerated meds (with name, address, contact)

Facility Security

- ☐ Security process to minimize external access
 - ☐ Measures to prevent/detect after-hours unauthorized entry
 - ☐ Restricted access policy for areas where prescriptions are held
 - ☐ Process to protect electronic records against tampering or theft
 - ☐ Emergency preparedness procedures (strikes, disasters, etc.)
 - ☐ Map or layout of wholesale facility with labels of each workstation and area
 - ☐ Pictures of facility, including medication storage from floor to ceiling

Recalls & Safety Issues

- ☐ Process to receive regulatory/manufacturer notices about recalls
- ☐ Process for handling/storing recalled, outdated, damaged, or opened drugs

International Distribution

- ☐ Does the wholesaler distribute internationally?
 - ☐ List of countries to which medications are exported
 - ☐ Process to validate international customer credentials (ensure no U.S. business resale)

Compounded Preparations

- ☐ Does the wholesaler sell compounded preparations (sterile/non-sterile)?
 - ☐ List of compounded preparations sold
 - ☐ List of dispensing pharmacies and countries where compounds are sold

Wholesaler Verification Checklist Contd.

Controlled Substances

- ☐ Does the wholesaler sell controlled substances?
- ☐ List of controlled substances sold
- ☐ List of countries where controlled substances are distributed

Direct-to-Patient Sales

- ☐ Does the wholesaler sell directly to patients?
- ☐ Does the wholesaler require proof of purchaser eligibility?
- ☐ Verification policy for customer eligibility (pharmacy license, prescriber, etc.)

Manufacturer Verification

- ☐ Process to verify manufacturer quality
- ☐ List of manufacturers and products (with authenticated authorization documents)

Supply Chain Traceability

- ☐ Three examples of pedigree checks (manufacturer → wholesaler → pharmacy, one must include multiple wholesalers)

Certification & Confidentiality

- ☐ Signed letter from wholesaler owner certifying distribution of ethically promoted products from Approved Global Manufacturers (with list of dispensing partners)
- ☐ Does the wholesaler request confidentiality of its name/participation in the Verification Program?