



Guidelines for the Use of Patients' Own Medicinal Products in Hospitals

Introduction

These guidelines are intended to assist the pharmacist in determining whether it is appropriate to “identify” and “dispense” a patient’s own medicinal product for use in the hospital when:

- the physician has written an order for the medicinal product; and
- there is no suitable alternative listed on the hospital’s formulary; and
- hospital policy permits the use of patients’ own medicinal products.

Hospital pharmacists are commonly involved in a process of “identifying” and “dispensing” a patient’s own medication before the product is used or administered in the hospital. With the usual process, the pharmacist reviews the prescription or medication container label, visually checks the container contents and compares the distinguishing features of the medication to a manufacturer’s or reference description of the product.

The hospital pharmacist may now also encounter physicians’ orders for medications from other countries, medicinal herbs, homeopathic medicines or other complementary, traditional or alternative therapies. When these medicinal products are sent to the pharmacy for “identification” and “dispensing”, the pharmacist may not always be able to follow the usual process. The situation may be further complicated by a pharmacist’s personal concerns about a product’s safety, efficacy, quality, the product’s labelled claims of therapeutic effect and possible drug interactions.

While there may be significant differences between prescription medications and other types of products with therapeutic or medicinal claims, the process for determining whether an individual product can be “identified and dispensed” for use in the hospital is similar for all patients’ own medications. Therefore, for the process described in this document, the term *patient’s own medicinal product(s)* will be used to include any medication or product used by the patient for therapeutic reasons.

This document neither endorses nor opposes the use of any specific type of patient’s own medicinal product. Rather, the pharmacist is encouraged to adopt the pharmaceutical care approach. Instead of considering the specific medicinal product alone, the pharmacist should consider the medicinal products in the context of the patient’s overall care and anticipated outcomes.

Important:

This document neither endorses nor opposes the use of any specific type of medicinal product.

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Why Should a Pharmacist be Involved?

The practice of pharmacy includes the responsibility for identifying, preventing and resolving the patient's drug-related problem. In assuming the responsibility for the patient's pharmaceutical care, the pharmacist must assess the patient's complete medication therapy, including the use of any medicinal products used prior to or during the hospital admission. The pharmacist is also an excellent resource to provide factual, unbiased information about drugs and medicinal products.

Ref: Pharmacists Regulation

"Practice of pharmacy" means the health profession in which a person provides the services of:

- (a) identifying and assessing drug-related and device-related problems and taking action to prevent or resolve those problems*
- (b) monitoring drug therapy and advising on therapeutic values, contents and hazards of drugs and devices, and*
- (c) compounding and dispensing drugs and devices;*

Ref: Pharmacy Operations and Drug Scheduling Act (PODSA):

"Drug" means a substance or combination of substances used, or for use in or on the body of a person or animal:

- (a) to prevent, diagnose, treat or mitigate a disease, disorder or abnormal physical or mental state or a symptom of them,*
- or,*
- (b) to restore, correct or modify organic functions.*

Guiding Principles

There are two important principles which must be simultaneously applied and balanced when deciding whether it is appropriate to "identify and dispense" a patient's own medicinal product in the hospital. These principles are:

Principle 1 *Protect the health and safety of the patient, staff, and general public.*

The hospital pharmacist is responsible for providing safe and effective pharmacy care in the hospital and for ensuring that the health and safety of patients, staff and members of the general public are protected.

Pharmacist's Role:

- The pharmacist is responsible for reviewing the medication order, the patient's medication profile and relevant medical history, if available. As with any medication, the pharmacist must assess the possible therapeutic benefits and the possible risks of taking the medicinal product.
- The pharmacist is responsible for providing unbiased, factual information about the medicinal product to the patient and to other health care providers, including the purpose, dosing information and any known or potential therapeutic effects, adverse effects or interactions.
- In conjunction with other hospital staff, the pharmacist must take actions to protect the safety of other patients, staff and visitors by ensuring that all medications and medicinal products are safeguarded from accidental or intentional ingestion by another person.

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Principle 2 Support the patient's right to access the therapy of his or her choice

Today's accepted societal value is an individual has the right to make choices about his or her own health care treatment, including the choice of using conventional and/or alternative therapies.

Ref: *College of Pharmacists of BC, Code of Ethics, Value 2 and 3:*

*Pharmacists honour the individual needs, values and dignity of the patient, and
Pharmacists support the right of the patient to make personal choices about pharmacy care.*

Pharmacist's Role:

The pharmacist is responsible for providing factual, unbiased information about the medicinal product to the patient and to the health care team and for ensuring that this information is documented in or attached to the patient's health record.

The Process for "Identifying and Dispensing"

Prior to engaging in the process of "identifying" and "dispensing" a patient's own medicinal product, ensure that:

- the physician has written an order for the medicinal product; and,
- there is no suitable alternative listed on the hospital's formulary; and,
- hospital policy permits the use of patients' own medicinal products.

Next, use the checklists in Appendix A to determine whether to "identify" and "dispense" the patient's own medicinal product.

- If the pharmacist has determined that a patient's own medicinal product is suitable for use in the hospital, follow the hospital's standard policies and procedures for medication profile entry, labeling and medication administration record entry.
- If the pharmacist has determined that a patient's own medicinal product cannot be identified and dispensed for use in the hospital, the pharmacist should again follow the hospital's standard policies and procedures. In addition, the pharmacist must communicate this decision to the patient, physician and nurse.

If there are any other issues with the therapeutic suitability of the medicinal product, the pharmacist is responsible for providing factual, unbiased information about the medicinal product to the patient and health care team.

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Communication

The pharmacist is responsible for providing the available information to the physician, nursing staff about medicinal products that are not listed in references on the nursing unit. The information provided should include at least the reported benefits, adverse reactions, potential or theoretical drug interactions and any other relevant information. The pharmacist is also responsible for making the information available to the patient and for providing factual, unbiased counselling to assist the patient in making an informed decision about whether to continue using the medicinal product.

There may be cases where the patient has been advised that the risks outweigh any potential benefits of using a medicinal product and that the hospital and health care professionals do not support or recommend the use of the medicinal product. If the patient decides to continue the use of the medicinal product, the pharmacist should notify the physician and ensure that the hospital administration or risk management office is aware of the issue.

Documentation

The pharmacist must document the process, decisions and outcomes of reviewing the patient's own medicinal products in the patient's health record. The documentation should demonstrate that the guiding principles were upheld and that the information was communicated to the patient and health care team.

Reasonable and Prudent Judgement

There may be times when there is little known information about a patient's medicinal product. The pharmacist should recognize that the answers to some of the checklist questions might not be absolute as long as they are "reasonable and prudent", as judged by professional peers. Document the information that was available, the actions that taken and the reasoning used to make the decision.

Waivers

When a patient decides to continue the use of their own medicinal product in the hospital against the advice of the health care team, the hospital may decide to have the patient execute a waiver of responsibility form. Waiver forms should indicate that the specific risks have been communicated to the patient, that the patient wishes to continue the use of the medicinal product(s) and waives any claim against the hospital and its staff. Significant risks (e.g. cardiac events, paralysis, stroke, and death) should be specifically noted on the waiver form. In these circumstances, documentation on the chart should indicate that the patient is using the medicinal product against professional advice and that the risks have been communicated to the patient.

The hospital administration should seek information about hospital policies and procedures, advice about waivers and the limit of health professionals' legal liability and responsibilities from the hospital lawyer, risk management office and/or BC Health Care Risk Management Society.

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Appendix A

Checklists

A pharmacist MAY “dispense” a patient’s own medicinal product, if:

The identity of the medicinal product is known,

The pharmacist can make a reasonable and prudent determination of the identity of the medicinal product on the basis of unique distinguishing features of the dosage form

- e.g. *A prescription vial is labelled with the patient's name, medication name and strength. All of the doses in the vial are the same shape, colour and size and match the manufacturers' written description of the dosage form.*
- e.g. *The medicinal product is in the manufacturer's original sealed packaging and is labelled with the product name, purpose and usual dosage.*

AND

The medicinal product may be used legally in Canada,

The medicinal product is approved for use in Canada,

- e.g. *The generic ingredient has received a Notice of Compliance (NOC) or the product has a Drug Identity Number (DIN), or General Product (GP) number*
- e.g. *The medication is approved for use as an investigational agent or is available from the special access program and the patient is registered in a clinical drug trial or has special authority to receive the medication.*

or,

The medicinal product is not regulated by Health Canada but is not prohibited for use in Canada.

- e.g. *The product is a medicinal herb, homeopathic remedy or other alternative medicine.*
- e.g. *The patient's medicinal product is an approved medication in another country and is for his or her personal use. This is common when a resident of another country is admitted to a BC hospital with his or her own prescription medications.*

AND

The integrity of the active ingredients of the medicinal product has not been compromised,

The pharmacist can make a reasonable determination that the medicinal product has been properly stored.

- e.g. *The pharmacist can make a reasonable determination that items that require constant refrigeration have been refrigerated, that oral dosage forms are not damp, soiled or discoloured and that topical or liquid dosage forms are not separated or discoloured, etc.*

The pharmacist can make a reasonable determination that the medication or medicinal product is not past its expiry date.

- e.g. *A prescription label shows that the dispensing date was only one month ago.*
- e.g. *A bottle shows a manufacturer's "best before" or an expiry date that has not passed.*

AND

The established / potential benefits outweigh the established / potential risks of taking the medicinal product.

- e.g. *An elective surgery patient wishes to take her own glucosamine. A review of available information shows that it may have some beneficial effects and that there is little risk in taking the product as directed by the manufacturer's label.*

Appendix A

Checklists

A pharmacist MAY NOT “dispense” a patient’s own medicinal product, if:

The pharmacist cannot determine the identity of the patient’s medicinal product,

- e.g. *The product is a liquid in an unsealed jar bearing a handwritten label that states “Mrs. Jones - vitamin tonic.”*
- e.g. *The product is in a vial with a prescription label that is partially torn off. The bottle contains a mixture of a number of different tablets and capsules.*

OR

The medicinal product is illegal for use in Canada,

- e.g. *The product is classed as a new drug without notice of compliance (e.g. melatonin), is listed in schedule 3, 4 or 5 of the Controlled Drug and Substances Act (DHEA, anabolic steroids, “andro”, etc.)*
- e.g. *The product is or is suspected to be a narcotic or control drug obtained by illicit means (heroin, cocaine, etc.)*

OR

The integrity of the active ingredients of the medicinal product has been compromised,

- e.g. *The patient’s own medications arrive in pharmacy in a plastic bag. A liquid preparation has spilled and the capsules in a partially open bottle are conglomerated together.*
- e.g. *A prescription vial contains tablets that are distinctly yellowed. The manufacturer’s description notes that the tablet colour is white.*
- e.g. *A bottle shows a manufacturer’s “best before” or expiry date that has passed.*

OR

The established / potential risks outweigh the established / potential benefits of taking the medicinal product.

- e.g. *A woman who is breastfeeding complains of fatigue and has been using a herbal preparation which is labelled to contain ginseng. Your herbal reference notes that ginseng is contraindicated in women who are pregnant or breastfeeding.*

Examples given are for illustrative purposes only and are not all inclusive.