

# PHARMACY PRACTICE POLICY

## Prescription Labels

### Introduction

Medication misuse results in significant adverse drug events every year. Inadequate understanding of directions on prescription labels is widespread. Studies have found that almost half of patients taking medications misunderstand one or more dosage instructions and more than half misunderstand one or more auxiliary warnings. The problem of misunderstanding is particularly troublesome in patients with low or marginal literacy and in patients receiving multiple medications that are scheduled for administration using complex regimens, such as escalating or tapering dosage regimens.<sup>1</sup>

Evidence shows that the lack of good standards for labeling on dispensed prescriptions is a root cause of patient misunderstanding, non-adherence and medication errors. The following policy sets out the expectations for providing patients with the essential information on the prescription label that they need in order to understand how to safely and appropriately use the medication and to adhere to the prescribed medication regimen.

### Policy

The Pharmacy Manager must ensure that prescription labels generated by the Pharmacy:

- organize the information in a consistent manner that clearly presents the information that is critical for patient understanding and safe medication use;
- address literacy and limited language proficiency;
- in accordance with the Standards of Practice, include, at a minimum, the following information:
  - unique prescription number;
  - patient's name;
  - name, address and phone number of the dispensing pharmacy;
  - prescriber's name;
  - drug name: the generic name and strength will appear on the label first. The inclusion of the trade name after the generic name is discretionary. (exception: for insulins, the trade name will appear first);
  - the identity of the manufacturer;
  - for compounded drugs:
    - name of the product or a list of active ingredients and strength; and
    - the estimated beyond-use-date;
  - directions for use;
  - date filled;

- quantity of the drug or product dispensed;
- refill or part-fill information;
- prescription expiry date; and
- the safety advisory "Keep out of reach of children".

Pharmacy practitioners ensure:

1. The label is clear, legible, organized in a patient centered manner, and supports understanding by the patient.
2. The label includes all of the necessary information that, in the professional judgment of the pharmacist, is required for the safe and effective use of the drug.
3. A label is affixed in a permanent fashion to each vial or individual package, and where a drug product has both an inner and an outer container, that a label is affixed to the inner container. Extra attention is required in the following circumstances to ensure the effective labeling of the prescription and the safe and appropriate use of the drug:
  - a. Where a drug container is too small to accommodate a full label, affix a label to the container that includes the minimum information that, in the professional judgment of the pharmacist, is required for the safe and appropriate use of the drug. Affix a full label to a larger container and counsel the patient to keep the small container within the fully labelled larger container.
  - b. A label may be omitted from the inner or small container at the request of the patient or where the pharmacist considers that to do so will result in better patient care.
  - c. Where the complete information cannot fit on the label attached to the product, additional written information must be provided to the patient, the pharmacist must be satisfied that the patient understands the unique labeling of the prescription, and the primary label must:
    - include the information that in the professional judgment of the pharmacist is required for the safe and appropriate use of the drug by that patient, and
    - reference the additional information.
4. Auxiliary labels are used when appropriate to convey required information not printed on the primary label, including information concerning the use, storage or precautions pertaining to the particular drug or medication sold or dispensed. Limit auxiliary information to that which is evidence based and essential for the safe and effective use of the drug, to avoid distracting patients with non-essential information.
5. The date of expiration of the medication is included on the label or as a supplementary or auxiliary label when medications are dispensed or sold from bulk stock that will expire within the time frame that a patient might reasonably be expected to store the medication.
6. When the purpose of the medication is indicated on the prescription, the decision to include that information on the label is to be based on the patient's preference to protect privacy and confidentiality.
7. When the purpose is not included on the prescription, consideration should be given to including it on the label, with the patient's consent, when it may enhance compliance with therapy.

8. Drug names are never abbreviated.
9. Abbreviations included in the *List of Error-Prone Abbreviations, Symbols and Dose Designations* published by the Institute for Safe Medication Practices (ISMP) are avoided.
10. Re-packaging (i.e., providing a customer with non-prescription medication taken from a larger stock bottle or jar outside the prescription process) can only occur in accordance with federal legislation as Health Canada considers this activity to be manufacturing.
11. The principles and recommendations in the following references regarding prescription labels are considered: *ISMP Principles of Designing a Medication Label for community and Mail Order Pharmacy* and *USP General Chapter <17> Prescription Container Labelling*.

#### Labelling of Compliance Packages

- Pharmacy practitioners are responsible for ensuring that the patient and/or their agent understands the unique labelling of the package and that they are provided with the appropriate amount of instruction to support the safe use of the medication and the package.
- Where the individual blisters/compartments of a compliance package are too small to accommodate a complete label, a label will be affixed to the outer package that includes the necessary information as described in Section 1.\*\*
- The label shall provide a description of each drug's appearance in a manner that meets the needs of the patient.
- The label shall indicate the start date for each card/package, and if applicable, clear directions to indicate where a patient is to start.
- The label shall indicate the dosing specifications for each medication (i.e., the day and time or period of time that the contents are to be taken by the patient).
- Expiry dates and lot numbers are required on the label if preparing batches of compliance packages in anticipation of the prescription (e.g., medication provided to long term care facilities for their lock cupboard for after hour prescriptions).

\*\*For pharmacies preparing compliance packages for nursing homes, long term care homes, and other institutional settings:

- In situations in which a medication administration record is being used, professional judgment will be used to determine if affixing a label to an outer package is appropriate. In these situations, pharmacists must determine in consultation with the care facility, whether or not it is in the patient's best interest.

---

<sup>1</sup> <https://www.prnewswire.com/news-releases/first-universal-standards-guiding-content-appearance-of-prescription-container-labels-to-promote-patient-understanding-of-medication-instructions-173272741.html> accessed May 2018