

International Pharmacy Verification Program Inspection Program



Protecting the Public Health Across the Globe:
Helping patient-consumers, their caregivers
and healthcare providers find information
about safe online pharmacies that sell
affordable medicines.

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PharmacyChecker Inspection Program

I. Standard Operating Procedures Document

Pharmacy must have a Standard Operating Procedures (SOP) document that describes the policies and procedures that are followed and practiced ensuring that the pharmacy meets all the requirements contained herein. At a minimum, the SOP will describe the pharmacy's basic practices as they relate to the following areas:

- A. Pharmacy personnel
- B. Prescription processing system
- C. Drug safety
- D. Pharmacist consultation
- E. Sanitary condition of pharmacy
- F. Storage
- G. Mailing prescriptions

II. Personnel

Pharmacy staff must be sufficiently qualified and competent to carry out required duties.

Requirements:

- 2.1 All medications dispensed must be checked by a licensed pharmacist.
- 2.2 All staff members must be fully aware of patient confidentiality rules and subject to an agreement to protect health information.
- 2.3 New staff must receive appropriate training to ensure consistency of service.
- 2.4 Staff must be provided with, and aware of, SOPs to ensure consistency of service.

III. Prescription Processing System

Prescriptions must be processed in a methodical, consistent manner that ensures confidentiality, accuracy, and safety of dispensed medication.

Requirements:

Recording of Health Information

The pharmacy's records must be kept in a manner that is readily accessible while ensuring confidentiality.

3.1 All patient information must be stored in a manner that ensures confidentiality of such information.

3.2 Procedures must be maintained to provide for the secure storage and replication of the pharmacy's information system and data.

Dispensing Process

"Dispensing" means the process of a pharmacist providing a patient with a medication pursuant to a valid prescription. Dispensing includes all steps that occur from receipt of the prescription at the pharmacy to the medication being delivered to the patient.

There must be in place a dispensing procedure that ensures that the appropriate product is selected and dispensed correctly and efficiently.

3.3 All prescriptions dispensed must be checked by signature or recorded electronically by a licensed pharmacist before shipment to the patient.

3.4 A licensed pharmacist must verify the authenticity and appropriateness of the prescription being processed and/or dispensed. The roles of an affiliating online pharmacy and the dispensing pharmacy must be defined in writing, as defined by PharmacyChecker standards and included in the SOPs for each pharmacy.

3.5 A licensed pharmacist must ensure that the dispensed medication is selected and labeled correctly and sufficiently to ensure appropriate use.

3.6 Labels must include the following information:

Patient name

Prescriber name

Name of medication, strength and quantity

Easily recognizable instructions for taking medication

Prescription number (unique identifying number or code of the prescription issued by the pharmacy for reference)

Date prescription was filled

Initials of the pharmacist performing final verification

Name of the pharmacy, address and contact details

Font size and quality of the print must be sufficient to read easily

3.7 Appropriate cautionary and advisory labels must be used to assist the patient in using and storing the medication.

3.8 Quantities exceeding a 3-month supply of erectile dysfunction medications may not be marketed, processed and/or dispensed internationally under any circumstances, in accordance with PharmacyChecker Policy 16-04 *Maximum 3-Month Supply Dispensed Internationally*.

3.9 The dispensing pharmacy must confirm that an exception, as defined and in accordance with PharmacyChecker Policy 16-04 *Maximum 3-Month Supply Dispensed Internationally* is met and documented prior to dispensing quantities exceeding a 3-month supply of medications (excluding erectile dysfunction medications) marketed, processed and/or dispensed internationally.

3.10 If there is a guaranteed time by which the online and/or dispensing pharmacy indicates medication will be delivered; it must be met. A procedure must be available when delivery of medication within the guaranteed timeframe is not possible. The roles of the online pharmacy and dispensing pharmacy must be defined in writing as defined by PharmacyChecker standards and included in the SOPs for each pharmacy.

3.11 Pharmacist must check medication history of the patient for consistency of treatment and possible interactions and contact the prescriber when clinically significant interactions are found. The roles of the online pharmacy and dispensing pharmacy must be defined in writing as defined by PharmacyChecker standards and also included in the SOPs for each pharmacy.

3.12 A method of recording which pharmacist was responsible for final check is required for every dispensed medication. The suggested methods include:

- a) Initialing and dating each hard copy of the prescription checked.
- b) If checking in a computer system, a list of all prescriptions checked with prescription or order number, patient name, medication, strength and amount dispensed is printed at the end of the day, and the pharmacist signs each page, indicating he or she has done the final verification check for all prescriptions.

If a different method is used, it should be clearly detailed in the SOPs.

3.13 A hardcopy record of all prescriptions dispensed must be signed by the pharmacist if using 3.12 above, or the daily reports per 3.11.b. The record must be safely stored on the premises of the dispensing pharmacy for a period of two years from the date of dispensing.

If using methods other than 3.12.a or 3.12.b, appropriate documentation shall be maintained and readily retrievable for a period of two years from the date of dispensing.

Dispensing Area

The pharmacy must have sufficient facilities to carry out dispensing activities in a responsible and safe manner.

3.14 The layout of the dispensing area must promote safe and efficient flow of work and allow for effective communication and supervision.

3.15 Where medications are dispensed there must be adequate:

Heating/Air Conditioning

Lighting

Ventilation

3.16 The dispensing area may not involve any non-dispensing activities.

3.17 Waste must be dealt with in a manner that ensures confidentiality of patient information.

3.18 Dispensing incidents are to be recorded and regularly reviewed with all staff members so that strategies to prevent future incidents are implemented.

IV. Drug Safety

Drug Approval

All medications dispensed by the pharmacy must be manufactured under Good Manufacturing Practices (GMP) and approved for retail sale in at least one of the following countries: Australia, Canada, European Union members, India (in accordance with PharmacyChecker policy 16-05 *Marketing / Dispensing Indian Pharmaceutical Products Internationally*), Israel, New Zealand, Singapore, South Africa, Switzerland, Turkey, United Kingdom, or the United States.

Definitions

Indian Pharmaceutical Product: products approved for sale in Indian pharmacies.

Ethically promoted pharmaceutical products: pharmaceutical products approved for sale in India that have been manufactured by First-Tier Indian manufacturers (defined below) and that are marketed under a brand name directly promoted through the company's branded division.

First-tier Indian manufacturer: a pharmaceutical company based in India that:

- has a global presence in at least one of the following markets: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel,

Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa and United Kingdom, United States; **and** products approved for sale in at least one of the aforementioned countries or

- is registered with a drug regulatory authority of one of the following: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa and United Kingdom, United States.

Global pharmaceutical company: for the purposes of this policy, is a pharmaceutical company that is based in Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom, United States, that has products approved for sale in the aforementioned countries **and** sells pharmaceutical products internationally to one or more of the aforementioned countries.

Requirements:

- 4.1 There must be a procedure for ordering and checking incoming medications for safety and authenticity. The roles of the pharmacist and staff members must be defined in writing and included in the SOPs.
- 4.2 There must be a medication recall procedure in place that is clearly communicated in writing. The wholesalers supplying medications to the dispensing pharmacy must agree to forward any recall notifications to the pharmacy.
- 4.3 The pharmacy must ensure quality of supply to guarantee authenticity of medications.
- 4.4 The pharmacy must meet regulations in the country in which it operates.
- 4.5 The pharmacy must have a license to operate in the country in which it resides.
- 4.6 Pharmacy may not dispense controlled substances, as defined by the U.S. DEA, to customers in the U.S.
- 4.7 Except where required by law, the dispensing pharmacy may not substitute a generic prescription drug for a brand-name drug without the consent of the customer when dispensing the prescription internationally.
- 4.8 Where the pharmacy offers a refund policy in which medications are returned, there must be a separate area provided for the storage and disposal of such medications. Returned medications may not be re-dispensed; they must be disposed in an environmentally responsible manner.

4.9 If dispensing pharmaceuticals approved for sale in India, the pharmacy must comply with PharmacyChecker policy 16-05 *Marketing / Dispensing Indian Pharmaceutical Products Internationally*, and may only dispense:

4.9.1 Ethically promoted pharmaceutical products manufactured by first-tier Indian manufacturers and global pharmaceutical companies, and/or

4.9.2 Products manufactured in plants registered with regulatory authorities of one of the following: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom, and United States.

V. Sanitary Condition of Pharmacy

The pharmacy must be kept in a sanitary manner.

Requirements:

5.1 The dispensary must be kept clean, tidy and in hygienic condition.

5.2 Staff must have a high standard of hygiene.

5.3 There must be separate hand-washing facilities available for staff that are located in or adjacent to the dispensary area.

5.4 There must be a suitable method of hand drying available wherever hand washing takes place in the dispensary. Suitable methods include a hot air dryer or disposable towels.

5.5 Toilets must be located in such a manner that they do not open directly into the dispensary area.

5.6 All other parts of the premises must be maintained in a clean, tidy and hygienic condition including but not limited to:

Rubbish containers

Staff rooms

Storage areas

5.7 There must be an Infectious Disease Policy in place that prohibits staff members with active communicable diseases (such as flu) to work in the dispensing area.

5.8 There must be a Wound Management Policy in place not allowing staff members with open wounds to work.

5.9 Standard Operating Procedures must require hand washing at the beginning of the day, after using bathrooms, breaks, and lunch times. In between, hands may be sanitized using alcohol-based hand sanitizers.

5.10 Dispensary surfaces must be covered in smooth, impervious and washable surfaces and maintained in a good state of repair including:

Working surfaces

Shelves, cupboards and drawers (internal and external)

Ceiling

Walls

5.11 Flooring in the dispensing area must be in a good state of repair and maintained in a clean manner.

5.12 Dispensing equipment must be clean and dry.

5.13 There must be a record of cleaning of the dispensary area. For example: cleaning schedules and/or logs.

5.14 Dispensary waste (pharmaceuticals) must be disposed in a responsible manner that prevents contamination of environment.

VI. Storage

Medications must be stored in a manner that ensures they remain pharmaceutically stable and free from contamination.

Requirements:

6.1 Procedures must be in place to ensure medications are dispensed before the expiry date and patients receive medications with the necessary lead time before expiry.

6.2 Medications should be stored in the original containers and if not, should be stored correctly (as per manufacturer's instructions) and be sufficiently labeled so that they are still traceable.

6.3 All medications must be protected from:

Temperature extremes

Direct sunlight/light where applicable

Moisture

Insects, animals, vermin

6.4 The ambient room temperature in the dispensing and storage area must be monitored with procedures in place if the temperature exceeds 25°C.

6.5 A refrigerator must be provided for storing medications requiring refrigeration. The temperature within the refrigerator must be recorded. Records must indicate that the refrigerator temperature is maintained between 2° and 8°C. The refrigerator must be clean and frost free. It may not contain any non-medication products.

VII. Mailing Prescriptions

Dispensed medications must be mailed in accordance with safe practice to ensure they arrive safely to the correct patient.

Requirements:

7.1 Dispensed medications must be packaged with an invoice/receipt that includes the details of the order, including the name of the website that generated the order.

7.2 Dispensed medications must be suitably packaged for mailing to prevent deterioration or crushing. Bubble wrap or filler must be used to prevent movement inside cardboard cartons.

7.2 Mail dispatches should be timed so that there is minimum delay at airports, to the extent possible. This is particularly important in countries where the climate may lead to deterioration of medications.

7.3 If medications requiring refrigeration are dispensed, a written policy on packing temperature sensitive drugs must be in place (Refer to PharmacyChecker policy 16-03 *Temperature Sensitive Medications: Shipping Requirements*.) Medications requiring refrigeration must be suitably packaged to ensure correct temperature is maintained until delivery, in accordance with PharmacyChecker policy 16-03.

7.4 Packaging must ensure confidentiality.

7.5 Return address labels must be used.