

# PRESCRIPTION LABELLING

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## ABSTARCT:

The International Standard of Community Pharmacy Practice starts with prescription labeling. DATA COLLECTION begins here. It is essential to underscore the pivotal role of data collection in community pharmacies. Data serves as the cornerstone of informed decision-making in healthcare, and this knowledge empowers us as healthcare professionals to make the best decisions for our patients. The dream does not come in sleep, but the dream is what gives sleepless nights. Avoiding the data collection process at the community pharmacy is like kicking the can down the street to prevent the management of a nation's health care. It's not just about managing the nation's health care, but also about ensuring patient safety and well-being. The quality of the Global Standards is not just an expectation; they are our identity. Every prescription we dispense in healthcare promises life, trust, and healing. It is a fact, not a DREAM, that India is the world's major medicine supplier. BUT WHY DO INDIAN COMMUNITY PHARMACIES NOT FOLLOW THE WORLD STANDARD OF DISPENSING MEDICINE TO THE CONSUMER AT THE DISPENSING LEVEL? On a lighter note, when one buys a packet of idlis, sambhar, or dhokla mix, they get instructions on how to make them, heat them, or what setting the microwave is. Strangely, the medicine man does not have to do this when they hand the consumer a strip of medication!! Providing a clear and comprehensive prescription label is not just a task; it's a responsibility for pharmacists. It reassures consumers, helping them understand their medication and feel confident in their treatment plan. This commitment to patient care sets us apart in the healthcare system. India is the major supplier of generic (sometimes brand) medicines to many countries. Most of these countries require Prescriptions, labeling, and auxiliary labels before the medication is handed over to the consumer at the dispensing, say, a pharmacy. INDIA HAS BECOME & IS NOW KNOWN AS "THE PHARMACY HUB OF THE WORLD." Congratulations to all the members of the INDIAN ACADEMIA.

## WHY SHOULD PHARMACISTS DO THIS?

Prescribers write to the pharmacy instructing them to dispense medicine according to the consumer's name, the proper medicine name, the correct dose, the right directions for consumption, and the correct route of administration for their patients. On-demand Pharmacists usually pick up medicine strips from the pharmacy shelves and give oral instructions to consumers on how to use them. Just imagine how someone can remember all that if they are taking four or more medications. Sometimes, the person who takes the medication does not pick up the order. So now there is one more variation: a middleman who will transmit the information you gave orally.

## FOR A MINUTE, IS IT BETTER TO GIVE THE MEDICATION INSTRUCTIONS IN WRITING?

\*To a layman, antibiotics, blood pressure, diabetes, or pain medication mean nothing by their name. \*A layman knows medicines by color, shape, or form (liquid or cream). Blue, white & yellow color tablets or capsules. It could be a round, triangular, or elongated product. \*Consumers need to learn what it is for. \*A consumer can have more than one health condition. The same person can have pain, blood pressure, diabetes, arthritis, a cough, or a cold. How will consumers remember all these instructions if they are not given in writing? Pharmacovigilance (PV) applies to all aspects of pharmacy practices

## THE FOLLOWING ARE A FEW EXAMPLES

\*Data collection is an opportunity that should be noticed at the dispensing level. \*How about double-checking by writing the label to ensure you have given the right medicine? \*How will you trace back or contact consumers during a product recall? \*How will you perform ADR if you don't have an individual's medicine profile? \*How will you perform the drug interaction function without medicine profile data? I have always wondered how one can prevent the occurrence of ADR or ADE without the data! Are consumers supposed to end up at a hospital whenever there is an ADR or ADE?

Prescription labeling, a written, printed, or graphic representation of information about a drug or its container, is crucial to drug safety. It includes

instructions for use, storage, and disposal, as well as warnings about the drug. The FDA, a leading authority in drug regulation, mandates that all approved prescription drugs have labeling that communicates information to patients, caregivers, and healthcare professionals.

### HERE ARE SOME THINGS THAT PRESCRIPTION LABELS INCLUDE

- Patient information: The patient's name, the drug's name and strength, and clear instructions for use.
- Highlights: A concise summary of the label's information.
- Prescribing information: Information for healthcare professionals.
- Warnings and precautions: Information about potential adverse reactions and drug interactions.
- Dosage and administration: Instructions for how to take the drug.
- Patient labeling: Information for patients and caregivers, such as Medication Guides, Patient Package Inserts, or Instructions for Use.

The FDA's goal is to help patients use drugs safely and effectively by providing patient labeling in lay language.

### WHAT ARE THE LEGAL REQUIREMENTS FOR DRUG LABELING?

There is a legal requirement for the following to appear on the label of any prescribed medicine:

- Name of the patient;
- Name and address of the supplying pharmacy;
- Date of dispensing;
- Name of the medicine;
- Directions for the use of the medicine;
- Precautions relating to the use of the medicine.

### WHAT ARE THE STANDARDS FOR DISPENSED MEDICINE LABELS?

All medicines dispensed are legally required to have a label before being provided to the consumer. Although mandated requirements vary between states and territories, they include the consumer's name, the medicine's name, the strength and dose form, the date of dispensing, and the name and address of the dispensing pharmacy.

### WHAT MUST THE DISPENSING LABEL ON PRESCRIPTION MEDICATION INCLUDE?

The name and address of the pharmacy / medical practitioner. The trade name or common name of the

medicine. The dosage per unit. The method and dosage of administration.

### WHAT INFORMATION IS ALWAYS GIVEN ON PRESCRIPTION LABELS?

All prescription medicine containers have information on the label, including the patient's name, the name of the medicine, the dosage, and instructions on how often to take it. The pharmacy usually provides more detailed printed information about the medication when dispensing the prescription. Prescription label requirements vary by state but generally include the following information: Patient and prescriber information The patient's name, the prescriber's name, and the dispensing pharmacy's name and address Medication information The name and strength of the medication, the expiration date, and the date of dispensing Directions. The prescriber's directions for the patient to use the medication. Quantity. The number of dosage units or the number of millimeters dispensed if the medication is liquid. Some states also require that the label include the condition or purpose for which the drug was prescribed. In addition to state requirements, the FDA has issued guidelines that require prescription labels to be easier to understand and include information about the dangers of abuse. These guidelines include:

- Using clear, commonly understood terms
- Including abuse-deterrent information
- Providing better patient instructions, including visual elements Each item shall be printed in at least a 12-point sans serif typeface and listed in the following order: (A) Name of the patient, (B) Name of the drug, and strength of the drug.

### EXAMPLE #1 OF RX LABEL

(1) Pharmacy name and address

(2) Number used by the drugstore to identify this drug for your refills

(3) Person who gets this drug

(4) Instructions about how often and when to take this drug

(5) Name of drug and strength of drug

(6) Number of refills before certain date

(7) Doctor's name

(8) Drugstore phone number

(9) Prescription fill date

(10) Don't use this drug past this date

Local Pharmacy  
123 MAIN STREET  
ANYTOWN, USA 11111 (800) 555-5555

DR C. JONES  
DATE 06/23/09

NO 0060023-08291

JANE SMITH  
456 MAIN STREET ANYTOWN, US 11111

TAKE ONE CAPSULE BY MOUTH THREE TIMES DAILY FOR 10 DAYS UNTIL ALL TAKEN

AMOXICILLIN 500MG CAPSULES

QTY NO REFILLS - DR. AUTHORIZATION REQUIRED USE BEFORE 06/23/12 SLF/SLF

## EXAMPLE#2 RX LABEL

Pharmacy Information	Prescription Fill Date
Prescription number	YOUR PHARMACY 123 Healthy Street Bethesda, Maryland 20814 (800) 555-5555
Patient Name and Address	Rx# 1234567-90 DATE: 3/1/2025
Instructions	JOHN DOE 123 MAIN STREET, MARYLAND 20814
Medication Name and Strength	TAKE 1 TABLET BY MOUTH EVERY DAY. LISINOPRIL 10 MG
Medication Quantity	QTY: 30   2 REFILLS DISCARD AFTER 1/1/2027 DR. BOB SMITH
Discard Date	Prescriber Name

Note: This prescription label is an example only. It does not represent a real patient, prescription, doctor, or pharmacy and should not be used for any actual medical or legal purposes.

### REFERENCES TO READ FURTHER

- [Prescription Label Information, Translations, and Sample Labels - California State Board of Pharmacy](#)
- [Frequently Asked Questions about Labeling for Prescription Medicines | FDA Prescription Drug Container Labels](#)
- [Discussion of Pharmacy Prescription Labeling](#)

### AUXILIARY LABELS

Why are auxiliary labels needed when dispensing medications?



Auxiliary labels provide additional information about medication use and potential side effects, enhancing patient understanding and safety. They are a crucial part of patient education to be included.

### WHAT IS THE AUXILIARY LABEL?



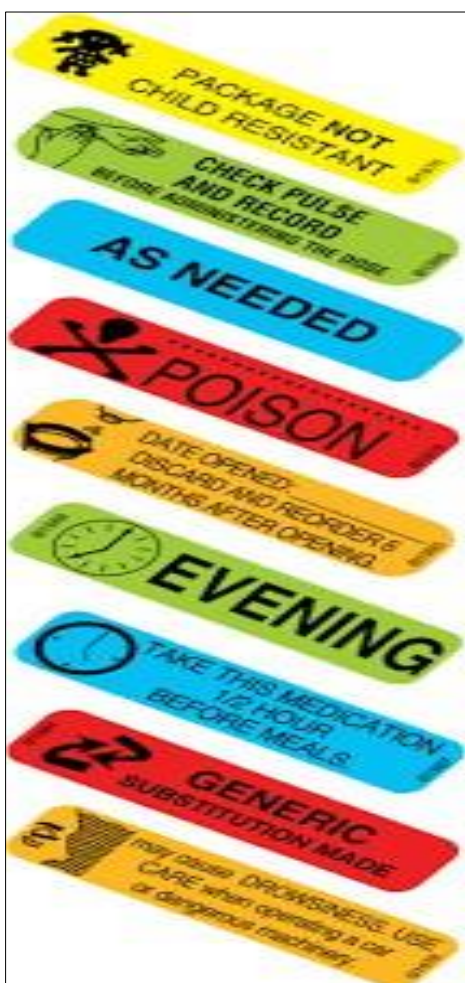
An auxiliary label (also called a cautionary, advisory, or prescription drug warning label) is a label added to a dispensed medication package by a pharmacist in addition to the usual prescription label.

### WHAT INFORMATION DOES AN AUXILIARY LABEL PROVIDE?

Patients must also know how to safely use, administer, and store their medicines. Auxiliary labels are medication labels that display various information, such as warnings, dietary information, administration instructions, or cautionary details.

### HERE ARE A FEW EXAMPLES OF COMMON TYPES OF AUXILIARY LABELS

- Do Not Chew or Crush
- Swallow Whole
- May Cause Urine Discoloration
- May Cause Drowsiness
- Take With Food or Milk
- Take on an Empty Stomach
- Keep Refrigerated
- Shake Well Before Use
- Protect From Sunlight
- For External Use Only
- For the Eye (or Ear) Only
- For Rectal Use Only



#### REFERECES TO EXPLORE

- <https://ptcbtestprep.com/auxiliary-labels/>
- <https://pubmed.ncbi.nlm.nih.gov/6839952/> <https://newsink.com/what-are-auxiliary-labels/>
- [https://en.wikipedia.org/wiki/Auxiliary\\_label](https://en.wikipedia.org/wiki/Auxiliary_label)