



National Association of Pharmacy Regulatory Authorities
Association nationale des organismes de réglementation de la pharmacie

Model Standards of Practice for Canadian Pharmacy Technicians

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INTRODUCTION

Over the past five years, there has been substantial focus placed on the regulated status of pharmacy technicians. In 2007, NAPRA prepared the *Professional Competencies for Canadian Pharmacy Technicians at Entry to Practice*¹. These competencies describe the roles and responsibilities of pharmacy technicians as regulated health care professionals, articulating that pharmacy technician’s expertise focuses on the knowledge, skills and abilities related to the technical elements of prescription and patient information, and of product and drug distribution. Pharmacy technicians are responsible and accountable for ensuring the safety and quality of prescription-product preparation and release, and pharmacy technicians collaborate with pharmacists in health and wellness promotion, disease prevention and chronic disease management, and in supporting the autonomy of patients*. Individual provinces/territories have adopted or adapted these competencies while developing related legislation, regulations and policies.

As a next step, NAPRA developed *Model Standards of Practice for Canadian Pharmacy Technicians* (MSOPPT). The format adopted for the MSOPPT draws from that of the *Model Standards of Practice for Canadian Pharmacists*², which includes four domains related to medication expertise, collaboration, safety/quality and professionalism / ethics. For the Pharmacy Technicians, these domains have been adjusted to reflect technician’s focus on the technical aspects of pharmacy practice. Within each of these domains the MSOPPT are grouped under general standard statements to provide structure and ease of reading as follows:

General Standard	Model Standards of Practice
Expertise in drug distribution systems <ul style="list-style-type: none"> • Pharmacy technicians maintain their competence. • Pharmacy technicians apply their drug distribution expertise while performing their daily activities. • Pharmacy technicians provide evidence of application of their drug distribution expertise through documentation. 	<ul style="list-style-type: none"> • ... • ... • ...
Collaboration <ul style="list-style-type: none"> • Pharmacy technicians work constructively with students, peers and members of the inter-professional team. • Pharmacy technicians communicate effectively. 	<ul style="list-style-type: none"> • ... • ... • ...
Safety and Quality <ul style="list-style-type: none"> • Pharmacy technicians undertake continuing professional development, quality assurance and quality improvement. • Pharmacy technicians respond to safety risks. 	<ul style="list-style-type: none"> • ... • ... • ...
Professionalism and Ethics <ul style="list-style-type: none"> • Pharmacy technicians demonstrate professionalism and apply ethical principles in their daily work. 	<ul style="list-style-type: none"> • ... • ...

* This Vision Statement from the *Professional Competencies for Canadian Pharmacy Technicians at Entry to Practice* is modified to be consistent with the terminology and definitions used within the *Model Standards of Practice for Canadian Pharmacy Technicians*.

To ensure clarity and compliance with the MSOPPT, NAPRA has structured the MSOPPT to clearly identify the MSOPPT that are required of all pharmacy technicians regardless of the role(s) that they are fulfilling, and the MSOPPT that are specifically associated with the roles pharmacy technicians can fulfill according to their *Professional Competencies*¹. Not all of the roles have specific MSOPPT identified for them: this occurs when the MSOPPT required of all pharmacy technicians adequately address the standards of practice expected within the specific pharmacy technician’s roles. The following table provides an **example** of this format:

General Standard	Model Standards of Practice
Expertise in drug distribution systems	
<ul style="list-style-type: none"> • Pharmacy technicians maintain their competence. 	<p>MSOPPT required of pharmacy technicians regardless of the role they are fulfilling:</p> <ul style="list-style-type: none"> • ... • ... <p>MSOPPT required of pharmacy technicians when collaborating to provide patient care:</p> <ul style="list-style-type: none"> • ... • ... <p>MSOPPT required of pharmacy technicians when distributing drugs:</p> <ul style="list-style-type: none"> • ... • ... <p>MSOPPT required of pharmacy technicians when contributing to management within a pharmacy:</p> <ul style="list-style-type: none"> • ... • ... <p>MSOPPT required of pharmacy technicians when acting as a mentor to other staff members, support personnel, or students:</p> <ul style="list-style-type: none"> • ... • ...
<ul style="list-style-type: none"> • Pharmacy technicians apply their drug distribution expertise while performing their daily activities. 	<p>MSOPPT required of pharmacy technicians regardless of the role they are fulfilling:</p> <ul style="list-style-type: none"> • ... • ... <p>MSOPPT required of pharmacy technicians when collaborating to provide patient care:</p> <ul style="list-style-type: none"> • ... • ... <p>MSOPPT required of pharmacy technicians when distributing drugs:</p> <ul style="list-style-type: none"> • ... • ... • ...

(continued)

General Standard	Model Standards of Practice
	<p>MSOPPT required of pharmacy technicians when contributing to management within a pharmacy:</p> <ul style="list-style-type: none"> • ... • ... <p>MSOPPT required of pharmacy technicians when acting as a mentor to other staff members, support personnel, or students:</p> <ul style="list-style-type: none"> • ... • ...

MODEL STANDARDS OF PRACTICE FOR PHARMACY TECHNICIANS

The following describe the model standards of practice required of pharmacy technicians licensed to practice in Canada. The MSOPPT is drawn from NAPRA’s *Professional Competencies for Canadian Pharmacy Technicians at Entry to Practice*¹, but do not replace them. Instead, the numbers in brackets that follow the model standards of practice refer to competency elements in NAPRA’s *Professional Competencies for Canadian Pharmacy Technicians at Entry to Practice*¹. If no number appears in parentheses after the model standard, this means that there is no reference to a competency element within NAPRA’s *Professional Competencies for Canadian Pharmacy Technicians at Entry to Practice*¹. However, it was felt important to add these standards for greater completeness of information.

1. Expertise in drug distribution systems

General Standard	Model Standards of Practice
Pharmacy technicians maintain their competence.	<p>Pharmacy technicians, regardless of the role they are fulfilling,</p> <ol style="list-style-type: none"> 1. fulfill the provincially / territorially mandated requirements for maintenance of competence (1.1.1) 2. adhere to current laws, regulations and policies applicable to pharmacy practice (1.1.1) 3. maintain all certifications / credentials required by pharmacy technicians in their practice (1.1.1)
Pharmacy technicians apply their expertise in drug distribution while performing their daily activities.	<p>Pharmacy technicians, regardless of the role they are fulfilling,</p> <ol style="list-style-type: none"> 4. adhere to current laws, regulations and policies applicable to pharmacy practice (1.1.1) 5. know and practice within their scope of practice 6. know and practice within the limits of their personal competence (1.2.3) 7. seek assistance or refer situations to the pharmacist that fall beyond their scope of practice or personal competence (1.3.2 and 2.1.4) 8. seek out and use appropriate information and/or resources. (1.3.3) <p>Pharmacy technicians, when collaborating to provide patient care,</p> <ol style="list-style-type: none"> 9. ensure confidentiality when gathering, using or providing patient information 10. gather, review, enter and/or update the information required to create and/or maintain a patient record including (3.1.1): <ol style="list-style-type: none"> a. patient demographics; b. health history; c. allergies; d. drug and medical device use, and; e. payment information.

(continued)

General Standard	Model Standards of Practice
	<ol style="list-style-type: none"> 11. assist pharmacists in compiling best possible medication histories[†] for patients, referring to the pharmacist patients who require assessment, clinical analysis or application of therapeutic knowledge[†] 12. identify and refer to the pharmacist patients who have discrepancies between their current drug therapy and their recent or intended drug therapy 13. provide information that does not require application of therapeutic knowledge to patients requiring assistance in selecting non-prescription drugs and medical devices[†] (7.2.4) 14. instruct patients about the operation and maintenance of medical devices[†] (7.2.4) 15. recognize when a patient potentially requires assessment, clinical analysis or application of therapeutic knowledge[†] and consult with the pharmacist in such instances (2.1.4, 3.1.3 and 3.2.5) 16. refer to the pharmacist patients with questions that require patient assessment, clinical analysis or application of therapeutic knowledge[†] (2.1.4) 17. transfer prescriptions to other pharmacies for authorized recipients (3.3) <ol style="list-style-type: none"> a. adhere to legal requirements for transfer and receipt of a transfer of prescriptions (3.3)[‡] b. confirm the accuracy of demographic and prescription information prior to the transfer, including that the prescription is still active and is the most recent prescription available for the drug (3.3.1) c. identify when requests for transfers of prescriptions potentially require patient assessment, clinical analysis or application of therapeutic knowledge[†] and consult with the pharmacist in such situations (3.1.3) 18. provide a copy of prescriptions to authorized recipients[‡] <ol style="list-style-type: none"> a. confirm the accuracy of demographic and prescription information prior to providing a copy, including that the prescription is the most recent prescription available for the drug[‡] b. adhere to legal requirements for providing a copy of prescriptions[‡] <p>Pharmacy technicians, when distributing drugs,</p> <ol style="list-style-type: none"> 19. receive prescriptions in person, electronically[‡], verbally[‡] and by fax, including transferred[‡] prescriptions (3.1) <ol style="list-style-type: none"> a. check the patient's demographic data for completeness and accuracy (3.1.1) b. use knowledge of insurance or other third party coverage to obtain and enter information required for billing and reimbursement (3.1.1) <ol style="list-style-type: none"> i. consult with the pharmacist when there are any questions or concerns requiring patient assessment, clinical analysis or application of therapeutic knowledge[†], including when there are changes in the drug, dosage, instructions for use, adherence, patient profile or health status of the patient (3.1.3) ii. document any changes in a prescription that are authorized by the original prescriber (5.3)

[†] See glossary.

[‡] Under conditions specified by an in accordance with authorities granted to Pharmacy Technicians by laws/regulations/policies/guidelines.

(continued)

General Standard	Model Standards of Practice
	<ul style="list-style-type: none"> c. use effective communication skills and follow applicable policies and procedures when receiving and transcribing verbal prescriptions[‡] d. use effective communication skills and follow applicable policies and procedures when receiving and / or transcribing transferred prescriptions[‡] e. maintain patient confidentiality when receiving verbal, electronic or transferred prescriptions (1.1.2) <p>20. review prescriptions to confirm that they are complete, authentic and meet all current laws, regulations and policies (3.1.2)</p> <ul style="list-style-type: none"> a. determine whether the prescription meets all legal requirements, and where it does not, notify the pharmacist and follow up using applicable policies and effective communication (3.1.2 and 3.1.3) b. inspect the prescription for authenticity and signs of tampering and follow current laws, regulations and policies for non-authentic or fraudulent prescriptions (3.1.2) c. check the prescription information for accuracy and completeness d. perform calculations as required (3.1.2 and 3.2.3) e. review the prescription for clarity of abbreviations, medical terminology, drug names, dosage forms, strengths, availability, schedule, route and related information (3.1.2) f. consult with the pharmacist regarding questions about authenticity, clarity of prescription information, discrepancies and questions requiring patient assessment, clinical analysis or application of therapeutic knowledge[†] (3.1.3) <p>21. process prescriptions (3.2)</p> <ul style="list-style-type: none"> a. record prescription information in the patient profile or health record (3.2.4) b. verify entered prescription information against the original prescription (3.2.4) c. identify and refer to the pharmacist any questions requiring patient assessment, clinical analysis or application of therapeutic knowledge[†] including but not limited to (3.2.5): <ul style="list-style-type: none"> i. changes in the drug, dosage, directions for use, refills, patient profile or health status of the patient; ii. alerts generated; iii. potential duplications in therapy, and; iv. potential adherence problems. <p>22. prepare prescription products[†] according to prescriptions (4.1)</p> <ul style="list-style-type: none"> a. select drugs consistent with applicable laws, regulations and policies including interchangeability (4.1.1) b. retrieve, count, pour, weigh or measure quantities of drugs (4.1.2)

[‡] See page 7.
[†] See glossary.

(continued)

General Standard	Model Standards of Practice
	<ul style="list-style-type: none"> c. compound in accordance with established formulae (4.1.3) <ul style="list-style-type: none"> i. follow formulation instructions, calculate and confirm calculations and use proper techniques to prepare / compound sterile, non-sterile, pre-packaged or reconstituted drug products, and document calculations and procedures (4.1.3) 23. select the container and label(s) for prescription products (4.1.4) 24. assemble patient information materials as specified by the pharmacist (5.2) 25. verify prescription products[§] (5.1.1) <ul style="list-style-type: none"> a. ensure that the prescription product is verified via a final check prior to release (5.1.1) b. complete final checks of prescription products prior to release, including ensuring that: (5.1.1) <ul style="list-style-type: none"> i. the prescription product is correct and in accordance with the prescription and applicable policies; ii. the dosage form, strength, manufacturer and quantity dispensed are correct and in accordance with the prescription and applicable policies; iii. the calculations have been performed correctly; iv. the proper amount of the drug is provided; v. the drug is not expired and will not expire within the duration of use, and; vi. the labelling is accurate including the patient, prescriber and drug name, quantity, directions for use, number of refills. 26. release prescription products[†] (5.2) <ul style="list-style-type: none"> a. confirm that a pharmacist has: <ul style="list-style-type: none"> i. reviewed the therapeutic appropriateness of the prescription including new or refill prescriptions; ii. evaluated the prescription (both for new and refill prescriptions), the patient, the patient’s health history, the patient’s allergies and the patient’s drug-use record, and; iii. provided consultation and education to the patient (5.2.1 and 5.2.2) b. ensure that the right prescription products are released to the right patient or authorized agent (5.2.3) c. answer patient’s questions, referring them to the pharmacist if the question requires patient assessment, clinical analysis or application of therapeutic knowledge[†] (3.2.5) d. alert patients to written information provided on prescription labels, auxiliary labels or patient inserts e. reinforce the availability of the pharmacist for discussion or recommendations

§ Whenever possible, a final check must be performed by a pharmacist or pharmacy technician who did not enter the prescription into the dispensing software system or who did not select the drug from stock.

† See glossary.

(continued)

General Standard	Model Standards of Practice
	<p>27. manage billing and payment for prescription products[†], including third party insurance and adjudication (8.3)</p> <ol style="list-style-type: none"> a. identify and resolve billing or adjudication issues encountered when processing prescriptions (8.3.2) b. assist patients and other health care team members in understanding the limitations and exceptions to formulary or insurance coverage (8.3.2) c. identify when billing or adjudication issues potentially require patient assessment, clinical analysis or application of therapeutic knowledge[†] and consult with the pharmacist in such situations (8.3.2) <p>Pharmacy technicians, when contributing to management within a pharmacy,</p> <p>28. manage the pharmacy environment to ensure the safety, quality and integrity of drugs (9.2)</p> <p>29. maintain inventory to maximize safe and efficient drug distribution, including (6.2.2):</p> <ol style="list-style-type: none"> a. setting order limits and calculating replenishment orders; b. preparing and placing orders in compliance with relevant legislation; c. identifying and minimizing risks associated with look-alike and sound alike products; d. acquiring, receiving, verifying and storing stock and supplies and identifying, investigating and resolving or reporting any discrepancies; e. receiving and storing all drugs and medical devices, including controlled substances (9.2.2): <ol style="list-style-type: none"> i. in compliance with legislation ii. to maintain drug stability and protect integrity; f. identifying / locating, reporting and removing expired, defective, unsafe or recalled drugs and medical devices, and; g. disposing of, destroying or returning expired, unusable or recalled drugs according to legislation. <p>30. complete required audits and reconciliations for controlled substances according to current laws, regulations and policies, identifying and reporting any discrepancies or potential issues to the pharmacist (6.2.3)</p> <p>31. support safe and effective drug distribution through workflow management, organizing their roles and responsibilities to allow the priority to be on patient care and to minimize diversion and dispensing errors (8.1)</p> <p>32. schedule and perform routine equipment maintenance (8.1.3)</p> <p>33. maintain the cleanliness, functionality and integrity of compounding, packaging, dispensing and storage equipment (9.2.1)</p> <p>34. organize, file and store documents according to legal requirements and in a manner in which they can be retrieved readily (8.2.3)</p> <p>35. maintain current records of and abide by policies governing provincial / territorial pharmacy procedures (8.2.4)</p>

[†] See glossary.

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General Standard	Model Standards of Practice
	<p>Pharmacy technicians, when acting as a mentor to other staff members, support personnel, or students (1.3.5), 36. comply with requirements, policies and procedures of relevant training programs as established by or in collaboration with the provincial regulatory authority</p>
<p>Pharmacy technicians provide evidence of application of their drug distribution expertise through documentation.</p>	<p>Pharmacy technicians, regardless of the role they are fulfilling (7.3), 37. maintain clear, accurate and legible records that are consistent with applicable legislation, regulations, policies and standards 38. record in a timely manner, either concomitant with performing of a task or as soon as possible afterwards (7.3.1) 39. document their activities and the information necessary to support the rationale and quality of these activities (5.1.1) 40. adhere to current laws, regulations and policies relating to documentation and applicable to pharmacy practice (5.3)</p> <p>Pharmacy technicians, when collaborating to provide patient care, 41. document their decisions / actions, supporting patient and related information and their interpretation of this information, including: a. documentation in the health record of demographic, health, drug and other relevant information obtained from the patient or their authorized agent (3.1.1), and; b. prescription transfers and copies (3.3.2).</p> <p>Pharmacy technicians, when distributing drugs, 42. document information, procedures, and actions clearly and in a timely manner (7.3.1) 43. record calculations, quantities, sources and procedures used in the preparation and compounding of drug products (4.1.3) 44. document when they have been responsible for ensuring (5.1, 5.3 and 6.2.5): a. that prescriptions received are complete, authentic and meet all legal and professional requirements; b. that a final check of prescription products prepared for distribution has been completed; c. the quality and legality of prescription products prepared for release, and; d. that inventory management and distribution of scheduled drugs and controlled substances has been completed in accordance with required applicable laws, regulations and policies (6.2.5).</p>

2. Collaboration

General Standard	Model Standards of Practice
<p>Pharmacy technicians work constructively with pharmacists, students, peers and members of the inter-professional team.</p>	<p>Pharmacy technicians, regardless of the role they are fulfilling,</p> <ol style="list-style-type: none"> 1. develop collaborative relationships with pharmacists and other health care professionals (2.1.1) 2. co-operate with and show respect for all members of the inter-professional team (2.1.3) 3. recognize and work within their scope of practice and limits of their competence 4. refer patients and other health care professionals to the pharmacist for any question or issue that potentially requires patient assessment, clinical analysis or application of therapeutic knowledge (2.3) 5. act as positive role models 6. fulfill their roles and obligations to colleagues in a timely manner 7. ensure their activities are consistent with the health care goals of maintenance of wellness and health promotion 8. adhere to laws, regulations and policies applicable to pharmacy practice (1.1.1) 9. participate as a team member in organized initiatives for disaster and emergency preparedness (2.1.6) 10. promote understanding of the pharmacy technician role and its relationship to the roles of other health care providers (1.3.4)
<p>Pharmacy technicians communicate effectively.</p>	<p>Pharmacy technicians, regardless of the role they are fulfilling,</p> <ol style="list-style-type: none"> 11. demonstrate comprehension and proficiency in written and verbal English or French (7.1.1) 12. select and use effective verbal, non-verbal, listening and written communication skills (7.1.1) 13. communicate with sensitivity, respect and empathy (7.1.2) 14. manage conflict in a professional manner (7.1.2) 15. respect patient confidentiality (1.1) <p>Pharmacy technicians, when collaborating to provide patient care,</p> <ol style="list-style-type: none"> 16. listen to patients and respect their views about their health and drugs (1.2.1) 17. maintain confidentiality while using communication techniques appropriate for patients or other health care professionals (7.1.1) 18. obtain from and share information with patient's care providers or other health care professionals as required (2.1.3): <ol style="list-style-type: none"> a. in accordance with applicable laws, regulations and policies, and; b. to support safe and effective therapy.

3. Safety and Quality

General Standard	Model Standards of Practice
Pharmacy technicians undertake continuing professional development, quality assurance and quality improvement activities.	<p>Pharmacy technicians, regardless of the role they are fulfilling,</p> <ol style="list-style-type: none"> 1. demonstrate a commitment to the quality and safety of the health care system (1.3.7 and Safety Competencies^{3**}) 2. participate in continuing professional development (1.3.6) 3. recognize and report any unsafe, illegal, unethical or unprofessional actions or situations to the appropriate person or authority and assist in their resolution (1.2.2 and Safety Competencies³) 4. comply with relevant workplace and occupational health and safety legislation (1.1.3) 5. ensure that staff or support personnel for whom they are responsible are assigned and undertake activities appropriate to their training and consistent with legislation, regulations and policies (8.1) 6. recognize and report problems within the distribution system (9.1.1) 7. contribute to quality and safety initiatives (9.1.2 and Safety Competencies³)
Pharmacy technicians respond to safety risks.	<p>Pharmacy technicians, regardless of the role they are fulfilling,</p> <ol style="list-style-type: none"> 8. recognize the occurrence of adverse events[†] or close calls[†] (9.1.1 and Safety Competencies³)[†] 9. determine the immediate safety and care needs of patients affected by adverse events and close calls, and provide appropriate interventions (Safety Competencies³) 10. report the occurrence of adverse events and close-calls to the pharmacist and disclose the event as appropriate (1.2 and Safety Competencies³) 11. participate in and promote patient safety initiatives (2.1.5 and Safety Competencies³) 12. collaborate in the documentation and review of adverse events and close calls and the development of policies and procedures to minimize adverse events and to promote safety initiatives (9.1.2 and Safety Competencies³)

^{**} A number of the standards contained in the MSOPPT relate to competencies identified by the Canadian Patient Safety Institute in their *Safety Competencies*³. The MSOPPT acknowledge these linkages but do not identify this common content. Only those MSOPPT that use CPSI terminology or phrasing taken from the safety competencies are referenced directly to the *Safety Competencies*³.

[†] See glossary.

4. Professionalism and Ethics

General Standard	Model Standards of Practice
<p>Pharmacy technicians demonstrate professionalism and apply ethical principles in their daily work.</p>	<p>Pharmacy technicians, regardless of the role they are fulfilling,</p> <ol style="list-style-type: none"> 1. treat others with sensitivity, respect and empathy (7.1.2) 2. demonstrate personal and professional integrity (1.2.3) <ol style="list-style-type: none"> a. maintain the patient’s best interest as the core of all activities (1.1.1) b. accept responsibility for their actions and decisions (1.2.3, 1.3.1) c. maintain professional boundaries (1.2.3) d. adhere to applicable laws, regulations and policies applicable to pharmacy practice (1.1) 3. ensure confidentiality of patient information and request and release such information only where appropriate and legally allowed (1.1.2 and 1.1.4) 4. provide information that does not require the application of therapeutic knowledge to patients, respecting their right to make their own, informed, decisions and supporting them in their ability to provide self-care (1.1.1)

PARTICIPANTS IN THE DEVELOPMENT OF THE MSOPPT

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Association of Faculties of Pharmacy of Canada	Newfoundland and Labrador Pharmacy Board
Canadian Association of Pharmacy Technicians	Nova Scotia College of Pharmacists
Canadian Council for the Accreditation of Pharmacy Programs	Ordre des pharmaciens du Québec
Canadian Society of Hospital Pharmacists	Ontario College of Pharmacists
College of Pharmacists of British Columbia	Pharmacy Examining Board of Canada
Government of the Northwest Territories	Prince Edward Island Pharmacy Board
Government of Nunavut	Saskatchewan College of Pharmacists
Manitoba Pharmaceutical Association	Yukon Consumer Services

***Acknowledgement:** Other individuals and organizations may have contributed via the pharmacy regulatory authorities in their respective jurisdictions.*

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GLOSSARY

The following definitions are provided for key terms used in the following document.

Adverse event³

An event that results in unintended harm to the patient, and is related to the care and/or services provided to the patient rather than to the patient’s underlying medical condition.

Best Possible Medication History (adapted from reference 4)

A list of all medications that a patient is or has been taking at home including drug name, dose, frequency and route.

Close call³

An event with the potential for harm that did not result in harm because it did not reach the patient due to timely intervention or good fortune (sometimes called a near miss). The term “good catch” is a common colloquialism to indicate the just-in-time detection of a potential adverse event.

Distributing/Distribution (modified from reference 1)

With respect to a drug, distribution is the safe transfer of a drug from the manufacturer to the patient in a manner that preserves both the integrity of the drug and the safety of the patient.

Drug

The definition of a drug from the *Food and Drugs Act* is used as follows⁵:

Drugs include any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring, correcting or modifying organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept

Drugs, therefore, include both natural health products and mixtures compounded or prepared in a pharmacy, but exclude medical devices.

Drug Distribution System (modified from reference 1)

A system designed to facilitate the safe transfer of a drug or medical device from the manufacturer to the patient in a manner that preserves both the integrity of the drug or medical device and the safety of the patient. Steps in the drug distribution system include manufacturing, storage, procurement, dispensing, administration and returns.

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Medical Devices

The definition of a device from the *Food and Drugs Act* is used as follows⁵:

Device means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring, correcting or modifying a body function or the body structure of human beings or animals,
- (c) the diagnosis of pregnancy in human beings or animals, or
- (d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug.

As a summary, medical devices may include but are not limited to: home monitoring devices, drug delivery devices, medical supplies and equipment, and home health care products.

Patient (modified from reference 1)

Any person or authorized agent who is provided a drug or medical device and/or service that is within the practice of pharmacy. The authorized agent refers to a family member, caregiver, or another person who has a close personal relationship with the patient and whom that patient has endorsed for this purpose.

Prescription Product

Any drug or medical device prepared for a patient further to a prescription.

Therapeutic Knowledge

Therapeutic knowledge refers to knowledge required for the evaluation, selection, use, monitoring, advice, education and/or recommendations related to appropriate drugs to assist in the:

- (a) management of individual patient's symptoms and disease states, and / or,
- (b) identification, management and/or resolution of drug-related problems.

Therapeutic knowledge does not include information and basic knowledge related to:

- (a) principles related to communication, collaboration, professionalism, ethics or legal aspects of pharmacy practice
- (b) drug distribution systems
- (c) basic pharmacology (i.e. mechanism of action, uses and customary doses of common drugs and drug classes)

(continued)

- (d) basic pharmaceuticals (i.e. drug contents, dosage forms, stability and physical compatibility, pharmaceutical calculations)
- (e) basic nutritional, social and other factors involved in health maintenance and well-being
- (f) principles and practices related to patient safety
- (g) principles and practices related to pharmacy management

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