Roles and Responsibilities of Pharmacists with Respect to Natural Health Products: Stakeholder Interviews

by

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A thesis submitted in conformity with the requirements for the degree of Master of Science Graduate Department of Pharmaceutical Sciences, University of Toronto

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Abstract

Roles and Responsibilities of Pharmacists with Respect to Natural Health Products: Stakeholder Interviews by Shade Olatunde, Master of Science, Department of Pharmaceutical Sciences, University of Toronto, 2008

Background: Although many pharmacies sell natural health products (NHPs), there is no clear definition as to the responsibilities (if any) of pharmacists towards these products.

Objective: The purpose of this study was to explore and compare pharmacy and stakeholder leaders’ perceptions of pharmacists’ professional NHP responsibilities.

Methods: Semi-structured key informant interviews were conducted with pharmacy leaders and stakeholder leaders representing: consumers, complementary and alternative medicine practitioners, conventional healthcare practitioners, and industry across Canada.

Results: Nearly all participants believed safety monitoring was a key responsibility of pharmacists. One challenge identified was pharmacists’ general lack of NHP knowledge. Stakeholder leaders did not expect pharmacists to be NHP experts, but should have a basic level of education on NHPs. Many pharmacy leaders seemed unfamiliar with current pharmacy NHP policies.

Conclusion: Participants described pharmacists’ professional responsibilities for NHPs as similar to those for over-the-counter drugs. More awareness of existing NHP-related pharmacy policies is needed.
To my family and friends who have always believed in me
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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>TITLE PAGE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSTRACT</td>
<td>ii</td>
</tr>
<tr>
<td>DEDICATION</td>
<td>iii</td>
</tr>
<tr>
<td>ACKNOWLEDGEMENTS</td>
<td>iv</td>
</tr>
<tr>
<td>FUNDING</td>
<td>v</td>
</tr>
<tr>
<td>TABLE OF CONTENTS</td>
<td>vi</td>
</tr>
</tbody>
</table>

1. INTRODUCTION
   1.1 Purpose
   1.2 Rationale
   1.3 Organization of Thesis
   References

2. BACKGROUND
   2.1 Regulatory Framework
      2.1.1 Federal Framework
      2.1.2 Pharmacist Regulation
   2.2 Pharmacists and NHPs
      2.2.1 Definitions
      2.2.2 Pharmacists’ Perceptions of their Role and Responsibility for NHPs
      2.2.3 Stakeholders and NHPs
      2.2.4 NHPs and Health Food Stores
      2.2.5 Pharmacist NHP Education
   2.3 Research Objective
   References

3. METHODOLOGY
   3.1 Methodological Design
   3.2 Sample
   3.3 Data Collection
      3.3.1 The Interview Guide
   3.4 Data Analysis
   3.5 Ethical Issues
      3.5.1 Confidentiality
      3.5.2 Risks and Benefits
      3.5.3 Compensation
      3.5.4 Conflicts of Interest
   References

4. ROLES AND RESPONSIBILITIES OF PHARMACISTS WITH RESPECT TO NATURAL HEALTH PRODUCTS: STAKEHOLDER INTERVIEWS
   Abstract
   Introduction
CHAPTER 1
1. INTRODUCTION

Over the past decade North American use of natural health products (NHPs) such as vitamins and minerals, herbal medicine and homeopathy, has risen significantly. (1-3) Although NHPs can be purchased from a variety of sources such as health food stores and grocery stores, Canadians often purchase NHPs in pharmacies. (1, 2) There is evidence to suggest that Canadian consumers are more likely to approach a pharmacist when seeking information about NHPs for the first time than any other health care professional. (4) Although numerous studies have examined pharmacists’ attitudes, perceptions and behaviours towards NHPs (5-13), much of this work did not receive stakeholder (e.g., from consumers, complementary and alternative medicine (CAM) practitioners, other conventional health care practitioners, or NHP industry) input. Since pharmacists interact with consumers as well as other members of the health care team regarding NHPs, their perceptions of what the pharmacists’ role should be will provide valuable insight. Literature on stakeholders has focused on consumers’ perspectives on CAM and NHPs and their reasons for using such therapies. (4, 14-16) Despite the widespread use of NHPs, almost no work has been done on other stakeholders’ perceptions of pharmacists’ professional roles and responsibilities with respect to NHPs. Since NHPs are available without a prescription in other retail settings such as health food stores, it is unclear whether consumers want or need pharmacists’ guidance in making health decisions about NHPs. Do non-consumer stakeholders consider NHPs a part of the pharmacist’s scope of practice? And if so, what roles and responsibilities would pharmacists’ have?
1.1 Purpose

The purpose of this study is to explore and compare pharmacy leaders’ and stakeholder leaders’ perceptions of the professional roles and responsibilities of pharmacists in regards to NHPs. On a wider scale this project also contributes to a larger body of work focused on influencing Canadian NHP pharmacy education and practice standards for pharmacists to align with stakeholder expectations.

1.2 Rationale

Pharmacists are considered to be drug experts (for both prescription and non-prescription drugs) and are responsible for ensuring complete pharmaceutical care of their patients. Studies with consumers have indicated that patients desire NHP information on duration, use, and safety. At the same time, a number of pharmacist surveys have indicated that front-line pharmacists generally are not knowledgeable about NHPs and want more information to properly counsel consumers.(6, 7, 10-12, 17) In pharmacy schools across North America there is generally a modest level of NHP-specific content in the pharmacy curricula.(18, 19) Pharmacy NHP policy documents across Canada use inconsistent language with some specifying conventional drugs, over-the-counter (OTC) medicines, or NHPs. With high consumer demand, the current variable (and often low) level of pharmacist NHP education, and unclear policies, can pharmacists truly claim to adequately counsel consumers about NHPs? It is clear that if pharmacists are to have any type of role and responsibility with NHPs, pharmacy education and policies need to be in line with stakeholder expectations.
1.3 Organization of Thesis

This is a paper-based thesis rather than a traditional format thesis. Essentially this means that the main findings of the thesis are presented in the form of a publishable paper. In this format, there is some necessary repetition of the topics throughout the thesis because the background and methods chapters are essentially repeated (in summary form) in the paper that forms the results chapter. This Master of Science thesis has been organized into a series of chapters covering background, results (the paper), discussion and summary of the work completed. A brief overview is described below.

Chapter 2: Background

A review of the literature was completed to provide a context for the study described here. A brief overview is given for how NHPs are regulated in Canada, the regulation of pharmacists in Canada; pharmacists’ perceptions of their roles and responsibilities toward NHPs; stakeholders’ perceptions of pharmacists’ roles and responsibilities toward NHPs; pharmacists’ NHP education; current view of the quality of NHP knowledge and advice provided by health food store staff.

Chapter 3: Methodology

A qualitative methodological approach was taken for this project. Semi-structured key informant interviews were conducted with pharmacy leaders and stakeholder leaders. Stakeholder leaders included consumer groups, CAM practitioners, conventional healthcare professionals (HCPs), and industry. Interview participants were selected by
criteria-based purposive sampling. This chapter provides a detailed description of the methods used.

Chapter 4: Results

The results section of this project has been captured in the form of an article that will be submitted for publication in the International Journal of Pharmacy Practice. Key themes identified by participants include: strong support for a role of pharmacists with respect to NHPs; and the identification of key tasks for pharmacists such as the ability to provide relevant NHP information, counsel on NHPs in a similar manner to OTCs, and monitor for potential NHP adverse events and interactions. This article will be submitted for publication immediately after the successful defense of the thesis.

Chapter 5: Discussion and Conclusion

Although there is agreement by both the pharmacy leaders and stakeholder leaders that the pharmacist has a role with respect to NHPs, there are a number of challenges to overcome in order for pharmacists to carry out their professional roles and responsibilities. Challenges identified by pharmacy leaders and stakeholder leaders to pharmacists carrying out NHP tasks include: level of pharmacists’ NHP knowledge and education; advice given by health food stores; and ambiguity around and lack of awareness of current NHP pharmacy policies. Despite recent federal regulations of NHPs there have generally been no significant changes to most pharmacy policies or pharmacy curricula. In order to assume professional responsibilities towards NHPs, changes will need to be made to the educational standards and licensing requirements for pharmacists. Minimum NHP
education standards and examination content need to be established such that pharmacists have a baseline level of knowledge for these products. Greater work needs to be done in ensuring that NHP policies are explicitly worded and disseminated to front-line pharmacists to ensure that their responsibilities are clear and aligned to stakeholders’ expectations.
References


CHAPTER 2
2. BACKGROUND

Most Canadians (71%) have used a natural health product (NHP) such as vitamins, herbs or other supplements at some time in their lives.(1) Over the past decade NHP use has been on the rise in North America as a whole(1-3) with some studies estimating 28-32% of consumers use NHPs concurrently with prescription and other conventional over-the-counter (OTC) medication.(4, 5) With this significant incidence of combined use, there is an increased potential for individuals to experience adverse events associated with NHPs and/or conventional medication-NHP interactions. Due to widespread consumer use of NHPs, the availability of NHPs for self-selection in various retail locations, the claimed expertise of complementary and alternative medicine (CAM) practitioners with respect to NHPs and the possible influence of other conventional health care providers on NHP consumption; it is clear that non-pharmacist stakeholder input will be instrumental in determining the pharmacist’s role (if any) with respect to NHPs. Although the pharmacists’ role with respect to conventional prescription and OTC products is well defined, it is not clear if non-pharmacist stakeholders consider NHPs part of the pharmacists’ scope of practice. And if NHPs are part of pharmacists’ scope, then what are their professional roles and responsibilities with respect to NHPs? The aim of this project is to examine pharmacy leaders’ and stakeholder leaders’ (i.e., consumer group leaders, NHP industry representatives, CAM group leaders, and leaders of conventional medicine groups) expectations of the professional roles and responsibilities of pharmacists towards NHPs. This chapter will begin with reviews of the regulation of NHPs and of the regulation of pharmacists across Canada. The literature suggests that the pharmacist may have potential roles and responsibilities with respect to NHPs. However, there are challenges to
effectively carrying out any role because of pharmacists’ general lack of knowledge of NHPs which is primarily a product of limited NHP education. Each of these topics will be discussed in greater detail in the following paragraphs.

2.1 Regulatory Framework

In Canada, the federal government sets the legal framework for the regulation of NHPs, but it is the responsibility of the various provinces/territories to define the scope of practice responsibilities of pharmacists.

2.1.1 Federal framework

The Natural Health Product Directorate (NHPD) is the health authority responsible for the regulation of the sale and manufacture of NHPs. According to the Natural Health Products Regulations of the Food and Drug Act that came into effect on January 1, 2004:

“NHPs are defined as: vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines such as traditional Chinese medicine, probiotics, amino acids and essential fatty acids” that are used for “(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; (b) restoring or correcting organic functions in humans; or (c) modifying organic functions in humans such as modifying those functions in a manner that maintains or promotes health.”

The Food and Drugs Act has generally defined NHP use similar to the use of conventional drugs for “(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or
abnormal physical state or its symptoms in humans; (b) restoring or correcting organic functions in humans; or (c) modifying organic functions in humans such as modifying those functions in a manner that maintains or promotes health.”(6) In addition to defining NHPs, the regulations also include requirements for: product licensing; site licensing; adherence to good manufacturing practices; clinical trials; labelling/packaging and adverse reaction reporting. NHPs must be safe, be available for self-care and not require a prescription to be sold.(7) That is, they must be safe for consumers to use based on the information provided with the product (labelling and packaging) without the intervention of a health care provider. Thus, it is not clear if pharmacist involvement is desired or needed with respect to NHPs.

2.1.2 Pharmacist Regulation

Pharmacists are a self-regulating health profession in Canada and individuals must be licensed by their respective province or territory in order to practice. Although their professional responsibilities vary among jurisdictions, all pharmacists have the responsibility to dispense prescription medications to consumers. Existing pharmacy policy documents define the responsibilities of pharmacists towards consumer usage of prescription drugs and non-prescription or OTCs, clearly indicating that these products are within their scope of practice. However, pharmacy policy documents are far less clear with respect to NHPs.

Generally the provinces/territories can be categorized into three broad groups: 1) those whose policies refer to “drugs” in general only; 2) those that refer to “drugs” (but clearly
state or strongly imply that the policy refers to drugs that require a prescription, and OTCs only); and 3) those that refer to drugs, OTCs and NHPs specifically. Among the pharmacy licensing authorities across Canada: six regions (Saskatchewan, Quebec, Newfoundland & Labrador, New Brunswick, Yukon Territory, Northwest Territories) have policy wording that fit category 1; two regions’ (British Columbia and Alberta) policies fall under category 2; and four regions (Manitoba, Ontario, Nova Scotia, Prince Edward Island) have policies that are in category 3.(8)

At the level of the Food and Drugs Act (where all products are categorized as foods or drugs), NHPs are defined as a sub-class of drugs. Thus, one could argue that policy documents referring to drugs generically now also apply to NHPs. At the same time, federal regulations clearly state that NHPs must “be available for self-care and self-selection”(7), thus implying that policy documents referring to OTCs could also apply to NHPs. This suggests that depending on how one interprets the current pharmacy policies, it could be argued that legally NHPs are already part of pharmacists’ professional scope of practice. However, the inconsistent use of terminology and lack of clear definitions in pharmacy policy documents has created a situation whereby multiple understandings of the pharmacists’ NHP practice responsibilities (if there are any) exist at the provincial/territorial level.

Previous studies indicate that pharmacists do not perceive NHPs to be the same as conventional medications, and they are generally less knowledgeable about NHPs in comparison to conventional medications.(9-13) Since NHPs are commonly sold in pharmacies, it is clear that pharmacists’ responsibilities need to be clarified for these
products. Several recent surveys provide some clues about what their professional responsibilities could entail.(9-14)

2.2 Pharmacists and NHPs

There is a significant amount of literature exploring pharmacists’ attitudes and behaviours toward NHPs.(9, 10, 12, 14, 15) Much of this work provides general suggestions about the tasks pharmacists’ could perform if NHPs are considered part of their scope of practice. However, there appears to be a gap in the literature when it comes to exploring stakeholders’ (e.g. consumers, CAM health care providers, and NHP/pharmacy industry) expectations of pharmacists’ professional roles and responsibilities with respect to NHPs. In addition, NHPs are sold in locations outside pharmacies (e.g., in health food stores) which prohibits any professional exclusivity claims of pharmacists with respect to the NHP domain. Finally, it is not clear if pharmacists have the knowledge to enact many of the professional roles and responsibilities suggested in the literature.

2.2.1 Definitions

In order to have an understanding of this project, one must have a clear definition of the terms: scope of practice, role, and responsibility. The pharmacy literature shows considerable inconsistency and overlap in the definitions of the aforementioned terms.(16) For the purposes of this project the terms are defined as follows:

- Scope of practice: the extent or range of the pharmacist’s opportunity to function(17)
• Role: a customary function (or position) of the pharmacist(18)
• Responsibility: having a moral/ethical/legal obligation for a specified task or duty.(19)

As is explored below, although there is growing consensus that NHPs are within pharmacists’ scope of practice, their specific NHP-related roles and responsibilities remain ill-defined.

2.2.2 Pharmacists’ Perceptions of their Role and Responsibility for NHPs

The majority of pharmacists surveyed in several studies believed they had a professional role to counsel patients, describing their position as educators and information providers with respect to NHPs.(9-13) Some key pharmacy organizations also appear to agree that pharmacists have roles and responsibilities with respect to NHPs. For example, the Canadian Society of Hospital Pharmacists as well as the American College of Clinical Pharmacy have written position statements on pharmacists’ roles with respect to NHPs.(20, 21) These position statements provide general guidance on how pharmacists should behave towards NHPs such as asking consumers about NHP use in an open non-judgmental manner; providing advice on potential risks and benefits; having access to reputable NHP resources; and reporting suspected adverse reactions associated with NHPs. The key issue with these statements is that they are completely theoretical and based primarily on “expert” opinion. Despite the fact they describe what pharmacists should be able to do for consumers and other groups, none of this work involved input from stakeholders such as consumers, CAM practitioners, conventional HCPs, or members of the NHP industry. Non-pharmacist stakeholder input could assist in shaping pharmacist NHP practices by
ensuring the practices are aligned with consumer expectations and promote collaboration within the patient’s health care team.

2.2.3 Stakeholders and NHPs

There has been no published research comparing or contrasting pharmacists’ and non-pharmacist stakeholders’ expectations of pharmacists’ professional roles and responsibilities with respect to NHPs. Much of the literature focuses on how pharmacists might help consumers make informed decisions about NHPs, yet it is not clear that consumers want help from pharmacists. Consumers may be consulting other sources of NHP information such as CAM practitioners, other conventional health care providers or health food store clerks. Pharmacists will find it difficult to assume a role with respect to NHPs if these other stakeholder groups oppose it. Only by exploring stakeholder needs and perceptions can pharmacists understand (and ensure they are equipped to meet the needs of) non-pharmacist groups.

Studies have examined consumer attitudes and behaviours toward NHPs/CAM and identified some opportunities and challenges for pharmacists and health professionals more broadly. Key concerns identified for consumers in the literature include: information needs and barriers to communication about NHPs. For example, a 2005 survey found that 84% of Canadian consumers polled indicated they needed more information about the safe use of NHPs.(1) Consumers indicated a high interest in safety information such as possible side effects; potential interactions with other drugs, NHPs or food; and duration of treatment.(4, 20, 22) Another study indicated that consumers believe they have insufficient information
about cost and uses for particular NHPs. (4, 23) Consumers have complained of having difficulty discerning among the vast amount of commercialized information on the internet as well as books, magazines and media coverage, yet many studies indicate that consumers most often turn to friends or family in selecting which NHPs to use. (1, 4) They also often seek advice from the retail outlet where NHPs are purchased. (4)

If pharmacists are to have a NHP-related role there are a number of challenges that will need to be addressed. Such challenges to pharmacists’ carrying out a role include: consumers not disclosing NHP use, satisfying consumer needs for NHP information, competing with the advice given by health food stores, and ensuring they have an appropriate level of knowledge on NHPs in order to adequately counsel consumers.

Studies suggest that consumers often fail to disclose NHP use, or are reluctant to bring up their NHP questions to their health care professionals. (14) Reasons cited by consumers included a concern of negative bias by the health care professionals and perception that the health care professionals will lack the knowledge about NHPs to answer their questions. (15, 24, 25) Many studies have also reported that consumers commonly believe that since NHPs are natural they are therefore “safe” and thus there is no need to discuss them with health care providers. (26) It is not clear if pharmacists can overcome these communication challenges to assume a role as information providers regarding NHPs.
2.2.4 NHPs and Health Food Stores

NHPs are sold in various retail settings besides pharmacies such as health food stores, convenience stores and grocery stores. Health food stores in particular often have a much wider selection of NHPs and are quite competitive in price in comparison to pharmacies, thus enticing consumers. However, in non-pharmacy retail settings consumers do not have access to regulated health care practitioners, such as pharmacists, and often rely on the NHP label, word-of-mouth or health food store employee to assist them with making NHP purchasing decisions.

Of particular concern is the advice provided by retail health food staff to consumers regarding NHPs. Health food store employees are not required to have any formal training or knowledge on NHPs. Several studies strongly suggest that many health food store employees do not take into account patients’ medical/medication history or regulatory authority advisories when advising consumers. As a result, recommendations made by health food staff may result in potential NHP-drug interactions and adverse events among consumers.

Given the lack of training of health food store clerks, it is not surprising that many consumers rated pharmacists as one of the most popular sources of information for NHPs. Many consumers appear to expect pharmacists to be able to answer questions about all health care products, especially those that are purchased in the pharmacy, whether they are conventional or NHP medications. Since health food store employees do not appear to give reliably appropriate information or advice about NHPs,
pharmacists may have a professional role as NHP information providers for consumers. One big question remains: are pharmacists prepared to take on such a role?

2.2.5 Pharmacist NHP Education

Although studies indicate that pharmacists support the notion of having a NHP role, pharmacists also indicated they had inadequate knowledge or training on NHPs to fulfill the responsibilities that may come with that role.(9, 10, 14) The concern about insufficient education was mirrored in virtually all the studies reviewed involving practicing pharmacists. Overall, many pharmacists reported they had insufficient knowledge about NHPs to be able to properly counsel or recommend NHP use to consumers.(9-13) Other studies have confirmed that pharmacists want more NHP continuing education programs and NHP information resources in order to confidently perform their professional NHP-related roles and responsibilities.(10, 30)

In spite of pharmacists indicating a need for more NHP/CAM education, in the North American literature the inclusion of NHP-specific training into undergraduate pharmacy curricula has been highly variable. In a number of studies, education about NHPs varied widely among pharmacists from none to required courses and curricula where NHPs are fully integrated throughout the program.(14, 31, 32) Pharmacists who are particularly interested in CAM/NHPs appear to seek training through continuing education courses or courses from schools specializing in CAM or NHPs.(32) If pharmacists plan to embrace a scope of practice that includes NHPs, minimum educational standards for these products
will need to be determined. Input from stakeholder groups could assist in determining what is expected (or not) by pharmacists with regards to NHPs.

2.3 The Research Objective

Ultimately, the question remains: what (if any) are pharmacists’ professional roles and responsibilities with respect to NHPs? Given that many roles and responsibilities suggested for pharmacists (e.g., information provider) involve other stakeholders (most notably consumers), then input is needed from these stakeholders to ensure that pharmacists are able to meet their needs and expectations. Another literature gap identified is that virtually no work has been done to investigate who consumers consider the expert on NHPs. Would consumers be better off having CAM practitioners such as naturopaths, herbalists, TCM providers advising them instead of conventional health care providers such as pharmacists? Who should be advising consumers when it comes to NHPs? This study addresses this problem by not only examining pharmacy leaders’ perspectives on NHPs, but also comparing and contrasting stakeholder leaders’ perspectives to get a realistic account of the expectations of pharmacists’ roles and responsibilities towards these products.
References


CHAPTER 3
3. METHODOLOGY

3.1 Methodological Design

A qualitative approach was chosen because there is insufficient information regarding the key issues and questions associated with what pharmacists’ responsibilities should be with respect to NHPs. Semi-structured key informant interviews were conducted with pharmacy leaders and stakeholder leaders.

Key informants are individuals who possess special knowledge or status. (1, 2) One advantage to interviewing key informants is that it is only necessary to speak to a few individuals (who are knowledgeable about the topic of interest) to explore a variety of different perspectives in depth. Good key informants, (“those that are articulate and culturally sensitive” (p.58)(1)) help the researcher understand and interpret the concepts being investigated.(2) Key informants are generally experts in their field and are well-connected. In this case pharmacy leaders represented various aspects of the pharmacy profession including regulatory, education, professional association, and retail pharmacy. Stakeholder leaders were chosen because of their abilities to provide rich information based on their positions of influence with respect to shaping the future of pharmacy, based on their perceptions of its current state. Since they have first-hand knowledge of the issues at hand, (e.g., pharmacy policy development, education and practice standards, consumer needs, collaboration with industry and other healthcare providers) they should be able to offer rich and detailed information about the changing roles and responsibilities of pharmacists. Due to the leaders’ distinct positions as head of their groups, they are
generally well-placed to implement higher level collective changes for their organizations and to disseminate information to front-line staff or members.

Key informant interviews allow one to capture candid and sensitive information from participants that may not feel comfortable sharing in writing or a focus group setting. The key informant interview setting gives the interviewer a chance to probe and clarify information that may not be possible using survey or focus group data collection techniques. For example, when conducting an exploratory study concerning people’s perceptions and opinions it is ideal to try and interact with participants in person to maximize the amount of information gathered, which may be lost in written responses in a survey. Probing as new themes emerged and clarifying participant responses would have been impossible using a survey.

Focus groups were also not a good alternative, because many of the leaders’ opinions were confidential and not to be shared with their peers or other stakeholder leaders. Their candid comments enrich the data by describing in-depth issues that would likely only be disclosed in a private setting such as a personal interview. There were also a number of participant responses that could be perceived as reflecting negatively on their organization, or contained negative opinions toward other types of organizations interviewed. Without confidentiality in place, it is unlikely that participants would be willing to speak about this topic for fear of repercussions or perceived bias by the public and/or their peers. In addition, it would have been practically impossible to attempt to schedule multiple leaders
from different provinces to participate in a common discussion at a single time and location.

3.2 Sample

Criteria-based purposive sampling was used for this study. The purpose of this type of sampling is to choose participants who are likely to provide insight into the research questions being explored, based on specific criteria. For this study, pharmacy leaders were defined as someone who is president, dean, head, chair or director of a pharmacy regulatory college, school, national association, voluntary pharmacy organization, or owner/manager of a chain or independent pharmacy. A list of pharmacy leaders was compiled based on all the known registered pharmacy schools, provincial pharmacy colleges, provincial and national pharmacy organizations; and major drug store chains in Canada. A number of independent pharmacy stores in Toronto, Vancouver and Halifax that were identified by the study team or by word of mouth as drugstores that had a particular emphasis on NHPs were also included in the list. The intention of creating a list of independent drugstores was not to be exhaustive but merely to ensure that the “independent pharmacy store” perspective would be captured in our data. The pharmacy leaders were chosen to ensure a range of different types (e.g., regulatory body, association leader, education leader, or pharmacy retail leader) and geography (to ensure a range across Canada). A variety of national and provincial representatives was chosen when possible.
The non-pharmacist stakeholder leaders were comprised of four main groups: consumer leaders, complementary and alternative medicine (CAM) practitioner group leaders, conventional healthcare practitioner (HCP) leaders, and industry leaders. A stakeholder leader was defined as an individual who is the president, head, chair or director of a consumer advocacy group, CAM practitioner association, conventional HCP organization, or NHP industry group. The stakeholder list was not exhaustive as it is impossible to identify all Canadian consumer, CAM, HCP, and NHP industry leaders. The list was created by the study team based on Internet searches, general knowledge and word of mouth. The goal of the list was simply to ensure that a range of stakeholder groups was identified for possible interviews for the project. The resulting list contained far more potential participants than was needed for interviews. Stakeholder leaders were chosen from the list to ensure a variety of groups representing a range of diseases, age populations, special interest groups, CAM modalities and geographical regions across Canada.

In all cases (both pharmacy and stakeholder), the head of each group was interviewed whenever possible, unless s/he recommended an alternate spokesperson that may have a specific interest in the legal and ethical responsibilities of pharmacists with respect to NHPs. At the conclusion of each interview, each participant was asked if s/he could recommend any other individuals (in their organization or others) that may be able to provide additional insight into the professional responsibilities of pharmacists with respect to NHPs (“snowball sampling”). This type of sampling allowed for identification of additional key informants throughout the study and was a way to ensure that no one with important or unique knowledge in the area of study was omitted from participation.
inadvertently. The only exclusion criterion identified was that consumer stakeholder leaders could not be licensed healthcare professionals (e.g., physicians, nurses, pharmacists, chiropractors or naturopathic practitioners).

### 3.3 Data Collection

A letter introducing the study and the consent form was sent to each potential interviewee via email or mail (see Appendices A and B). Approximately one week after the initial contact, a follow-up call or email was made to each potential interviewee that had not responded. A final call/email was made approximately one week after the initial reminder. No response after the second reminder constituted refusal to participate and another candidate was selected from the stakeholder list. Once a written or verbal confirmation was received from the participant, a time and convenient location for the interview was arranged. Written informed consent was obtained from each interviewee prior to beginning each interview (see Appendix B). Telephone participants were instructed to fax or mail the signed consent form prior to the interview date. In all interviews, consent was re-confirmed verbally at the beginning of each interview.

All interviews were conducted in English and interviews continued until saturation was reached for the key emergent themes such as possible NHP-related roles and responsibilities of pharmacists, counseling, pharmacist education, safety, and policy. Saturation was the point at which no new information or themes were observed from the interview participants. At that point, additional interviews did not appear to be adding to the findings as there was significant repetition to what was already found in previous
interviews. Each interview lasted 30 minutes to one hour and was audio-recorded. In most cases interviews were conducted in-person; however a few interviews were conducted by telephone. Interviews were transcribed verbatim and subsequently coded by two to three researchers.

A total of 35 interviews were completed. Of the total interviews 15 were conducted by Shade Olatunde, and the remaining 20 were conducted by Dr. Heather Boon and Dr. Kristine Hirschkorn. Twenty-nine of the interviews were conducted in person and six were done by telephone. Shade Olatunde participated in the coding and analysis of all the interviews.

3.3.1 The Interview Guide

The drafting of the semi-structured interview guide was an ongoing process that developed as participant interviews progressed. The semi-structured guide consisted of a series of focused open-ended questions to obtain a range of opinions on the topic of study. The initial interview guide was created based on key issues and gaps identified in a review of the literature. The intention of the interview guide was to explore participants’ perceptions of pharmacist NHP education, pharmacist NHP policies, pharmacists’ legal and ethical responsibilities towards NHPs, NHP knowledge by pharmacists, and stakeholder perceptions of pharmacists. The interview guide provided structure and consistency so that the key topics of interest were explored in each interview. However, it was not proscriptive with respect to the order in which issues were discussed. As new themes or
topics emerged from interviews, the interview guide was adjusted to incorporate the new information. Hence, the interview guide was changed several times during the early interviews and as the interviews progressed fewer changes were made as a result of fewer new themes being identified in later interviews.

In brief, the interview guide included questions designed to elicit the participants’:

- definitions of a NHP, and context of NHPs in their organization
- perceptions of pharmacists’ level of training or knowledge of NHPs
- descriptions of pharmacists’ current interaction with NHPs – are they seen as helpful or not
- comparison of participants’ expectations of pharmacists with respect NHPs and OTC
- perceptions about who are considered NHP experts

Probes were inserted into the interview guide to assist in gathering specific information related to the participant’s organization they represented. The full questions for the interview guides can be seen in Appendices C to E.

3.4 Data Analysis

Content analysis was used to identify specific professional roles and responsibilities for pharmacists with respect to NHPs. Content analysis involves analyzing the interview transcripts by categorizing segments of the transcripts into topic areas. Transcript segments varied in size from a single word to paragraphs. In this analysis, transcripts were divided into simple sentences with subjects and predicates, called themes. Each theme
was placed in a topic category based on its content. A list of category definitions was created and maintained throughout the coding process to help ensure consistency of coding throughout the analysis process. Initial categories were broad and focused on a range of relevant key issues identified for pharmacists with respect to NHPs. These were not identified a priori, but rather emerged from the data collected. As interviews continued and new categories emerged in the data, the coding team reviewed previous interviews and re-coded these transcripts to capture the new themes. The coding scheme definition of terms was revised with the generation of each new category and reviewed by the main research team and thesis committee to ensure agreement.

All team members participated in establishing preliminary coding categories. After the initial coding categories were established, two to three team members coded transcripts individually and met every two to four interviews to compare coding and ensure consensus. Detailed coding of all the transcripts was facilitated by the use of NVivo computer software.(7) Based on the themes and sub-themes identified, coding trees were created for pharmacy leaders and stakeholder leaders. A copy of the coding trees as well the coding definitions can be seen in Appendices F to H. Analysis was performed throughout the data collection period to allow for adjustment to the key informant interview questions guide to address new issues or topics that emerged from early interviews.

Dependability or consistency in the data was ensured via a number of strategies. Firstly, each transcript was independently coded by two to three researchers using a coding
definition list created by the coders. Secondly, after coding independently all three team members met to conduct a coding comparison to ensure agreement and reviewed the list of coding categories to establish if a new coding category was needed. Thirdly, the list of coding categories was revised regularly to capture new themes that emerged from the data or if refinement of existing categories was necessary. Fourthly, the thesis committee reviewed the coding definitions, as well as a sample of interview transcripts for confirmation. Rich descriptions using direct participant quotations were used whenever possible to illustrate data findings.

Credibility or internal validity of this project was ensured by grounding the findings in the data (interview transcripts), using participants’ words as code name identifiers whenever possible, as well as involving multiple coders in data analysis. The coders represented a range of backgrounds: a graduate student new to qualitative research, a sociologist with substantial knowledge of qualitative research, and a pharmacist with sociology training and extensive experience in conducting qualitative studies in the area of CAM and NHPs. This variety in the coders’ backgrounds meant that each had unique biases which could be balanced and checked by the others. The coding meetings were essential in ensuring consistency and agreement between the coders for documenting themes. As an additional check, the list of coding definitions, as well as a sample of interview transcripts was reviewed by the thesis committee that varied in background as well including: a sociologist and a pharmacist focused on pharmacy practice. A larger research team made up of pharmacist educators, an ethicist, a lawyer, and key decision maker partners also provided input into the coding definitions. Finally, information from another source such as focus
groups contributed to the interview guide and was used to triangulate some of the key themes emerging from the data.

3.5 Ethical Issues

3.5.1 Confidentiality

Confidentiality was an ethical issue for this study in particular because many leaders shared information about their organization that was not necessarily public knowledge, as well as their own personal opinions and experiences. All of the information collected for this study was kept strictly confidential. The participant’s names were not used at any stage of the research process. The participants were identified by a unique study identifier code to ensure privacy, and the names of persons identified in the interviews were removed from the transcriptions. All the data was kept on a secure computer and access to the computer was by specific passwords known only to the principal investigator, and research coordinator. The completed interview schedules, transcriptions and audio recordings were stored in a secure locked cabinet at the Leslie Dan Faculty of Pharmacy. No information was released or printed that would disclose anyone’s personal identity.

Confidentiality was also vital to this study because quotations from some participants were used in the preparation of final reports and journal publications. Participant quotes used in publications contained no personal identifiers. Quotations were identified generically by indicating the type of leader (pharmacy, consumer, industry, CAM) and number i.e. Pharmacy Leader 5. This protocol received ethics approval from the University of Toronto
Health Sciences Research Ethics Board. A copy of the initial approval and annual renewal form for the project has been included in Appendix I.

3.5.2 Risks and Benefits

There was minimal risk to the participants. Each participant was informed that his or her identity would be kept confidential and any reports or papers that contain data from the study would not have any identifying information. A benefit for the participants was that they had the opportunity to discuss their feelings about the natural health products. Furthermore, a summary of the results of the study will be distributed to the participants, which will allow them to reflect on other pharmacy leaders’ perceptions of the new regulations as well as public perceptions of the pharmacist’s role.

3.5.3 Compensation

No compensation was offered or provided to any of the participants.

3.5.4 Conflicts of Interest

There were no known or anticipated conflicts of interest among the researchers for this project.
References

7. QSR International Pty Ltd. NVivo Qualitative Data Analysis Software 7ed; 2006.
This chapter is a summary of the overall results of the study. As this is a non-traditional format paper-based thesis, this chapter has been written in the form of an article that is to be submitted to the International Journal of Pharmacy Practice.

**TITLE:** Roles and Responsibilities of Pharmacists with Respect to Natural Health Products: Stakeholder Interviews

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**ABSTRACT**

**Background:** Although many pharmacies sell natural health products (NHPs), there is no clear definition as to the responsibilities (if any) of pharmacists with respect to these products.

**Objective:** The purpose of this study was to explore and compare pharmacy and stakeholder leaders’ perceptions of pharmacists’ professional NHP responsibilities.

**Methods:** Semi-structured key informant interviews were conducted with pharmacy (n= 17) leaders and stakeholder (n=18) leaders representing consumers, complementary and alternative medicine practitioners, conventional healthcare practitioners, and industry across Canada.
Results: Overwhelmingly all participants believed a main responsibility for pharmacists was in safety monitoring. One challenge identified in the interviews was pharmacists’ general lack of NHP knowledge. Stakeholder leaders did not expect pharmacists to be experts on NHPs, and reported pharmacists should have a basic level of education on NHPs. Many pharmacy leaders appeared to be unfamiliar with current pharmacy policies and guidelines concerning NHPs.

Conclusion: Participants described pharmacists’ professional responsibilities for NHPs as similar to those for over-the-counter drugs. More awareness of existing NHP-related pharmacy policies is needed.

Introduction

Over the past decade use of natural health products (NHPs) such as vitamins and minerals, herbal medicine and homeopathy, has dramatically increased in North America.(1-3) Although NHPs can be purchased from a variety of sources such as health food stores and grocery stores, Canadians often purchase NHPs in pharmacies.(1, 2) There is evidence to suggest that Canadian consumers are more likely to approach a pharmacist when seeking information about NHPs for the first time than any other health care professional.(4)

Due to widespread consumer use of NHPs, the availability of NHPs for self-selection in various retail locations, the claimed expertise of complementary and alternative medicine (CAM) practitioners with respect to NHPs and the possible influence of other conventional health care providers on NHP consumption, it is clear that non-pharmacist stakeholder input will be instrumental in determining the pharmacist’s role (if any) with respect to NHPs. Although the pharmacists’ role with respect to conventional prescription and OTC products
is well defined, it is not clear if non-pharmacist stakeholders consider NHPs part of the pharmacists’ scope of practice. The objective of this study was to explore and compare pharmacy leaders’ and stakeholder leaders’ perceptions of the professional roles and responsibilities of pharmacists in regards to NHPs. Stakeholder groups in this study included consumers, CAM practitioners, conventional health care professionals (HCP) and NHP industry groups.

Background

In Canada, the federal government sets the legal framework for the regulation of NHPs, but it is the responsibility of the various provinces/territories to define the scope of practice responsibilities of pharmacists in regards to these products. The Natural Health Product Directorate (NHPD) is the health authority responsible for the regulation of the sale and manufacture of NHPs.(5) According to the Natural Health Products Regulations that came into effect on January 1, 2004, “NHPs are defined as: vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines such as traditional Chinese medicine, probiotics, amino acids and essential fatty acids”(6) that are used for “(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; (b) restoring or correcting organic functions in humans; or (c) modifying organic functions in humans such as modifying those functions in a manner that maintains or promotes health.”(5) In addition to defining NHPs, the regulations also include requirements for: product licensing, site licensing, adherence to good manufacturing practices, clinical trials, labelling/packaging and adverse reaction reporting. NHPs must “be
safe for consideration as over-the-counter products, be available for self-care and self-selection and not require a prescription to be sold”.(6)

Pharmacists are a self-regulating health profession and must be licensed by their respective province or territory in order to practice. Although their professional responsibilities vary among jurisdictions, all pharmacists have the responsibility to dispense prescription medications to consumers. Existing pharmacy policy documents define the responsibilities of pharmacists towards prescription drugs and non-prescription or over-the-counter medications (OTCs) clearly indicating that these products are within their scope of practice. However, pharmacy policy documents are far less clear with respect to NHPs. Generally the provinces/territories can be categorized into three broad groups: 1) those whose policies refer to “drugs” in general only; 2) those that refer to “drugs” (but clearly state or strongly imply that the policy refers to drugs that require a prescription, and OTCs only); and 3) those that refer to drugs, OTCs and NHPs specifically. Among the pharmacy licensing authorities across Canada: six regions have policy wording that only refer to “drugs” in general; two regions’ policies refer to drugs and OTCs, and four regions have policies that refer to drugs, OTCs and NHPs.(7) According to the federal Food and Drugs Act, NHPs are technically considered a sub-class of drugs, so it could be argued that policy documents referring to drugs generically now also apply to NHPs. At the same time, federal regulations clearly state that NHPs must be available without a prescription for self-care, thus implying that policy documents referring to OTCs could also apply to NHPs.

The inconsistent use of terminology and lack of clear definitions in pharmacy policy documents has created a gap with respect to defining practice responsibilities with respect to NHPs at the provincial/territorial level. Previous studies indicate that pharmacists do not
perceive NHPs to be the same as conventional medications and they are generally less knowledgeable about NHP in comparison to conventional medications.(8-12) Since NHPs are commonly sold in pharmacies, it is clear that pharmacists’ roles and responsibilities need to be more defined for these products. Several recent surveys provide some clues about what their professional roles and responsibilities could entail.(8-13)

**Pharmacists and NHPs**

The majority of pharmacists surveyed in several studies believed they had a professional responsibility to counsel patients, describing their position as educators and information providers with respect to NHPs; but, indicated they had insufficient knowledge about NHPs to fulfill these responsibilities.(8, 9, 13) The concern about insufficient training was mirrored in virtually all the studies reviewed involving practicing pharmacists. Reported education about NHPs varied widely among pharmacists from none to required courses.(13-15) Pharmacists who were particularly interested in CAM/NHPs indicated they sought additional training through continuing education courses or courses from schools specializing in CAM or NHPs.(15) Overall, many pharmacists reported they had insufficient knowledge about NHPs to be able to properly counsel or recommend NHP use to consumers.(8-12) Other studies have confirmed that pharmacists want more NHP continuing education programs and NHP information resources to confidently perform their professional responsibility.(9, 16) If pharmacists plan to embrace a scope of practice that includes NHPs, minimum educational standards for these products will need to be determined. Input from stakeholder groups could assist in determining what is expected (or not) by pharmacists with regards to NHPs.
The pharmacy literature shows considerable inconsistency and overlap in the definitions of scope of practice, role, and responsibility.(17) For the purposes of this paper, the terms are defined as follows:

- **Scope of practice**: the extent or range of the pharmacist’s opportunity to function(18)
- **Role**: a customary function (or position) of the pharmacist(19)
- **Responsibility**: having a moral/ethical/legal obligation for a specified task or duty.(20)

As is explored below, although there is growing consensus that NHPs are within pharmacists’ scope of practice, their specific NHP-related roles and responsibilities remain ill-defined.

Several key pharmacy organizations appear to agree that pharmacists have roles and responsibilities towards NHPs. For example, the Canadian Society of Hospital Pharmacists as well as the American College of Clinical Pharmacy have written position statements on NHPs.(21, 22) These position statements provide general guidance on how pharmacists should behave towards NHPs such as asking consumers about NHP use in an open non-judgmental manner; providing advice on potential risks and benefits; having access to reputable NHP resources; and reporting suspected adverse reactions associated with NHPs. The key issue with these statements is that they are completely theoretical and based primarily on “expert” opinion. Despite the fact that they often describe what pharmacists should be able to do for consumers and other groups, none of this work involved input from stakeholders such as consumers, other conventional HCPs, CAM practitioners or members of the NHP industry. If NHPs are part of the pharmacists’ scope of practice, it appears
important that input about professional roles and responsibilities is received from
stakeholders to ensure that pharmacists are able to meet their needs and expectations.

Although there has been no published research comparing or contrasting pharmacists’
versus stakeholders’ expectations of the pharmacist’s professional roles and responsibilities
with respect to NHPs, some studies do explore the topic of consumer attitudes and
behaviours toward NHPs/CAM, which raises some opportunities and challenges for
pharmacists and health professionals more broadly. Key concerns identified for consumers in
the literature include: barriers to communication as well as information-seeking needs and
behaviours.

Studies suggest that consumers often fail to disclose NHP use, or are reluctant to
bring up their NHP questions to their health care professionals (HCP).(13) Reasons cited by
consumers included a concern of negative bias by the HCP and perception that the HCP will
lack the knowledge about NHPs to answer their questions.(23-25) There was also the
common perception among consumers that since NHPs are natural they are therefore “safe”,
thus there is no need to discuss them with HCPs.(26) These issues will need to be addressed
if pharmacists hope to assume a role as information providers regarding NHPs.

Despite a documented reluctance among consumers to discuss NHPs with HCPs, a
2005 survey found that 84% of Canadian consumers polled indicated they needed more
information about the safe use of NHPs.(1) Consumers indicated high interest in safety
information such as possible side effects; potential interactions with other drugs, NHPs or
food; and duration of treatment.(21, 27) Another study indicated that consumers believe they
have insufficient information about cost, duration, and uses for particular NHPs.(4, 28)
Consumers have complained of having difficulty discerning among the vast amount of
commercialized information on the internet as well as books, magazines and media coverage. Consumers appear to often turn to friends or family in selecting which NHPs to use. That being said, many consumers reported that pharmacists were seen as the most accessible source of information about NHPs. Many appear to expect the pharmacist to be able to answer questions about all health care products especially those that are purchased in the pharmacy, whether they are conventional or NHP medications.

The goal of this project was to explore pharmacists’ and stakeholders’ expectations of pharmacists’ roles and responsibilities with respect to NHPs. Understanding these expectations will provide valuable insight to shaping pharmacist policies and education to ensure that pharmacists can adequately meet the needs of consumers.

Methods

Semi-structured key informant interviews were conducted with pharmacy and stakeholder leaders selected using criterion-based purposive sampling. Key informants are individuals who possess special knowledge or status. Due to the leaders’ distinct positions as head of their groups, they are generally well-placed to implement higher level collective changes for their organizations and to disseminate information to front-line staff or members. For this study, pharmacy leaders were defined as someone who is a president, dean, head, chair or director of a pharmacy regulatory college, school, national/provincial association, voluntary pharmacy organization, or owner/manager of a chain or independent pharmacy. The pharmacy leaders were chosen to ensure a range of different types (e.g., regulatory body, association leader or education leader) and geography (to ensure a range across Canada). A stakeholder leader was defined as an individual who is the president, head,
chair or director of a consumer advocacy group, CAM practitioner association, conventional HCP organization, or NHP industry group. The only exclusion criterion identified was that consumer stakeholder leaders could not be licensed healthcare providers (e.g., physician, nurse, pharmacist, chiropractor, naturopathic practitioner). Stakeholder leaders were chosen to ensure a variety of groups representing a range of diseases, age populations, special interest groups, CAM modalities and geographical regions across Canada. A variety of national and provincial representatives was chosen when possible. At the conclusion of each interview, participants were asked if they could recommend other individuals (in their organizations or others) that may be able to provide additional insight into the professional roles and responsibilities of pharmacists with respect to NHPs (“snowball sampling”). This type of sampling allowed for identification of additional key informants throughout the study and was a way to ensure that no one with important or unique knowledge in the area of study was omitted from participation inadvertently.

All interviews were conducted in English and interviews continued until saturation was reached for the key emergent themes such as possible NHP-related roles and responsibilities of pharmacists, counselling, pharmacist education, safety, and policy. Saturation is the point at which no new information or themes were observed from the interview participants.(29) Each interview lasted 30 minutes to one hour and was audio-recorded. Prior to the interview, written informed consent was obtained from each participant. In most cases interviews were conducted in-person; however, a few interviews were conducted by telephone. Interviews were transcribed verbatim and subsequently coded by two to three researchers. This protocol received ethics approval from the University of Toronto Health Sciences Research Ethics Board.
The semi-structured guide consisted of a series of focused open-ended questions to obtain a range of opinions on the topic of study. The initial interview guide was created based on key issues and gaps identified in a review of the literature. The intention of the interview guide was to explore participants’ perceptions of pharmacist NHP education, pharmacist NHP policies, pharmacists’ potential roles and responsibilities towards NHPs, NHP knowledge by pharmacists, and stakeholder perceptions of pharmacists.

**Data Analysis**

Content analysis was used to identify specific professional (including legal and ethical) roles and responsibilities for pharmacists with respect to NHPs. Content analysis involves analyzing the interview transcripts by categorizing segments of the transcripts into topic areas.\(^{(32, 33)}\) Transcript segments varied in size from a single word to paragraphs. In this analysis, transcripts were divided into simple sentences with subjects and predicates, called themes.\(^{(32)}\) Each theme was placed in a topic category based on its content. A list of category definitions was created and maintained throughout to help ensure consistency of coding throughout the analysis process. Initial categories were broad and focused on a range of relevant key issues identified for pharmacists with respect to NHPs. These were not identified \textit{a priori}, but rather emerged from the data collected. All team members participated in establishing preliminary coding categories, after which three team members coded all transcripts together to ensure consensus. Analysis was performed throughout the data collection period to allow for adjustment to the key informant interview questions guide to address new issues or topics that emerged from early interviews. Computer software was used to facilitate the coordination of data for coding.\(^{(34)}\)
RESULTS

A total of 35 key informant interviews were completed with individuals representing a variety of national and provincial groups across Canada (see Table 1). Figure 1 provides the geographic distribution of the participants. Surprisingly, in spite of the differences in the types of leaders, there was high agreement among both the pharmacy and stakeholder groups on the pharmacist’s professional responsibilities with respect to NHPs. The information collected from the participants was grouped into six main themes: overall agreement that pharmacists do have responsibilities with respect to NHPs; concerns about pharmacy NHP-related policies; discussion of key responsibilities; challenges to enacting NHP responsibilities in everyday pharmacy practice; and legal concerns associated with NHPs and pharmacy practice. Each of these themes is discussed in detail below.

Pharmacists and NHPs: Support for Role

There was overwhelming support from all the pharmacy and stakeholder leaders that pharmacists have a role to play in regards to NHPs.

Well, first of all let me say that I think pharmacists are an incredibly important part of the healthcare system, and I think we hear – I know we hear from our patients that that is somebody who is really a trusted part of their care team, and a place where people really feel comfortable and confident going for advice or information about all manner of medications, whether they are natural or not. I think there is a really high credibility that pharmacists have with patients. So, to me it is the perfect and proper delivery system for better information and advice about these things. (Consumer Leader 2)

Just have a little bit of knowledge in that area. That would be amazing. And it would provide an amazing service to the public. And I truly believe that if they did have
more knowledge and are more open about it would also benefit the store. (CAM Leader 3)

One of the reasons many stakeholder groups gave for supporting a role for pharmacists was that quality, objective information about the safety and efficacy of NHPs was not always easily accessible to consumers. Consumer group leaders talked about how their members often do not know where to find answers to their questions about NHPs. Industry leaders thought pharmacies would be a credible place for consumers to learn about NHP products and how to use them appropriately. Despite the widespread agreement that there was a role for pharmacists to play with respect to NHPs, there was less agreement on the scope of that role. A few respondents attempted to interpret pharmacy policies to define the scope of the role, but most felt there was a need for policy development to define the scope of pharmacists’ role with respect to NHPs.

**Puzzling Policies**

Generally our data suggest there needs to be greater clarity in current policies and guidelines concerning NHPs. Throughout the course of interviews the vast majority of pharmacy leaders rarely referred to policy documents for guidance regarding questions they had about the pharmacist’s responsibilities towards NHPs. Often the interviewer had to specifically ask the pharmacist leaders if any pharmacy policy documents existed. A few pharmacy leaders claimed there were no policy documents on NHPs.

Pharmacy leaders did not automatically interpret (nor believe that individual pharmacists would interpret) policy documents regarding OTC products to include NHPs.

_Interviewer – The standards of practice now that talk about the over-the-counter products, in your mind they don’t…that doesn’t automatically include natural health products?_
Participant – I guess in my mind it really doesn’t, and that’s just based on my own experience. (Pharmacy Leader 14)

Interviewer – So when you say we need to change the standards of practice to say something about over-the-counter products, do you take that to include natural health products as well, or not?
Participant – Well you know I don’t think I’ve ever actually put my mind to it, I mean when you asked me, I’d say yes! And I wonder what each individual pharmacist would think…(Pharmacy Leader 4)

Clearly the policy documents that do exist are not perceived as helpful in assisting pharmacists to define their responsibilities towards NHPs.

Scope of Responsibilities

All participants agreed that pharmacists had a vital responsibility in the area of safety monitoring of adverse events, drug-NHP interactions, and contraindications for consumers.

...a pharmacist has to know what else could interact with what I am buying because as a pharmacist you have to know pharmacokinetics, pharmacodynamics of the medication and how it is going to react and you are responsible to tell the client you know if you are taking aspirin, but they are also taking Crestor® and they also decide to go out and buy ginkgo biloba the pharmacist should know as you are thinning your blood a little too much so you may want to drop one of them, like drop the ginkgo or something. So pharmacists need to know. If clients are having some sort of weird side effects then the pharmacist needs to be able to research what could be the potential interactions between what has been prescribed. (Consumer Leader 5)

The pharmacist’s role is first and foremost that they should ensure that these products do not cause any harm so making sure that there are no adverse events, interactions with traditional medicines, when I say traditional it is not the right word, it is more conventional medicines, and that there are no contraindications for taking the natural health products. (Pharmacy Leader 13)

Although there was high agreement with respect to pharmacists’ responsibilities concerning the safety of NHPs, expectations about pharmacists’ knowledge of other aspects of NHPs were more mixed. Several stakeholder groups asked questions about the level of
expertise pharmacists could be expected to have with respect to NHPs. Although all participants indicated pharmacists should have some NHP knowledge, just how much knowledge was not clearly defined. It appeared there was a distinction between pharmacists serving as a source of information to assist consumers with making basic decisions about NHPs self-medication compared to regularly recommending NHPs based on extensive knowledge of their uses.

Some participants clearly identified that pharmacists should be able to counsel consumers about NHPs to the same level as they currently do for all other OTC medications. This implies an expectation that pharmacists are knowledgeable about the range of NHPs available (at minimum in their stores):

So you know, I don’t see the natural health products being any different than any other products they recommend on. (Pharmacy Leader 2)

...[pharmacists] have the open mindedness to be able to recommend them these types if they think they are superior or equivalent to pharmaceutical type products. (Industry Leader 2)

Others advocated that pharmacists only needed, and realistically could only be expected to have, a more basic knowledge of NHPs. Although exactly what this “basic” knowledge was or how it would be defined was not clearly articulated, participants described that pharmacists could not be expected to be “experts” about NHPs. Instead, they expected that pharmacists should know when and how to refer patients to other experts who could answer their questions about NHPs:

I could see some problem with pharmacists that set themselves up as a homeopathic physician. Then we would have some concern about that. (Pharmacy Leader 1)
CAM leaders identified themselves as having “expert” knowledge about NHPs, but acknowledged that consumers did not always have access to CAM practitioners. Pharmacists were identified by CAM leaders as a good option to provide basic information for consumers. They suggested that the pharmacist’s main responsibility was to focus on potential NHP-conventional medication interactions, contraindications and adverse events. CAM leaders then expected pharmacists to refer to CAM providers when consumers needed more in-depth counselling. Lack of clarity around this issue is related to the other practice challenges discussed in the following section.

**Practice Challenges**

Despite the strong agreement that pharmacists had professional responsibilities related to NHPs, a number of challenges associated with meeting those responsibilities were identified such as: the lack of scientific evidence to support recommendations about NHPs; insufficient training about NHPs resulting in lack of knowledge; as well as being open with consumers about their level of knowledge of NHPs.

Some stakeholders identified a lack of available information about NHPs in general as being the main concern:

*There isn’t necessarily a lot of scientific information on natural health products.* (Consumer Leader 6)

Participants noted that one of the challenges of treating NHPs the same as other OTCs was whether or not evidence was available to support the safety and effectiveness of
NHPs. Although it was generally accepted that pharmacists should be able to recommend NHPs in the same manner as other OTCs, many of the pharmacy leaders as well as one consumer and one industry leader noted there was often insufficient information to make recommendations:

...when it comes to natural health products, unfortunately, very often there is no data. (Consumer Leader 4)

I don’t think they should be recommended when there’s not solid evidence. (Pharmacy Leader 1)

Sometimes it wasn’t a lack of evidence that limited pharmacists’ ability to counsel patients about NHPs, but rather that pharmacists were thought not to know about the evidence that does exist:

I basically feel that they don’t have a lot of information to provide on natural health products. (Consumer Leader 3)

I found when I was in retail practice in a store, generally the person who was asking you the questions knew more about the product than you did, and I found that very frustrating. (Pharmacy Leader 9)

I have gone into other pharmacies for product and have not found the same knowledge, understanding. (CAM Leader 5)

I have to say that the knowledge is more on the side of naturopathic doctors and homeopaths today and not on the side of the pharmacist (Industry Leader 3)

All the participants, except the consumer leaders, unequivocally argued that individual pharmacists should limit their counselling to products they had knowledge about.

I think it’s important for any professional, whether it’s a pharmacist or whoever, to know what they know about; and so if they’re specializing in those kinds of things then they could give advice on it; but if they don’t know anything about it then they have to limit their advice on whatever they’re talking about. (Pharmacy Leader 1)
Consumer leaders and other stakeholder leaders were very concerned that pharmacists honestly represent their level of knowledge about NHPs:

For many herbal products a pharmacist will have to be honest and say that there is little or no proof that this works. (Consumer Leader 8)

Several pharmacy leaders linked the lack of pharmacists’ knowledge to insufficient training about NHPs at the undergraduate level. Stakeholder leaders generally reported that pharmacists were less knowledgeable about NHPs in comparison to conventional medications and were unclear as to how much training pharmacists received on NHPs. There was general agreement across all participants that pharmacists should receive more education about NHPs in order to adequately assist the consumer in making decisions.

...from my point of view it is frustrating that in our training, our background we don’t really get enough information on herbal supplements...I wish we had more proper training in school. (Pharmacy Leader 12)

I have never asked a pharmacist how much training they have in dealing with natural health products, I suspect it is not very much...(Consumer Leader 6)

... if they are selling these products, then they need to take x number of hours as continuing education, this is a compulsory course you have to have taken. If you haven’t done it in the last five years, you need to do it. (CAM Leader 5)

Despite the majority of all leaders indicating strong support for pharmacists’ responsibility to counsel about and recommend NHPs, there were a number of concerns that emerged with respect to selling NHPs and liability.
Selling NHPs

There was a strong agreement among both pharmacy and stakeholder leaders that pharmacists had an obligation to be knowledgeable about the products carried in their stores. All pharmacy and stakeholder leaders indicated that if pharmacists chose to sell NHPs they had a responsibility to be able to counsel consumers on all the NHPs that were carried in the pharmacy.

*So as pharmacists we have a moral and professional obligation to be aware of these things and to really make good consultations with our patients.* (Pharmacy Leader 16)

*Generally speaking anything you put in your mouth that you buy in a pharmacy, you are going to think is fair game to go and ask the pharmacist about whether or not he or she knows.* (Consumer Leader 2)

*They are in the majority of local pharmacies and because they are there I think it is their responsibility to inform their patient. You can’t carry these products and not provide your patient with any kind of advice.* (Pharmacy Leader 15)

Despite the majority of participants agreeing that pharmacists have a responsibility to be familiar with the products they sell, this was not always found to be the case.

*They may sell the product but not all of them know.* (Consumer Leader 5)

Participant - I think there is an expectation that if a product is carried in a pharmacy, the pharmacist is conversant with it.
Interviewer - Do you think that is always the case?
Participant - Very definitely not, unfortunately, but I think there is an expectation by the public that they do in fact have a very basic knowledge (Pharmacy Leader 9)

*I think they need to know... and they don’t always, in my experience, if I had gone in looking for a supplement and I’d asked the pharmacist something about it, they haven’t really known.* (CAM Leader 4)
The majority of stakeholder leaders, as well as a few pharmacy leaders, indicated a concern that NHPs were carried in pharmacies for the revenue they generated rather than because pharmacists thought they were effective for patients.

*Drug stores are in it because people are buying it and the theory is let’s get it into our stores so we can generate more income.* (Consumer Leader 5)

*I think that people who are making those decisions are making it based on sales data...* (Pharmacy Leader 14)

*I know that for obvious commercial reasons most pharmacies stock natural health products, huge aisles.* (Consumer Leader 8)

Despite the concerns about pharmacists not knowing enough about the NHPs sold in their stores, few people thought health food stores were a better option for advice about the use of these products. Some stakeholders reported that health food stores had more to offer in terms of the variety of types of NHPs, brands, and price. However, the vast majority of pharmacy leaders, as well as a few consumer leaders, reported that health food store staff lacked the proper training and knowledge to monitor or counsel on potential interactions between NHPs and conventional medications. Many pharmacy leaders were quite skeptical about the quality of advice provided by health food store employees to consumers about NHPs. Some consumer leaders noted there were some health food stores that had very knowledgeable staff that were able to provide helpful assistance to consumers in making product choices; however they also acknowledged that this was not often the case with many health food store employees.
Legal Concerns

Among the pharmacy leaders, liability was clearly identified as a major concern for pharmacists making NHP recommendations to consumers:

*In the legal aspect I would say that because we do have the liability issue that’s why we really have to watch closely to what we recommend to make sure that it is not causing any harm and that is one of the reasons why when other product specialists [CAM practitioners] make a recommendation we always ask them to check with us to make sure that there is no interaction because we have to protect ourselves legally too. (Pharmacy Leader 12)*

*Interviewer – Is your liability any different whether you are recommending Sudafed or a natural health product, an herb?*
*Participant – I don’t think so. Whatever we recommend, if it is causing any harm you would be liable for that. I don’t think so. I don’t think there is any difference. It would still be on us. (Pharmacy Leader 12)*

Some pharmacy leaders expressed concern that pharmacists may be liable for advice given on NHPs, but there were no applicable regulations for NHPs sold by non-pharmacists in other retail settings such as health food stores.

*I think that if a pharmacist chooses to stock natural products that standards of practice would fall there. They need to be judged within those standards. The problem is I wouldn’t be able to apply those standards to non-pharmacists though. (Pharmacy Leader 1)*

*I would be very hesitant to create an environment where the clerk at 7/11 can sell these things with no responsibility, but the pharmacist sells them with responsibility. That’s an inconsistency. (Pharmacy Leader 14)*

Among the stakeholder leaders, pharmacist liability for NHP recommendations was not raised as a concern.
DISCUSSION

Like all studies, this one has some limitations. For example, only a relatively small number of pharmacy and stakeholder leaders were interviewed. The purpose of this study was to explore the range of options, rather than to generalize about the relative frequency of each point of view. By including participants from both national and provincial organizations, conducting interviews until we reached saturation in the participants’ responses (i.e. the point at which no new themes emerged), analyzing the data and modifying the interview guide as new concepts arose, it is unlikely that more interviews would have generated different results. Ideally we would have liked to interview a participant from each province or territory. However, it is unlikely that this significantly influenced our results because nearly half of the participants were national representatives and their responses did not differ significantly from the provincial participants.

To our surprise, there was considerable agreement between the various participants on the pharmacists’ roles and responsibilities towards NHPs. There was strong support by nearly all the pharmacy and stakeholder leaders that pharmacists have a role to monitor NHPs for safety, for example identifying and preventing adverse events and drug interactions. All the leaders expected pharmacists to have a basic level of knowledge of NHPs sold in their stores (although the concept of “basic” knowledge was not clearly defined by anyone), and the ability to locate additional information if necessary. Many pharmacy and stakeholder leaders noted pharmacists should be able to counsel about NHPs in the same manner as they currently do for all other OTCs.

The literature indicates that there is strong support for these roles among practising pharmacists.(8, 9, 28, 35) One study indicates that 91% of pharmacists surveyed agreed that
it is necessary to have knowledge of both CAM and conventional medicines to be able to inform patients about their options. This project clearly demonstrates that consumer, industry, and CAM leaders strongly support this notion as well. This agreement is important because it suggests that it will be easier to implement pharmacy NHP-related standards of practise and educational standards with regards to NHPs, since it is in alignment with stakeholder and pharmacist expectations.

The scope of pharmacists’ role emerged as three main areas: safety monitoring, provision of a basic level of information to consumers, and the ability to recommend NHPs in a similar manner to OTCs. Most stakeholders noted there were limits to pharmacists’ knowledge of these products; however, there was little agreement on who were the experts to whom pharmacists could refer patients. Similarly, a review of the literature does not provide a clear answer as to who is considered to be an “expert” on NHPs. Biomedical literature tends to identify physicians and occasionally pharmacists as the “experts” to help patients make decisions about NHP therapy options based on scientific information. At the same time, the literature also points out that physicians, not unlike pharmacists, rarely can credibly claim “expertise” in this area due to their general lack of knowledge of NHPs, or exposure to only brief NHP-training sessions. In a recent Canadian survey, consumers ranked pharmacists a close second behind physicians when asked who they completely trust for NHP information. Since pharmacists are well trained in regards to prescription and OTC medication, it has been argued that pharmacists are well placed to effectively monitor drug-NHP interactions. In contrast, CAM practitioners are typically identified as “experts” in the CAM literature. Studies on health care professionals’ attitudes, knowledge, and practices towards NHPs generally contain caveats that physicians and
pharmacists may not have enough knowledge to answer patient questions about NHPs; however, the literature does not generally identify any other expert options.

Although there was strong support by nearly all the participants that pharmacists do have roles and responsibilities with regards to NHPs carried in their stores, there were a number of challenges identified to pharmacists in carrying out their duties such as: 1) a lack of clear policies, 2) limited NHP education resulting in pharmacists’ general lack of knowledge, 3) the current pharmacy organizational climate with dual (and sometimes competing) priorities of running a business and pharmacists’ professional responsibilities, and 4) NHPs being sold by health food store staff who have little or no NHP knowledge. Each of these will be discussed in detail below.

It is clear from this project that the majority of pharmacy leaders are not familiar with existing policy documents relating to NHPs. A brief review of the pharmacy regulatory documents across Canada demonstrates there are a number of policies that provide some guidance about the basic responsibilities of pharmacists with respect to NHPs.(7) It appears that more work needs to be done to improve pharmacy leaders’ awareness of the growing number of NHP policies, and to ensure that they are effectively disseminated to front-line pharmacists as well as those who make decisions about which NHPs will be sold in retail pharmacies.

Although there was strong support by nearly all the participants that pharmacists should have basic knowledge of the NHPs carried in their stores, there were a number of
challenges for pharmacists trying to meet this expectation. NHPs are a multi-billion dollar industry in North America. (2, 3) Consumer demand for NHPs has risen significantly over the last several years (1, 3, 4) resulting in pharmacists facing increasing questions about NHPs. (7-9, 11) Many front-line pharmacists are confronted by consumers who want information on NHPs to make informed health choices, or are eager to buy NHPs based on positive testimonials.

Despite federal NHP regulations coming into force over four years ago and widespread NHP use, pharmacists receive typically little, to varying amounts of, training on NHPs as part of their undergraduate education. (14) Several studies indicate that pharmacists who have additional training on NHPs are more likely to be more proactive in raising inquiries about NHPs, discussing NHP related issues as well as safety-monitoring for these products. (12, 16) Providing pharmacists with additional training in NHPs whether at an undergraduate, continuing education or store level may help prevent adverse events and ensure consumer safety. With pharmacists admitting they are not as knowledgeable as they would like, and NHPs being widely available, it is not surprising that many stakeholder leaders suggested that pharmacies carried NHPs simply to generate profit. (42)

Our results clearly demonstrate that pharmacists face a dilemma when they work in a store that offers NHPs for sale and they do not have enough knowledge to answer questions about them. Thus they are generating revenue from (and some might argue meeting consumer demand for) products that they cannot ensure are safe and effective for their patients. With many NHPs lacking sufficient evidence to support safety and effectiveness, pharmacists are having to “balance their obligations to make a living, with their professional duties as providers of advice and support to optimise the use of medicines”. (43) Since NHPs
are available for self-medication it is more important than ever for pharmacists to be informed about these products in order to counsel consumers. The findings of our study stress the need for minimum NHP education standards if pharmacists hope to take on roles such as NHP information providers and safety monitors for NHPs as part of providing pharmaceutical care.

An additional complication is the fact that front-line pharmacists are generally not involved in the purchasing decisions for products carried in the pharmacy, yet are expected to be knowledgeable about all products carried on the shelves. In chain pharmacies, purchasing decisions are usually made by the corporate head office. In independent pharmacies, the storeowner and/or manager is more likely to be responsible for deciding which brands and products will be carried in the store. Pharmacy NHP stock purchasing decisions are often based on consumer demand, price, manufacturer reputation, and product quality. (11, 44) In spite of pharmacist leaders expecting front-line pharmacists to be knowledgeable, surprisingly very little information was provided from pharmacy retail leaders on how as a business they ensure front-line pharmacists are educated about NHPs carried in their pharmacy. Although some pharmacy chains and independent stores provide training to their employees this may need to become the norm. Our findings indicate that the provision of education/learning resources to support pharmacist counselling about all medicinal products sold in the stores may need to become a practice standard. Providing pharmacists with additional training in NHPs whether at an undergraduate, continuing education, or store level will help in preventing adverse events and ensuring consumer safety. However, it is unlikely change will occur unless there is an organized lobby on the part of pharmacy professional associations to insist that pharmacists not be placed in
positions where they are expected to sell (and counsel about) products which they have little or no training.

Pharmacy leaders were uncomfortable with pharmacists potentially being held liable for NHP recommendations, particularly in light of what was perceived as an “uneven playing field” because there were no standards for non-pharmacists selling similar NHPs in other retail settings such as health food stores. The literature also highlights a concern about unproven verbal claims made by health food store staff to consumers.\(^{(35, 45, 46)}\) Verbal claims and treatment options made by health food store employees often do not take into account prescription medications a consumer is taking or their medical history. Health food stores have also been found to sell restricted NHPs despite health authority warnings and advisory postings.\(^{(45, 47)}\) The literature indicates that a lack of formal education on NHPs may result in increased probability of the health food staff employee being unaware of current issues regarding the NHPs such as advisories or warning issued by the regulator.\(^{(45-47)}\) These findings emphasize the real need for pharmacists to take on the responsibility of counselling patients about NHPs. If consumers understood the differences (in terms of accountability) between NHP recommendations made by pharmacists and those made by health food store clerks, they may seek more help from pharmacists. This may be an issue that can be explored by pharmacy associations as a way to promote the profession.
CONCLUSION

There is agreement among a wide range of stakeholder leaders that pharmacists have roles and responsibilities with respect to NHPs. Our findings demonstrate that stakeholder leaders and pharmacy leaders strongly believe pharmacists’ primary role is to identify and prevent possible interactions between NHPs and conventional medications. Many participants in this study suggested that pharmacists should have enough knowledge of NHPs to provide information about NHPs the same way they currently do for other OTC products, and refer to experts if needed. The vast majority of participants also strongly recommended that more NHP specific training be added to the pharmacy undergraduate curriculum to ensure that pharmacists have a basic knowledge of NHPs. The lack of pharmacy leader awareness of current NHP pharmacy policies highlight the need for such policies to explicitly state they apply to NHPs so there is a clear understanding of pharmacists’ responsibilities towards these products. Overall our data contain a clear message that stakeholder leaders believe owners/managers of pharmacies must be more accountable in ensuring that front-line pharmacists have appropriate knowledge of NHPs sold in the pharmacy by providing training to their employees.
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Table 1. Representation among participant groups
Figure 1. Geographic Distribution of Participants Interviewed
REFERENCES


34. QSR International Pty Ltd. NVivo Qualitative Data Analysis Software 7ed; 2006.


CHAPTER 5
5. DISCUSSION

There is strong agreement by both pharmacy leaders and stakeholder leaders that pharmacists have professional roles and responsibilities for natural health products (NHPs) specifically: providing information, safety-monitoring, and counseling on NHPs in a similar manner to other over-the-counter (OTC) products. However, there are a number of issues that need to be addressed if pharmacists are to have any role or responsibility in this area. Pharmacists are challenged with selling NHPs in a climate of ambiguous policies, insufficient education, and lack of evidence on these products to adequately counsel consumers. Another challenge to pharmacists claiming a professional NHP role is the fact NHPs are also available in other retail outlets such as health food stores where training is not required by staff members. There appears to be a need for pharmacists to step up to the challenge because of reports that advice given by health food staff poses a danger to consumers by not taking into account the consumer’s medication history or regulatory authority warnings. However, pharmacists can only help consumers if they are knowledgeable about NHPs. Finally, there needs to be an increased awareness of NHP pharmacy policy documents which should be explicit in outlining pharmacists’ responsibilities for these products, and widely circulated to all pharmacists. Each of these issues will be discussed in order in greater detail below.

5.1 Limitations

Like all studies, this one has some limitations. Only a relatively small number of pharmacy and stakeholder leaders were interviewed. The purpose of this study was to
explore the range of options, rather than to generalize about the relative frequency of each point of view. It is unlikely that more interviews would have generated different results because we interviewed participants from national and provincial organizations, and interviews were conducted until saturation was reached in the participants’ responses (i.e. the point at which no new themes emerged).(1) Furthermore, the interview guide was modified as new concepts arose and data analysis occurred concurrently with ongoing interviews. Ideally we would have liked to interview a participant from each province or territory. However, it is unlikely that this significantly influenced our results because nearly half of the participants were national representatives and their responses did not differ significantly from the provincial participants.

Although slightly more than half of all the interviews were conducted by one researcher, three researchers conducted interviews overall. As a result of having multiple interviewers there will be variability among the participant interviews. It is unlikely this caused any major inconsistencies because each interviewer used the same interview guide, which was also updated as interviews continued incorporating new themes as they arose. Moreover, at least two of the three researchers took part in coding all interviews to ensure agreement in themes identified, as well as to discuss direction and advice for upcoming participant interviews.

Since only organizational leaders were interviewed for this study one might suggest that our results may not be generalizable to front-line pharmacists and consumers. This study is part of a larger program of research which allowed us to obtain input from another
study of focus group interviews of front-line pharmacists and consumers, to assist in creating and modifying the interview guide for this study. The key themes emerging from the two studies were surprisingly similar, and the results of both have been used to develop a survey that will be mailed to a large random sample of practicing pharmacists across Canada to provide direct, quantitative feedback from front-line pharmacists that is generalizable across the country.

### 5.2 Pharmacists’ Professional Roles and Responsibilities for NHPs

To our surprise, there was considerable agreement between the various participant groups on the pharmacists’ professional roles and responsibilities towards NHPs. There was strong support by nearly all the pharmacy leaders and stakeholder leaders that pharmacists have a responsibility to monitor NHPs for safety; for example, identifying and preventing adverse events and drug interactions. All the leaders expected pharmacists to have a basic level of knowledge of NHPs sold in their stores, and the ability to locate additional information if necessary. Many pharmacy and stakeholder leaders noted pharmacists should be able to counsel about NHPs in the same manner as they currently do for all other OTCs.

The literature indicates there is strong support for a number of roles among practising pharmacists.(2-5) One study indicates that 91% of pharmacists surveyed agreed that it is necessary to have knowledge of both complementary and alternative medicines (CAM) and conventional medicines to be able to inform patients about their options.(2) Our research clearly demonstrates that consumer, industry, and CAM leaders strongly support
this notion as well. This agreement is important because it suggests that it will be easier to implement pharmacy NHP-related standards of practise and NHP educational standards since the expectations of all the key stakeholders are aligned.

Most stakeholders noted there were limits to pharmacists’ knowledge of these products; however, there was little agreement on who were the experts to whom pharmacists could refer patients. Similarly, a review of the literature does not provide a clear answer as to who is considered to be an “expert” on NHPs. Biomedical literature tends to identify physicians, and occasionally pharmacists, as the “experts” to help patients make decisions about NHP therapy options based on scientific information.(6) In a recent Canadian survey, consumers ranked pharmacists second behind physicians when asked who they completely trust for NHP information.(7) At the same time, the literature reveals that physicians can rarely credibly claim “expertise” in this area due to their general lack of knowledge of NHPs.(8) Similarly, pharmacists generally receive a modest amount of training on NHPs as part of their undergraduate education.(9-11) Many pharmacists are unaware of the information about NHPs that currently exists in the literature, and hence cannot readily counsel consumers on these products.(12-14) Since pharmacists are well trained in regards to prescription and OTC medication, it has been argued that pharmacists are well placed to effectively monitor drug-NHP interactions.(10, 15-17)

In contrast, CAM practitioners are typically identified as “experts” in CAM literature.(18-20) Although some individual CAM practitioners may have extensive
knowledge about NHPs, the lack of uniform standards governing CAM providers across Canada can make it very difficult for both consumers and pharmacists to identify those individuals. In many provinces most types of CAM practitioners are not regulated at all. Current regulations and educational standards for CAM practitioners vary depending on the type of CAM modality and the province/territory. Since practice standards and training are inconsistent ranging from those who have no training, or have taken a brief course, to those with serious in-depth training spanning years, there is no guarantee to consumers that a given CAM practitioner is actually knowledgeable about NHPs. If NHP education and practice standards were developed and enforced for pharmacists, consumers could be guaranteed to receive safe and objective information about NHPs to assist them in making informed health care decisions.

Although participants in this study did not expect pharmacists to be experts, it was expected that pharmacists should have a “basic” level of knowledge on NHPs. However, no one was able to clearly define what “basic” meant. In addition, some of the tasks they thought pharmacists should be able to perform, such as counselling about NHPs sold in their stores in the same manner as they do for OTCs, could in fact require considerable expertise. Establishing minimum knowledge standards for pharmacists requires additional research and is an important step in setting practice standards in this area.

Challenges identified by participants to the pharmacist carrying out any role or responsibility for NHPs include: 1) a lack of clear policies, 2) limited NHP education resulting in pharmacists’ general lack of knowledge, 3) the current pharmacy...
organizational climate with dual (and sometimes competing) priorities of running a business and pharmacists’ professional duties, and 4) NHPs being sold by health food store staff who have little or no NHP knowledge. Each of these will be discussed in detail below.

5.2.1 Pharmacy NHP Policies

It is clear from this project that the majority of pharmacy leaders are not familiar with existing policy documents relating to NHPs. A brief review of the pharmacy regulatory documents across Canada demonstrates there are a number of policies that provide some guidance about the basic roles and responsibilities of pharmacists with respect to NHPs.(21) Approximately half of all pharmacy regulatory bodies across Canada have specific wording about OTCs or NHPs in their standards of practice. In the remaining half that refer to “drugs” only, there is wording in their policies indicating that pharmacists should be knowledgeable and equipped to handle questions regarding non-prescription drugs.(21) It appears that more work needs to be done to improve pharmacists’ awareness of the growing number of NHP policies. If the leaders we talked to (who were often involved in developing and implementing pharmacy policy) did not understand current NHP policies, it raises concern that front-line pharmacists and those who make NHP stocking decisions in retail pharmacies are also likely to have limited knowledge of these policies as well. This would be an area for further research. Without a solid base of policy guidance or standards of practice with regards to NHPs, it will be difficult for pharmacists to clearly understand their roles and responsibilities.
5.2.2 Pharmacist NHP Education

Although there was strong support by nearly all the participants that pharmacists should have basic knowledge of the NHPs carried in their stores, there were a number of challenges for pharmacists trying to meet this expectation. NHPs are a multi-billion dollar industry in North America. (22, 23) Consumer demand for NHPs has risen significantly over the last several years (7, 23, 24) resulting in a larger range of NHPs sold in pharmacies and pharmacists facing increasing questions about NHPs. (2, 3, 21, 25) Despite federal NHP regulations coming into force over four years ago and widespread NHP use, there has been very little change in the level of NHP education in the undergraduate pharmacy curriculum, which is generally modest at best. (10)

Several studies in the literature have demonstrated that pharmacists with prior education in NHPs are more likely to score better on NHP tests (15, 26), and are more likely to be proactive in asking consumers about NHP use and dealing with NHP-related issues in comparison to their counterparts who received less or no NHP training (16). With pharmacists admitting they are not as knowledgeable as they would like, and NHPs being widely available, it is not surprising that many stakeholder leaders (including a few pharmacy leaders) suggested that pharmacies carried NHPs simply to generate profit. (27) One survey indicated that pharmacists ranked “patient request” and “consumer demand” as the two most important reasons for stocking NHPs in their pharmacy, thus highlighting the business side of pharmacy. (25)
Pharmacists are faced with a potential dilemma if they are selling NHPs, of which they have little (or no) knowledge: they are generating revenue from (and some might argue meeting consumer demand for) products they cannot ensure are safe and effective for their patients. With many NHPs lacking sufficient evidence to support safety and effectiveness, pharmacists are having to “balance their obligations to make a living, with their professional duties as providers of advice and support to optimise the use of medicines”. For some NHPs there is a little information available in terms of research for pharmacists to be able to look up or even counsel on these products. Since NHPs are available for self-medication it is more important than ever for pharmacists to be informed about these products in order to counsel consumers. The findings of our study stress the need for minimum NHP education standards if pharmacists hope to take on roles such as NHP information providers and safety monitors for NHPs as part of providing pharmaceutical care.

The results of this study also demonstrate that changing education standards will simply not be enough to ensure that pharmacists can carry out any role or responsibility in regards to NHPs. There are a number of structural forces at work that pose an additional challenge to the pharmacist. For example, front-line pharmacists may not be involved in the purchasing decisions for products carried in the pharmacy, yet are expected to be knowledgeable of all products carried on the shelves. In chain pharmacies, purchasing decisions are usually made by the corporate head office. In independent pharmacies, the storeowner and/or manager is more likely to be responsible for deciding which brands and products will be carried in the store. Pharmacy NHP stock purchasing decisions are
often based on consumer demand, price, manufacturer reputation, and product quality. (13, 25) When it comes to OTC preparations (including NHPs) carried in the pharmacy, it has been suggested that community pharmacy proprietors/managers are more influenced by the commercial business need for profit in comparison to employee pharmacists, again highlighting the financial side of pharmacy. (29) In spite of pharmacist leaders expecting front-line pharmacists to be knowledgeable, surprisingly very little information was provided from pharmacy retail leaders on how as a business they ensure front-line pharmacists are educated about NHPs carried in their pharmacy. Although some pharmacy chains and independent stores provide training to their employees this may need to become the norm. Our findings indicate that the provision of education/learning resources to support pharmacist counselling about all medicinal products sold in the stores may need to become a practice standard. Providing pharmacists with additional training in NHPs whether at an undergraduate, continuing education, or store level will help in preventing adverse events and ensuring consumer safety. However, it is unlikely change will occur unless there is an organized lobby on the part of pharmacy professional associations to insist that pharmacists not be placed in positions where they are expected to sell (and counsel about) products which they have little or no training.

5.2.3 Pharmacists vs. Health Food Stores

Pharmacy leaders were uncomfortable with pharmacists potentially being held liable for NHP recommendations, particularly in light of what was perceived as an “uneven playing field” because there were no standards for non-pharmacists selling similar NHPs in other
retail settings such as health food stores. The literature also highlights a concern about unproven verbal claims made by health food store staff to consumers. (5, 30-35) Verbal claims and treatment options made by health food store employees often do not take into account prescription medications a consumer is taking or their medical history. Health food stores have also been found to sell restricted NHPs despite health authority warnings and advisory postings. (34, 35) The literature indicates that a lack of formal education on NHPs may result in an increased probability of the health food store employee being unaware of current safety issues regarding NHPs such as advisories or warnings issued by the regulator. (30, 34, 35) These findings underline the need for pharmacists to take on the responsibility of counselling patients about NHPs. If consumers understood the differences (in terms of accountability) between NHP recommendations made by pharmacists and those made by health food store clerks, they may seek more help from pharmacists. This may be an issue that can be explored by pharmacy associations as a way to promote the profession.

5.3 Future Work

There needs to be a concerted effort placed on incorporating standard NHP education into the pharmacy undergraduate curricula and license examinations to ensure that pharmacists have a basic level of understanding of NHPs. The lack of pharmacy leader awareness of policies highlights the need to study how changes made to pharmacy policies are disseminated to front-line pharmacists to ensure they are aware of new information. It would also be worthwhile to explore the possibility of regular collaboration of pharmacists and CAM practitioners to provide information to consumers
in the pharmacy setting. Although work has been done individually in some independent pharmacies specializing in NHPs, there is reason to suggest that such collaboration would enhance consumer safety while using NHPs.

5.4 Conclusion

Pharmacist and stakeholder leaders strongly believe NHPs are part of the pharmacists’ scope of practice, specifically in being information providers and safety monitors. Stakeholder leaders do not expect pharmacists to be “experts” on NHPs. However, the vast majority of participants strongly believe pharmacists should have a minimum level of NHP education in order to counsel and answer basic questions about NHPs, access to NHP resources and be able to refer consumers to other experts if necessary. The lack of pharmacy leader awareness of current NHP pharmacy policies emphasizes the need for such policies to explicitly state they apply to NHPs so there is a clear understanding of pharmacists’ roles and responsibilities towards these products and ensure that stakeholders’ needs are met.
References


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Table 1. Representation among participant groups
FIGURES
Figure 1. Geographic Distribution of Participants
APPENDICES
Appendix A: Introductory Letter

DATE

ADDRESS

Dear X,

At least 60% of all herbal products are purchased in pharmacies and it has been argued that pharmacists are in the best position to provide patients with evidence-based information about natural health products (NHPs), especially regarding potential interactions with conventional medications. This project asks the question: What are the legal, ethical and practice responsibilities of pharmacists with respect to natural health products (NHPs)?

I am writing to ask for an interview (30-60 minutes in length). The interview will explore your ideas and expectations regarding the professional responsibilities of pharmacists with respect to NHPs. Our goal is to achieve a nuanced and balanced picture which includes the expectation of and challenges faced by the pharmacists across Canada. We hope and expect that our findings will contribute to debate about what undergraduate pharmacists should learn about NHPs and in the development of pharmacy NHP practice guidelines. Because your time is valuable, we have designed the interview with just a few critical questions. I will contact you by telephone to arrange a time and place that suits your convenience.

You can be assured that what you tell us will be reported in such a way that no personal references will be made and your identity will be protected. You may, of course, refuse to answer any questions and can terminate the interview at any time. You also have the right to refuse to participate in this research. The information you provide will be available only to members of our research team, and transcripts of the interview will be stored on a password protected computer and hard copies of the transcripts and tapes in locked filing cabinets. All interview transcripts will be identified by code number only, and the master code will be stored separately from the transcripts and tapes.

If you have any questions about this research, we can be reached at: (tel) 416-946-5859, (fax) 416-978-1833, (Email): heather.boon@utoronto.ca or shade_o@yahoo.com. We look forward to talking with you.

Sincerely,

Shade Olatunde, BSc, and

Heather Boon, PhD
Assistant Professor
Study: Natural Health Products (NHPs) and Pharmacy Practice

DATE

Dear Name:

You have been asked to participate in a research study exploring the legal, ethical and practice responsibilities of pharmacists with respect to natural health products (NHPs).

What is the purpose of the study?
The purpose of the study is to:
1. critically assess the legal and ethical responsibilities of pharmacists with respect to NHPs as defined by current regulations, policies, professional and ethical guidelines and case law; and
2. explore key stakeholders’ (pharmacists, other conventional health care providers, the public, and complementary/alternative medicine practitioners) perceptions of pharmacists’ professional (including legal and ethical) responsibilities with respect to NHPs.

When and where will the study take place?
Data for the study will be collected through your participation in an interview at the location most convenient to you.

Who is being asked to take part and what will they do?
We are interested in learning more what is expected of pharmacists with respect to natural health products. We would also like to know about the challenges pharmacist may face in meeting these expectations. During the interview, you will be asked to describe your opinions on this topic. The interview will take one hour or less. The interview will be tape-recorded and transcribed verbatim.

What are the risks and benefits of the study?
The study has minimal risk. Participation is voluntary. You are not required to answer any questions that you do not want to and participation or non-participation will not have any effect on your professional or personal life. You have the right to withdraw from the study at any time with no adverse consequences.

A potential benefit from your participation is the opportunity to air your views on the professional role of pharmacists with respect to the sale and use of natural health products. Your opinion will help to inform the debate about what undergraduate pharmacists should learn about natural health products and about development of pharmacy practice guidelines with respect to natural health products.

Is the study confidential?
All of the data collected will be kept strictly confidential by the research team. Your name will not be used at any stage of the research process. You will be given a unique study identifier code to ensure privacy, and the names of persons identified in interviews will be removed from the transcriptions. All data will be kept on a secure computer and access to the computer will be by use of specific passwords known only to the Principal Investigator and the Research Coordinator. No information will be released or printed that would disclose any personal identity.
Quotations from the interview transcript may be used in the final report. To ensure confidentiality, no names or identifying information will be presented with the quotations. The final report may be submitted for publication in a peer-review journal.

**What if something new comes up during the study that may affect my participation?**
You will be notified if anything comes to light during the course of this research, which is not included in this information sheet, that may influence your decision to participate in the study.

**Will I be compensated for participating in this study?**
Your participation is strictly voluntary. There is no compensation for participating in this study.

**What are my rights as a participant?**
If you have any questions about your rights as a participant, please contact Marianna Richardson at the University of Toronto Research Ethics Board. Tel: 416-978-3165; email: marianna.richardson@utoronto.ca.

Your participation is very important to the study and we hope that you will agree to take part. Please keep the information sheet and a copy of the informed consent for your own records.

Sincerely,

Shade Olatunde, BSc, and

Heather Boon, BSc Phm, PhD
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Della Kwan, Leslie Dan Faculty of Pharmacy, University of Toronto
Shade Olatunde, Leslie Dan Faculty of Pharmacy, University of Toronto
Appendix B: Consent Form

<table>
<thead>
<tr>
<th>Study: Natural Health Products (NHPs) and Pharmacy Practice</th>
</tr>
</thead>
</table>

I have read the accompanying letter of information, I have had the nature of the study explained to me, and I agree to participate in the study described. I understand that the interview will be tape-recorded. All questions have been answered to my satisfaction.

I understand that any information I provide for the study will be kept confidential by the research team. All audiotapes and transcripts from the study will be stored in a locked cabinet at the University of Toronto. Any identifying names or information will be removed from the interview transcripts.

I understand that quotations from interview transcripts may be used in the final report. To ensure confidentiality, no names or identifying information will be presented with the quotations.

I understand that my participation in this study is voluntary and that I have the right to withdraw at any time.

DATE: ____/____/_____ (to be dated by participant)

SIGNATURE OF PARTICIPANT: _________________________

PRINTED NAME OF PARTICIPANT: ______________________

DATE: ____/____/_____ (to be dated by individual obtaining consent)

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT: ______________________
Appendix C: Key Informant Interview Questions –

**Pharmacy, Industry**

**Views about Current Situation – Organization Specific**
1. Briefly describe your role in this organization.
2. What do you think of when you hear the term “natural health products”?
3. Explain how (and when) natural health products such as vitamins, herbals and homeopathy arise in the context of your work/organization?

**Views about Current Situation – General**
4. Where do you think [these products – i.e. their term for NHP] fit in the practice of pharmacy?

**Roles & Responsibilities Relative to OTCs & NHPs**
5. Are [these products] the same as any other OTC? Why or why not? [list the reasons they give].
   - **If yes**, OPTIONAL PROBES [probe/challenge them on each point to determine how this is different from OTCs]
   - **If not**, are these products within the current scope of pharmacy practice? Why or why not? [list each of their reasons and probe/challenge them on each point to determine how this is different from OTCs]
   - **For Regulators** use REGULATOR PROBEEs

6. (a) What should all pharmacists know and be able to do with respect to [these products]?
   - Use INDUSTRY PROBES

   (b) Is there a place for specialization of pharmacists or pharmacies with respect to [these products]? Why or why not?

**Context – Inter-professional Responsibilities**
7. Who do you identify as the (other/potential) professional experts in the area of NHPs?
   - **If none**, ask about roles of dietitians [and use PROBES below]
   - Can you compare [these providers’] roles with the roles of pharmacists with respect to these products?
     - **NECESSARY PROBE**: What are the similarities and differences between pharmacists’ and [these providers’] roles?
     - **OPTIONAL PROBE**: Do you regard these providers as pharmacy collaborators or as competitors? e.g. do you refer or would you see yourself referring?
In Closing
8. Our project is about the legal and ethical responsibilities of pharmacists with respect to these products. Does anything else come to mind that I haven’t asked you about?

9. Are there any additional questions/issues you would like to see raised in future interviews, focus groups or a survey?

10. Do you have any suggestions of other individuals who we should be interviewing?

11. Do you have any documents (e.g. reports, protocols, etc.) about this topic that are available to us for review?
**Key Informant Interview PROBES – Pharmacy, Industry**

**NECESSARY PROBES:**
- **If terminology unclear:** What do you mean by the term [vitamin/mineral, herbal]?
- Do you think this is the same for all kinds of pharmacists (e.g. hospital pharmacists and community pharmacists)?

**OPTIONAL PROBES & PROMPTS:**
- If [these products] are similar to OTCs, pharmacists should be able to sell them:
  - Are pharmacists able to ensure that these [NHP] products they sell are evidence-based and of good quality, as they do for other OTCs? **If not, why not?**
- If [these products] are similar to OTCs, pharmacists should be able to counsel on them:
  - Can or do pharmacists currently counsel on [these products]? **If not, why not?**
  - Can or do pharmacists currently answer about [NHPs] that are not sold in their pharmacies? **If not, why not?**
- Are pharmacists able to provide the same level of information about [these products] that they do for other OTCs? For example,
  - About how [these products] should be used, e.g. dosage? **If not, why not?**
  - About the safety of [these products]? For example, are they able to provide information about possible interactions, adverse effects, contraindications? **If not, why not?**
  - About expected results or efficacy of [the product]? **If not, why not?**
- If [these products] are similar to OTCs, pharmacists should be able to recommend them to patients:
  - Should they be able to recommend them in lieu of or as confidently as any other OTC?
  - Should they be able to recommend specific brands of [this product]? (e.g. echinacea vs. a particular brand or product containing echinacea?) Why or why not?
- If [these products] are similar to OTCs, pharmacists should be able to provide information about them to other members of the health care team. Are they currently able to do this? **If not, why not?**
- **[Review and refer to any documents that exist within the organization that are specific to NHPs]**
REGULATOR PROBES

• **If within current scope of practice:**
  o What if any, policy changes do you think are needed in order to provide guidance for pharmacists using [these products], since they are different than existing drug schedules/categories and OTCs? (e.g. revise/expand practice standards, protocols, code of ethics)?
  o Are there any mechanisms/processes currently in place that are transferable or that provide general guidance in this area?

• **If not within current scope of practice:**
  o Should [these products] be brought into the scope of practice? Why or why not?
    ▪ **If so,** how?
    ▪ **If not,** how would you expect pharmacists to respond to clients/patients using or asking about these products?

EDUCATOR PROBES

• What should the minimum requirements be for all pharmacists with respect to undergraduate curricula?
  o What should be the content of pharmacy courses? (e.g. research literacy, review of available trials and systematic reviews, regulatory issues, etc.)
  o What styles of delivery are the best ways to approach this content? (e.g. bring in guest speakers, have cases, lectures, field trips, etc.)
  o Which, if any, should be mandatory or elective?
  o Should this training be included in existing courses or constitute stand-alone courses?
  o How difficult is it for you to identify someone with the expertise to teach this topic?

• What should the minimum requirements be for all pharmacists with respect to continuing education?
  o [as above]

• What should the minimum requirements be for all pharmacists with respect to practical training?

• Can you identify any examples of current curricula or continuing education that meet any of pharmacists’ needs in this regard?

• What training would facilitate specialization in this area? [as per types of questions above]
PHARMACY OWNER/MANGER and INDUSTRY PROBES:

- How was the decision made to carry [these products]?
  - Why is a particular section dedicated to these products?
  - Who decides what to sell and how to sell these products?
  - What factors are taken into account in deciding which products to carry, e.g. evidence, quality, brand, etc.?

- What if any, resources are made available for front-line pharmacists?
  - What if any resources have you developed for front-line pharmacists?

- What if any, training is required of front-line pharmacists?
APPENDIX D: Key Informant Interview Questions – Consumers

Views about Current Situation

1. Briefly describe your role in this organization.
2. What do you think of when you hear the term “natural health products”? Probe for examples…. then clarify that we want to talk about vitamins & minerals, herbs and homeopathics (if s/he doesn’t know what homeopathics are then just leave this out for the rest of the interview)
   To start with a general question,
3. Do natural health products such as vitamins, herbals and homeopathy arise in the context of your work/organization? If so, please explain where and when. E.g., is this an issue for your constituents? Probe for details about any issues they bring up
   Note: Ask them to tell us what their group thinks; if they don’t know, then ask for their personal opinion….
4. Where do you/members of your organization go for information about NHPs?
   • PROBE: What kind of information do you usually ask about?
   • PROBE: Does your organization or recommend specific sources of info?
5. Where do you/members of your group usually purchase NHPs?
   • PROBE: Do you buy NHPs at the pharmacy? Why or why not?
   • PROBE: How do you decide where to buy NHPs?
   • PROBE: Is there a difference in purchasing NHPs at a pharmacy compared to a health food store?
   • PROBE: What do pharmacists currently do well? What do pharmacists currently do poorly?

Roles & Responsibilities Relative to OTCs & NHPs

7. Are [these products] the same as any other OTC? Why or why not? [list the reasons they give].
   • If [these products] are similar to OTCs, pharmacists should be able to sell them:
     o Are pharmacists able to ensure that these [NHP] products they sell are evidence-based and of good quality, as they do for other OTCs? If not, why not?
   • If [these products] are similar to OTCs, pharmacists should be able to counsel on them:
     o Can or do pharmacists currently counsel on [these products]? If not, why not?
     o Can or do pharmacists currently answer about [NHPs] that are not sold in their pharmacies? If not, why not?
- Are pharmacists able to provide the same level of information about [these products] that they do for other OTCs? For example,
  - About how [these products] should be used, e.g. dosage? **If not**, why not?
  - About the safety of [these products]? For example, are they able to provide information about possible interactions, adverse effects, contraindications? **If not**, why not?
  - About expected results or efficacy of [the product]? **If not**, why not?

- If [these products] are similar to OTCs, pharmacists should be able to recommend them to patients:
  - Should they be able to recommend them in lieu of or as confidently as any other OTC?
  - Should they be able to recommend specific brands of [this product]? (e.g. echinacea vs. a particular brand or product containing echinacea?) Why or why not?

- If [these products] are similar to OTCs, pharmacists should be able to provide information about them to other members of the health care team. Are they currently able to do this? **If not**, why not?

- [Review and refer to any documents that exist within the organization that are specific to NHPs] Why did your organization feel the need to develop documents/guidelines specific to [these products]? Does that mean you feel they are deserving of different attention than OTCs? Please explain.

- **Scenario 1: ‘Products are the same as other OTCs’:**
  - Patient X indicates that they have cold or flu symptoms and asks the pharmacist to recommend a product, then proceeds to ask the pharmacist to compare how effective a conventional cold/flu medication (e.g. Sudafed) is relative to an NHP product/formula such as (a) Oscillococcinum [*sounds like ‘oskillokōsĭnum*’; a homeopathic flu medication purported to relieve cold/flu symptoms; is diluted past Avogadro’s number] OR (b) a high dose of Vitamin C, OR (c) Cold-FX [*made from North American ginseng extract; some evidence suggesting this is useful for prevention] OR (d) a product containing yarrow, elderflower, etc. [*herbals that are not well documented or that are in dosages too small to be considered to be effective]*

- **Scenario 2: ‘Products are/should not be part of pharmacy scope of practice’:**
  - Patient X comes into the pharmacy to fill a prescription for warfarin holding St. John’s Wort in their hands. What should a pharmacist do?
  - Supplementary info SJW clinically significantly decreases INRs [*International Normalized Ratio – what they measure to determine how much warfarin is in the blood; warfarin is a blood thinner with a very narrow therapeutic range; it interacts with many things there is a clinically significant and well documented interaction with SJW]*
8. What would you like to see pharmacists do with respect to NHPs? How could they meet the needs of your group?
   NOTE use these very sparingly – DO NOT go through them all
   • PROBE: Should pharmacists sell NHPs? Why or why not?
   • PROBE: Should NHPs be sold only in the pharmacy?
   • PROBE: Should pharmacists recommend NHPs to patients? Under what circumstances?
   • PROBE: What kind of information should pharmacists provide to patients about NHPs (e.g., instructions for use, potential adverse effects, whether there is evidence to support the efficacy and safety of the product, etc.)?
   • PROBE: Should pharmacists be responsible for detecting interactions between NHPs and drugs?

Inter-professional Responsibilities

9. Who do you identify as the (other/potential) professional experts in the area of NHPs?
   • PROBE: Are these experts for NHPs in general or only for particular NHPs?
   • PROBE: What do you think is the role of the dietitian with respect to NHPs?

In Closing

10. Our project is about the legal and ethical responsibilities of pharmacists with respect to these products. Does anything else come to mind that I haven’t asked you about?
11. Do you have any suggestions of other individuals who we should be interviewing?
12. Do you have any documents (e.g. reports, protocols, etc.) about this topic that are available to us for review?
APPENDIX E: Key Informant Interview Questions – CAM Practitioners

Views about Current Situation

1. Briefly describe your role in this organization.
2. What do you think of when you hear the term “natural health products”?
   Probe for examples….. then clarify that we want to talk about vitamins & minerals,
   herbs and homeopathics (if s/he doesn’t know what homeopathics are then just leave
   this out for the rest of the interview)
   To start with a general question,
3. How do natural health products such as vitamins, herbals and homeopathy arise in the
   context of your work/organization? E.g., is this an issue for your constituents? Probe
   for details about any issues they bring up

Note: Ask them to tell us what their group thinks; if they don’t know, then ask for their
personal opinion….

4. Where do you/members of your organization go for information about NHPs?
   • PROBE: What kind of information do you usually ask about?
   • PROBE: Does your organization or recommend specific sources of info?

5. Where do you/member of your group usually purchase NHPs?
   • PROBE: Do you buy NHPs at the pharmacy? Why or why not?
   • PROBE: How do you decide where to buy NHPs?
   • PROBE: Is there a difference in purchasing NHPs at a pharmacy compared to a
     health food store?

   • PROBE: What do pharmacists currently do well? What do pharmacists currently do
     poorly?
   • Does your organization or recommend specific sources of info?

Roles & Responsibilities Relative to OTCs & NHPs

7. Are [these products] the same as any other OTC? Why or why not? [list the reasons
   they give].
   • If [these products] are similar to OTCs, pharmacists should be able to sell them:
     o Are pharmacists able to ensure that these [NHP] products they sell are
       evidence-based and of good quality, as they do for other OTCs? If not, why
       not?
   • If these products are similar to OTCs, pharmacists should be able to counsel on them:
     o Can or do pharmacists currently counsel on [these products]? If not, why not?
     o Can or do pharmacists currently answer about [NHPs] that are not sold in
       their pharmacies? If not, why not?
• Are pharmacists able to provide the same level of information about [these products] that they do for other OTCs? For example,
  o About how [these products] should be used, e.g. dosage? If not, why not?
  o About the safety of [these products]? For example, are they able to provide information about possible interactions, adverse effects, contraindications? If not, why not?
  o About expected results or efficacy of [the product]? If not, why not?

• If [these products] are similar to OTCs, pharmacists should be able to recommend them to patients:
  o Should they be able to recommend them in lieu of or as confidently as any other OTC?
  o Should they be able to recommend specific brands of [this product]? (e.g. echinacea vs. a particular brand or product containing echinacea?) Why or why not?

• If [these products] are similar to OTCs, pharmacists should be able to provide information about them to other members of the health care team. Are they currently able to do this? If not, why not?

• [Review and refer to any documents that exist within the organization that are specific to NHPs] Why did your organization feel the need to develop documents/guidelines specific to [these products]? Does that mean you feel they are deserving of different attention than OTCs? Please explain.

• **Scenario 1: ‘Products are the same as other OTCs’**:
  o Patient X indicates that they have cold or flu symptoms and asks the pharmacist to recommend a product, then proceeds to ask the pharmacist to compare how effective a conventional cold/flu medication (e.g. Sudafed) is relative to an NHP product/formula such as (a) Oscillococcinum [sounds like ‘oskillokōsin’]: a homeopathic flu medication purported to relieve cold/flu symptoms; is diluted past Avogadro’s number] OR (b) a high dose of Vitamin C, OR (c) Cold-FX [made from North American ginseng extract; some evidence suggesting this is useful for prevention] OR (d) a product containing yarrow, elderflower, etc. [herbals that are not well documented or that are in dosages too small to be considered to be effective]

• **Scenario 2: ‘Products are/should not be part of pharmacy scope of practice’**:
  o Patient X comes into the pharmacy to fill a prescription for warfarin holding St. John’s Wort in their hands. What should a pharmacist do?
  o Supplementary info SJW clinically significantly decreases INRs [International Normalized Ratio – what they measure to determine how much warfarin is in the blood; warfarin is a blood thinner with a very narrow therapeutic range; it interacts with many things there is a clinically significant and well documented interaction with SJW]

8. What would you like to see pharmacists do with respect to NHPs? How could they meet the needs of your group?
NOTE use these very sparingly – DO NOT go through them all

- PROBE: Should pharmacists sell NHPs? Why or why not?
- PROBE: Should NHPs be sold only in the pharmacy?
- PROBE: Should pharmacists recommend NHPs to patients? Under what circumstances?
- PROBE: What kind of information should pharmacists provide to patients about NHPs (e.g., instructions for use, potential adverse effects, whether there is evidence to support the efficacy and safety of the product, etc.)?
- PROBE: Should pharmacists be responsible for detecting interactions between NHPs and drugs?

**Inter-professional Responsibilities**

9. Who do you identify as the (other/potential) professional experts in the area of NHPs?
   - PROBE: Are these experts for NHPs in general or only for particular NHPs?
   - PROBE: What do you think is the role of the dietitian with respect to NHPs?

**In Closing**

10. Our project is about the legal and ethical responsibilities of pharmacists with respect to these products. Does anything else come to mind that I haven’t asked you about?
11. Do you have any suggestions of other individuals who we should be interviewing?
12. Do you have any documents (e.g. reports, protocols, etc.) about this topic that are available to us for review?
APPENDIX F: Pharmacist Coding Tree

Pharmacist Legal
- Standards & Guidelines
- Liability

Pharmacist Ethical
- Profit Motive
- Ethical General

Pharmacist Role and Responsibilities

Attitude

Pharmacist Education
- Undergraduate Education
- Continuing Education

Specialization

Perception of Pharmacists

Role

Retailing

Counselling

Safety Issues

Sharing Info with Healthcare Team

Knowledge

Hospital Role

Recommendation

Support for role
- Barriers
- Not a Role

Selling

Merchandising

Approach

Content

Counselling as a Role

Time

Lack of

Lack of

Reimbursement

Information

Knowledge

FREE NODES: Quotes, Other Experts
APPENDIX H: Coding Scheme - Definition of Terms

Below is a draft description of the themes and categories identified so far in the key informant interviews. These definitions and the coding tree should be used when analyzing the interviews.

CONTEXT

1. POLICY: Empty parent node that has child nodes for policy and NAPRA
   a. Policy general: any generic reference made to policy
   b. NAPRA/scheduling: references made to where NHPs should be sold

2. NHPs: Empty parent node containing child nodes for NHP regulations, NHP types, NHP definitions, important issue, not on radar, comparison to OTC, product quality, and evidence.
   a. NHP regulations: comments regarding NHP-DINs, and NHP federal regulations, or generic references to regulations
   b. NHP types: references made to specific types of NHPs
      i. Vitamins/minerals
      ii. Herbals
      iii. Homeopathy
      iv. Other NHP types – captures all other references to particular NHPs not captured in the above subcategories
   c. NHP definitions: how NHPs have been defined by the interviewee; includes how they describe or perceive NHPs, boundaries with foods and medicine, and distinguishes between levels and forms of NHPs
   d. Relevance: statements referring to how relevant or not NHPs are within the context of their organization or communication with consumers; includes comments such as not on radar, important issue, and references made regarding research in the area of NHPs
   e. Product quality: statements referring to the traits or characteristics of an NHP
   f. Effectiveness: any generic statement made by the interviewee referring to proof, or evidence as to whether a NHP works or not, includes research around a product

3. COMPARISON to OTCs or PRESCRIPTION MEDICATION: any comments made that compare NHPs to OTCs or prescription medication.

4. OTHER HCPs: HCPs that the interviewee identifies as playing a role in NHPs
   a. Naturopaths: any generic references made to naturopaths
   b. Physicians: any generic references made to physicians
   c. Dietitians: any generic references made to dietitians
   d. Pharmacy technicians: any generic references made to pharmacy technicians
   e. Competition: any references made to a rivalry between conventional HCPs and CAM practitioners
f. Other CAM providers: includes other CAM providers not captured in the other sub-categories such as: herbalists, homeopaths, chiropractors etc.
g. Other regulated HCPs: includes other HCPs not captured in the other sub-categories such as nurses, dentists, physiotherapists etc.
h. Collaboration: any references made to a joint effort between pharmacists and CAM practitioners working together, or referring to one another about NHP concerns

5. CONSUMERS: Empty parent node containing the child nodes consumption, and perception of consumers
   a. Consumption: any comments regarding product purchasing and/or product use
   b. Perception of consumers: general references to the perception of what the consumer thinks/does/is, and excludes references to consumption or consumer needs.
c. Needs: references made to what consumers require in regards to NHPs (includes references to tolerability and accessibility to NHPs)
d. INDUSTRY GENERAL: any generic references made about the NHP industry or the conventional medication industry, also includes references made to deals made between companies and pharmacies

6. INFORMATION SOURCES: references made towards sources of information for NHPs
   a. Electronic monitoring system: pharmacy computer repository that handles patients’ non-prescription and prescription medication history, drug interactions, as well as any electronic pharmacy database for prescription, OTC products and NHPs.
b. On-line Databases: references made to using on-line databases (some of which may require a user fee or subscription) as sources of information. i.e. The Natural Medicines Database on-line.
c. Internet search: references made to using the internet or search engines such as Google etc. as sources of information
d. Text: NHP references made to books, pamphlets, journals, product packaging/labeling
e. Industry Resources: refers to NHP industry & corporate pharmacy industry sponsored training, handbooks, etc.
f. Consumer groups: refers to consumer organizations as a source of information about NHPs
g. Other: includes all other sources of information not captured in the other subcategories such as advisories posted by Health Canada, media, conferences, drug information centres etc.

7. HEALTH FOOD STORES: Any generic references made by the interviewee about health food stores
1. **PHARMACIST LEGAL**: relates to any references the interviewee identifies as a potential legal issues for NHPs and pharmacists
   a. **Standards and guidelines** for pharmacists incl. licensing and accreditation: rules created by associations/stores/licensing bodies that pharmacists must abide by
   b. **Liability**: references regarding the legal repercussions/consequences for pharmacists

2. **PHARMACIST ETHICAL**: refers to any issues identified by the interviewee as “ethical”
   a. **Profit motive**: references made to the financial or monetary gain of carrying or selling NHPs
   b. **Ethical general**: any generic reference made to the ethical responsibility of pharmacists

3. **PHARMACIST ROLES/RESPONSIBILITIES**: refers to practices believed to be within the scope of the pharmacist’s role or duty with respect to NHPs
   a. **ROLE**: Empty parent node grouping support, no role, and barriers to the pharmacist carrying out their duties.
      i. **Support for role**: any statements supporting pharmacists as this is their role
      ii. **Not a role**: refers to things that pharmacists should not do, i.e. pharmacists that set themselves up as a homeopathic doctor
      iii. **Barriers**: any kind of barrier or thing that impedes a pharmacist from carrying out their role/responsibilities.
         * **Time**: lack of time
         * **Lack of information**: references made from the interviewee’s perspective (pharmacist) to information that does not exist; also includes poor quality of information, lack of research for a product
         * **Lack of knowledge**: statements identifying pharmacists lack of knowledge of NHPs
         * **Reimbursement**: statements referring to the pharmacist receiving no payment for providing services such as counseling, recommending or providing general information about NHPs
   b. **RETAILING**: empty parent node grouping references made to selling and merchandising
      i. **Selling**: refers to the decision to sell NHPs (or not) in pharmacies
      ii. **Merchandising**: decision-making of which product brands should be carried in the pharmacy; location of product placement in pharmacy, this can also include non-NHPs.
   c. **COUNSELLING**: refers to any advice, opinion or instruction given by a pharmacist when directing the conduct of a consumer in regards to medication or NHPs
i. **Approach**: the way a pharmacist acts with patients and processes the information; refers to the quality of “how” a pharmacist should counsel a patient, also includes a pharmacist’s ability to look up information about NHPs or a pharmacist referring to other pharmacists that are knowledgeable in NHPs.

ii. **Content**: “what” a pharmacist talks about when counseling patients

iii. **Counselling as a role**: any generic reference made to counseling

iv. **Counselling limitation**: References made to a pharmacist limiting the counselling they give to a patient because of lack of knowledge

d. **SAFETY ISSUES**: references made to ADRs, drug-NHP interactions, contraindications

e. **SHARING INFORMATION WITH THE HEALTHCARE TEAM**: any reference made about the pharmacist sharing information about a patient with other HCPs caring for the patient in the healthcare team

f. **KNOWLEDGE**: statements referring to expectations that pharmacists have knowledge

g. **HOSPITAL ROLE**: any reference made specifically about hospital pharmacists

h. **RECOMMENDING**: comments made referring to a pharmacist recommending, advising or endorsing NHP use to a consumer

4. **ATTITUDE**: statements referring to a pharmacist’s subjective (internal) view or personal bias towards NHPs.

5. **PHARMACIST EDUCATION**: refers to any formal training a pharmacist has received and statements made to pharmacists being trained
   a. **Undergraduate**: education/training received during their bachelor of science pharmacy program
   b. **Continuing education**: education or training courses a pharmacist takes part in post-graduation

6. **SPECIALIZATION**: any references an interviewee makes towards having a group of pharmacists training to become ‘experts’ in the area of NHPs, also refers to having specialized knowledge and not just training they have received; includes informal and holistic training the pharmacist has received

7. **PERCEPTION OF PHARMACISTS**: statements referring to what pharmacists generally do/are etc, this also includes references made to the general relationship with pharmacists

**FREE NODES**

**QUOTES**: statements made by the interviewee that uniquely summarize an important idea

**OTHER EXPERTS**: Names of any specific individuals the interviewee considers as having special knowledge or training in regards to NHPs.
Appendix I – Ethics Approval and Renewal Letter

UNIVERSITY OF TORONTO
Office of the Vice-President, Research and Associate Provost
Ethics Review Office

PROTOCOL REFERENCE #15854

December 20, 2005

Prof. H. Boon
Pharmaceutical Sciences
19 Russel Street
University of Toronto
Toronto M5S 2S2

Dear Prof. Boon:

Re: Research protocol entitled, “Natural Health Products (NHPs) and Pharmacy Practice” (Revised December 12, 2005) by Prof. H. Boon

ETHICS APPROVAL

Original Approval Date: December 20, 2005
Expiry Date: December 19, 2006

We are writing to advise you that a member of the Health Sciences I Research Ethics Board has granted approval to the above-named research study, under the Board’s expedited review process, for a period of one year. Ongoing projects must be renewed prior to the expiry date. Your ethics protocol approval is valid for a period of 1 year. It is the responsibility of the investigator to maintain a valid approval throughout the duration of the research activity, and to report to the Ethics Review Office of its completion. Annual Renewal of Ethics Approval forms and Study Completion Report forms can be found at http://www.rrr.utoronto.ca/ethics_hsmaterials.html. Consequences of expired ethics protocol approvals may include the freezing of funds and/or refusal to review new ethics protocol submissions.

The following documents (revised December 12, 2005) have been approved for use in this study: Key Information Interview/Focus Group Questions (Appendix A), Letter to Participants (Appendix B), Information Letter – Interviews (Appendix C), Consent Form – Interviews (Appendix D), Advertisement (Appendix E), Letter to Focus Group Participants (Appendix F), Information Letter – Focus Groups (Appendix G), Consent Form – Focus Groups (Appendix H). Participants should receive a copy of their consent form.

During the course of the research, any significant deviations from the approved protocol (that is, any deviation which would lead to an increase in risk or a decrease in benefit to participants) and/or any unanticipated developments within the research should be brought to the attention of the Ethics Review Unit. Best wishes for the successful completion of your project.

Yours sincerely,

Mariana Richardson
Ethics Review Coordinator

xc: Mr. W. Maurice, Grants Officer, Health Sciences

Swinner Hall 27 King’s College Circle Toronto Ontario M5S 1A1
Telephone 416 978-3165 Fax 416 946-5763 email: ethics.review@utoronto.ca
UNIVERSITY OF TORONTO  
Office of the Vice-President, Research and Associate Provost  
Ethics Review Office  

PROTOCOL REFERENCE #15854 now #19267  
January 29, 2007  

Prof. H. Boon  
Faculty of Pharmacy  
144 College St.  
Toronto, ON M5S 3M2  

Dear Prof. Boon:  

Re: Research protocol entitled, ‘Natural Health Products (NHPs) and Pharmacy Practice’  

| ETHICS APPROVAL | Original Approval Date: December 20, 2005  
|---|---  
| Next Expiry Date: December 19, 2007  
| Renewal: 1 of 4  

We are writing to advise you that the Health Sciences I Research Ethics Board has granted annual renewal of ethics approval to the above referenced research study through the REB’s expedited process. Ongoing projects must be renewed prior to the expiry date.  

We understand that there have been no changes to the consent documents since the original approval date. Participants should receive a copy of their consent form.  

During the course of the research, any significant deviations from the approved protocol (that is, any deviation which would lead to an increase in risk or a decrease in benefit to participants) and/or any unanticipated developments within the research should be brought to the attention of the Ethics Review Office.  

Best wishes for the successful completion of your project.  

Yours sincerely,  

Jenny Pelo  
Ethics Review Coordinator  

xc: Mr. W. Maurice (Grants Officer, Health Sciences)