Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies

by

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A thesis submitted in conformity with the requirements for the degree of Master of Science
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Abstract

Objective: To reach consensus on entry-to-practice natural health product (NHP)-related competency statements for Canadian pharmacy students.

Methods: Four rounds of a modified Delphi method were conducted. Participants; pharmacy educators, and representatives from Canadian pharmacy organizations (n=17), ranked their level of agreement using a 5-point Likert scale.

Results: Consensus occurred when all participants ranked a statement 4 or 5. Three core NHP-related competencies were identified: 1) the ability to incorporate NHP knowledge when providing pharmaceutical care; 2) the ability to access and critically appraise NHP-related information sources, and 3) the ability to provide appropriate education to patients and other health care providers on the effectiveness and potential adverse effects and drug interactions of NHPs. Two additional NHP-related competency statements emerged as important, but consensus was not achieved.

Conclusions: If the developed core NHP-related competency statements are widely implemented, Canadian pharmacists will be able to fulfill their NHP-related professional responsibilities upon entry-to-practice.
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Chapter 1
Introduction
1.0 Introduction to this Study

Pharmacists have a key role to play with respect to natural health products (NHPs), such as herbal medicines and vitamins according to Canadian consumers,\(^1\) pharmacy regulatory bodies,\(^2-4\) professional pharmacy associations,\(^5,6\) pharmacy examining boards,\(^2,6\) and pharmacists themselves.\(^1,2,5,7\) Previous research indicates that a range of stakeholders, including consumers, pharmacists, and other health care providers (HCPs), believe that pharmacists have an important role to play in providing consumers with guidance regarding the safe and effective use of NHPs.\(^1,2,5,8-10\) The role of pharmacists with regards to NHPs is becoming increasingly important especially in light of market trends which indicate that consumer usage of NHPs is high,\(^11-13\) and that the majority of NHPs sold in Canada and the United States (as much as 60% in 2000) were purchased in pharmacies.\(^14,15\) Experts suggest reasons for the resurgence of natural medicines to include patients’ perceptions of the failures of allopathic medicine and a desire to play active roles in their health care.\(^16\)

The Canadian federal government has taken action to ensure that consumers are buying NHPs which are of high quality and safe for self-use through the creation of the Natural Health Products Regulations (NHP Regulations). The NHP Regulations were created in 2004 in response to increased consumer use,\(^1,13,17\) reports of adverse effects,\(^12\) and inconsistent regulation.\(^13,17,18\) They legally categorize NHPs as “drugs” at the level of the Food and Drugs Act,\(^1,5,6,19\) and thus it has been argued that NHPs are part of pharmacists’ scope of practice.\(^1,6\) These regulations also require that companies provide evidence that NHPs are safe and effective before they are available for purchase.\(^20,21\) Additionally, as pharmacists are increasingly viewed as “front line” providers of information regarding the safety and efficacy of NHPs,\(^22\) regulatory associations in Canada and the United States have created specific policies for these products.\(^5,20,23,24\) For example, the majority of Canadian jurisdictions now include some explicit reference
to NHPs in their standards of practice documents for pharmacists.\textsuperscript{25} In 1999, the National Association of Pharmacy Regulatory Authorities (NAPRA), released a position statement entitled “Pharmacist’s Responsibility in Providing Advice About or Selling Alternative Health Products” which recommends pharmacists play an active role in maintaining public safety with respect to NHPs.\textsuperscript{26}

Despite these strong messages that pharmacists must play a role with respect to NHPs, many pharmacists appear to have little knowledge of NHPs.\textsuperscript{6} Research demonstrates that pharmacists are not equipped by their formal education to meet standards of practice and consumer expectations related to NHPs, as professional pharmacy curricula content pertaining to NHPs varies widely across North America.\textsuperscript{6, 22, 27, 28} So while NHP content is increasingly presented in a formalized manner at schools of pharmacy, it is often as an elective course (as compared to a mandatory course) offered during the final years of schooling,\textsuperscript{6} and thus it is up to individual students if they choose to take the course or not. Thus, while pharmacists are increasingly being identified as important sources of information on NHPs,\textsuperscript{1, 2, 5, 8-10} and perhaps the HCPs most suitable to counsel consumers about NHPs, this role appears to be at odds with their actual training in NHPs.\textsuperscript{1, 2, 5, 6, 8-10, 29-32}

The research explained in this thesis attempted to bridge the gap between Canadian pharmacists’ formal education and their NHP-related professional responsibilities. A modified Delphi method was used to achieve consensus in identifying core NHP-related competencies that pharmacy educators and representatives from pharmacy organizations agreed were important for pharmacy students to have when entering pharmacy practice in Canada. The process of developing core NHP-related competencies culminated at an invitational consensus building meeting held in Toronto, Ontario, Canada, on November 6 & 7, 2008. This research is the final stage of a multi-stage research project which examined the role of NHPs in pharmacy practice.
The project began with qualitative research that included: a document analysis; 8 35 key informant interviews; 2 16 focus groups with practicing pharmacists and consumers, 1 testing of 4th year Canadian pharmacy students’ herbal knowledge; 6 and a survey of 3356 licensed Canadian pharmacists. 10 The final stage (this research) was to have “informed individuals” or “experts,” 33 (i.e., those who are actively involved in teaching/administering NHP content or setting/enforcing NHP-related pharmacy policies) synthesize this information make the final decision regarding core NHP-related competencies.

This study is important because it has the potential to shape the future direction of pharmacy curriculum as the developed NHP-related core competencies will be widely disseminated with the hopes of influencing the implementation of changes in NHP-related pharmacy curriculum. More importantly, if pharmacists are better prepared to assist their patients with making safer, more informed NHP-related decisions this will ultimately lead to better health outcomes for Canadians.

1.1 Research Problem

What core NHP-related competencies do pharmacy educators and representatives from pharmacy organizations agree are important for pharmacy students to have when entering pharmacy practice in Canada?

1.2 Study Objective

The specific objective of this study was to use the Delphi method to achieve consensus on general NHP-related core competencies by hosting an invitational consensus building meeting.

1.3 Organization of Thesis

This thesis follows the alternative thesis format and thus consists of a first-authored paper that will be submitted for publication in a peer-reviewed journal. Chapter 2 provides a literature
review of related research in this subject area. Chapter 3 contains a description of this study’s design, methodology and data collection/analysis. Chapter 4 focuses on the results that emerged through data collection/analysis and is written as a paper that will be submitted to the American Journal of Pharmaceutical Education. Chapter 5 includes a discussion of the results, recommendations for further research, and conclusions.

1.4 Summary

In summary, the research described in this thesis attempted to bridge the gap between Canadian pharmacists’ formal education and their NHP-related professional responsibilities through the use of a modified Delphi method to achieve consensus in identifying core NHP-related competencies for Canadian pharmacy students upon entry to practice. Participants of the Delphi method representing Canadian and American pharmacy educators and Canadian pharmacy organizations came to agreement on core NHP-related competencies culminating at an invitational consensus building meeting held at the University of Toronto – Leslie Dan Faculty of Pharmacy in November 2008. This research is the final stage of a multi-stage research project which attempted to examine the role of NHPs in pharmacy practice.

1.5 References


2.0 Introduction and Definitions

This chapter provides a literature review examining the context in which it has become necessary for Canadian pharmacists to be knowledgeable about natural health products (NHPs) given the realities of pharmacy practice in Canada. It will include a review of previous research related to what pharmacists should know about NHPs. The goal of this study was to develop core consensus-based NHP-related competencies for Canadian pharmacy students who are entering pharmacy practice using a modified Delphi method. This chapter includes discussion of: i) the definition and regulation of NHPs in Canada, ii) consumer use of NHPs, iii) pharmacists’ role with respect to NHPs, iv) competency based accreditation and licensure, and v) trends in pharmacists’ NHP-related education.

Three key terms (core competencies, outcomes and standards of practice) are used in this thesis. They are defined here to provide clarity for the text that follows. Core competencies are defined as: “significant job related knowledge, skills, attitudes, and/or judgments required for competent performance by members of the profession (p.16).”¹ These attributes are a necessary part of the educational preparation for the general practice of pharmacy,² and they are used to define what is minimally required of pharmacists at the point of licensure in Canada.¹ An outcome (in the educational sense) is what a pharmacy graduate should be able to do with what they have learned.³ Outcomes can be described as the effective use of resources (skills, attitudes and knowledge).² Outcomes should be realistic, quantifiable and measureable.² The use of the word “outcome” is found primarily in the documents from educational bodies, for example, the Canadian Council of Accreditation of Pharmacy Programs (CCAPP),² and the Association of Faculties of Pharmacy of Canada (AFPC).³ Standards of practice are competency-based and define the levels of achievement required by pharmacists for competence in key areas of pharmacy practice.⁴ The language of “standards of practice” is used primarily by the National
Association of Pharmacy Regulatory Authorities (NAPRA),\(^4\) and pharmacy regulatory bodies (i.e. the Ontario College of Pharmacists).\(^5\) Throughout this thesis every effort has been made to use these terms in their correct context to avoid confusion for the reader; however, some authors of pharmacy documents use these terms interchangeably. In some circumstances I have used the term identified by the author(s) when referring to these documents.

### 2.1 The Regulation of NHPs in Canada

The way NHPs are regulated in Canada leads to one of the reasons NHP-related core competencies for pharmacists have become an important issue. Since January 1 2004, NHPs have been defined and regulated in Canada by the Natural Health Products Directorate (NHPD), a branch of Health Canada under the Food and Drugs Act.\(^6\)\(^-\)\(^8\) For the purposes of this study, NHPs were defined according to Health Canada’s Natural Health Products Regulations (NHP Regulations) as any substance found in nature, …that is manufactured, sold or represented for use in: (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in 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 (p.42).\(^9\)

The list of approved medicinal ingredients of NHPs, according to the above definition includes:

(a) a plant or plant material, an alga, a bacterium, a fungus, or non-human animal material; (b) an extract or isolate of (a), the primary molecular structure of which is identical to that which it had prior to its extraction or isolation; (c) a vitamin; (d) an amino acid; (e) an essential fatty acid; (f) a synthetic duplicate of (b) to (e); (g) a mineral; (h) a probiotic (a term which is defined in the Regulations and is intended to capture such things as Lactobacillus acidophilus) (pg.43).\(^9\)

By definition, NHPs must be suitable for self care and safe for over-the-counter (OTC) use.\(^8\)

After a series of comprehensive consultations with consumers, other health care providers (HCPs), and the NHP industry,\(^5\)\(^,\)\(^9\)\(^-\)\(^13\) the NHP Regulations were created in response to increased consumer use,\(^11\)\(^13\)\(^,\)\(^14\) reports of adverse effects,\(^7\) and inconsistent regulation.\(^10\)\(^,\)\(^11\)\(^,\)\(^13\) NHPs are
now classified as a sub-category of drugs according to the Food and Drugs Act. The NHP Regulations state that companies must submit pre-market license applications that include evidence that the NHP is safe and effective before it can be approved for sale in Canada. The NHP Regulations are meant to “ensure that all Canadians have ready access to NHPs that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity (p.16).”

As the NHP Regulations classify NHPs as “drugs” at the level of the federal Food and Drug Act, it appears that the NHP Regulations imply that NHPs are a part of Canadian pharmacists’ professional scope of practice. To practice within legal requirements, pharmacists must demonstrate professional integrity and act to uphold professional standards of practice and codes of ethics:

…[to] meet appropriate standards of professional conduct and patient care, increasingly, these obligations – as set out in standards of practice, codes of ethics and other instruments – include a responsibility to be knowledgeable about NHPs, counsel patients in regard to NHP selection and use, and importantly to protect patients from adverse interactions between NHPs and prescription drugs (p.37).

One driving force behind pharmacists’ obligations towards NHPs has been a consumer usage trends.

2.2 Consumer Use of NHPs

2.2.1 Consumer Usage and Purchasing Trends

Much research has been conducted in the area of consumer NHP usage trends and it confirms high levels of consumption in Canada and the United States. In Canada, the 2005 Baseline NHP Survey found that 71% of Canadians have used an NHP at least once in their lifetime. Of this 71%, 1/3 reported that they use an NHP on a daily basis. Why has there been such a rise in the use of NHPs? Experts suggest reasons for the increase in NHP use include patients’ perceptions of the failures of conventional medicine and a desire to play active roles in
their health care\textsuperscript{21} - in this case by making their own choices regarding the selection of NHPs for self-care.

Consumers appear to prefer buying NHPs or dietary supplements (DS) - as NHPs are most commonly referred to in the United States, in pharmacies than other locations.\textsuperscript{22} A survey by the Non-prescription Drug Manufacturers Association of Canada (NDMAC) in 2000 found that 60\% of consumers who buy herbal products purchase them in a pharmacy.\textsuperscript{23} Similarly, in the United States, half of the adults polled (n=1000) in a phone survey conducted for Reader’s Digest, preferred to shop for alternative health care products in a pharmacy.\textsuperscript{24}

2.2.2 Consumerism – Beliefs, Expectations and Information Sources

Consumerism is an important concept related to current NHP usage trends. Generally, consumers are described as being more literate, better educated, with more resources at their disposal than consumers 20-30 years ago.\textsuperscript{25} Expert knowledge is no longer accepted at face value, but rather is open to skepticism due to increased public awareness of the uncertainties in science, and individuals’ desire to be involved in their own health care decisions.\textsuperscript{16} Many consumers seek out their own information regarding NHPs and many turn to informal sources such as family, friends or the internet for advice, instead of consulting with health care providers.\textsuperscript{21} Attitudes about self-care with NHPs tend to come from two schools of thought: i) the belief that since these products have been used in traditional systems of healing for generations they must be effective or people would have stopped using them,\textsuperscript{6, 19, 26} and ii) the belief that NHPs are “safe” because they are made from natural ingredients.\textsuperscript{6, 10, 19, 26, 27}

When patients do seek expert advice, they view pharmacists as trustworthy and knowledgeable sources of information about NHPs.\textsuperscript{10, 15} The majority of consumers agree that pharmacists should be knowledgeable about NHPs and feel that pharmacists should be able to
help them manage drug-NHP interactions as well as identify and assess the range of information available to help consumers make informed decisions.\textsuperscript{16}

\textbf{2.3 NHPs and the Role of Pharmacists}

\textit{2.3.1 Consumers and Pharmacists}

A combination of factors related to consumer use of NHPs has lead to increased pressure on pharmacists to know about NHPs. Research by Kwan et al. indicates that the majority of Canadian consumers and practicing pharmacists agree that pharmacists need to be knowledgeable about NHPs because usage of NHPs is so common.\textsuperscript{16} Consumers identified the informative role of the pharmacists to be especially important since NHPs can be pharmacologically active and dosing instructions, as well as safety information for NHPs, are often confusing or missing from labels.\textsuperscript{28}

Also of importance are trends that indicate that a significant proportion of Canadian and American pharmacists reported receiving questions about NHPs from patients and other health care providers\textsuperscript{10, 19, 29} regarding: product differentiation, the suitability of a product for a specific indication, and the safety of products when taken with other medications or for patients with multiple medical conditions.\textsuperscript{30} Since pharmacists are readily accessible to consumers at the point of sale as they are making decisions about NHPs, pharmacists are, in theory, situated in a good position to provide patients with evidence-based information about NHPs.\textsuperscript{15} According to the National Association of Pharmacy Regulatory Authorities (NAPRA), whose mission is to enhance the activities of the pharmacy regulatory authorities in Canada\textsuperscript{31} – many consumers have a “thirst for health information,” creating a greater need for pharmacists to be capable of advising consumers who are inundated with health information from a wide range of sources of varying credibility.\textsuperscript{14}
2.3.2 Pharmacists’ Professional NHP-related Roles and Responsibilities

As pharmacists are increasingly viewed as “front line” providers of information regarding the safety and efficacy of NHPs, regulatory bodies and pharmacy associations in Canada and the United States have created specific policies related to these products. For example, the American College of Clinical Pharmacy (ACCP), the American Society of Health-System Pharmacists (ASHP), and the Canadian Society of Hospital Pharmacists (CSHP) have recommended that the profession of pharmacy actively embrace NHPs/DS as part of the pharmacist’s scope of practice. The ACCP White Paper on Herbal Products argues that, “the basis for pharmacists’ involvement with herbal products is an extension of their established roles in pharmaceutical care... (p.883),” and “the variability in the degree of scientific evidence on efficacy and safety available to support the use of herbal products makes it even more imperative that pharmacists assume an active role in this area (p.883).” Such statements demonstrate the expectation for pharmacists to have knowledge regarding NHPs, and yet one study determined only 12% of Canadian pharmacists said they are very satisfied with the quality of information available to them on herbal products. Likewise, in the United States, a 2003 study found that 95% of surveyed pharmacists in the state of Minnesota felt available information on herbal and other natural products was not adequate or only somewhat adequate. Additionally, the rate of documenting, monitoring and inquiring about patients’ use of NHPs by pharmacists is low in both Canada and the United States. A Canadian study of community pharmacists’ (n=132) found that 47% of the pharmacists surveyed had identified a potential NHP-drug interaction or NHP-related adverse event at some point in the past; however, only two pharmacists had reported this information to Health Canada. One American study reported a documentation rate of 11% and a monitoring rate of 38.4% for drug related problems in patients that used complementary/alternative medicine (CAM).
There is some disagreement among stakeholders (including pharmacists, consumers and other CAM practitioners) regarding the amount of knowledge pharmacists should have with respect to NHPs. Some believe that pharmacists should be able to counsel patients about NHPs at the same level as they do for all other OTC medications, while others advocate that pharmacists only needed to have a more basic knowledge of NHPs, where “basic” meant knowing when to refer patients to other HCPs who were experts on NHPs. A survey of Canadian dietitians found they were more comfortable with pharmacists (as opposed to dietitians) recommending nutraceuticals (a type of NHPs) to patients because “pills are equated in the public mind with pharmacists” (pg.123). These authors contend that partnerships with other HCPs amongst allopathic providers (pharmacists, doctors and nurses) and alternative practitioners (dietitians, other CAM providers) is important in the managing NHP self-use in patients. Thus, there appears to be a clear expectation that pharmacists do in fact have some professional NHP-related obligations. Exactly what those obligations are, and how pharmacy students can be prepared to fulfill these obligations is less clear.

2.3.3 Responsibilities in the Canadian Policy Context

In Canada, pharmacy is a self-regulating profession, and each jurisdiction (province or territory) has a statute which sets out the scope and standards of practice for pharmacists. The majority of Canadian jurisdictions now include some explicit reference to NHPs. For example, the Ontario College of Pharmacists (the licensing body of Ontario pharmacists) states in its Standards of Practice that patient profile information should include known risk factors for adverse drug reactions including non-prescription drugs, NHPs and CAM, and that the pharmacist should be accessible and approachable to consult with patients seeking to self-medicate with a non-prescription drug, a NHP or CAM. Some provinces and territories (e.g., Quebec, New Brunswick, Yukon, Northwest Territories and Nunavut) do not contain specific
standards of practice relevant to NHPs in their standards of practice documents. However, often NHPs are included with OTCs, and thus professional responsibilities for OTCs are defined as also pertaining to NHPs.

Other provinces follow NAPRA’s Model Standards of Practice for Canadian Pharmacists (2003) guidelines for these products (e.g. Newfoundland and Labrador, Nova Scotia and Prince Edward Island). This document created by NAPRA’s National Competency-Based Standards of Practice Working Group, contains competency-based standards which define the levels of achievement required for pharmacists for competency in key area of pharmacy practice. Mention of non-prescription drugs, self-care and NHPs are made explicitly throughout NAPRA’s five Professional Competency statements contained in this document. NAPRA also released a position statement entitled “Pharmacist’s Responsibility in Providing Advice About or Selling Alternative Health Products (1999),” which recommends pharmacists play an active role in maintaining public safety with respect to NHPs. Additionally, the Prince Edward Island Pharmacy Board issued a policy statement on the subject, “Pharmacist’s Responsibility in Providing Advice About or Selling Alternative Health Products (2000),” while the Nova Scotia College of Pharmacists has a section in their Policies, Positions and Guidelines on the “Sale of Natural Health Products in Pharmacies (2006).” Clearly, most provincial/territorial pharmacy licensing bodies and national regulatory associations recognize the importance of NHPs in contemporary Canadian pharmacy practice which arguably make NHPs part of pharmacists’ professional responsibility in all Canadian jurisdictions.

Also of importance is the message that Canadian regulatory bodies and associations are sending to patients, as they are increasingly advertising the role of pharmacists in advising patients about NHPs and state that pharmacists are “experts” in this area. For example, Ontario’s Standards of Practice recommends signage in pharmacies encouraging consumers to
consult with a pharmacist about selecting non-prescription products including NHPs.\textsuperscript{5, 14} Thus, there is a clear expectation that pharmacists will have the knowledge to counsel patients about NHPs, even though few in the profession report confidence in this area.\textsuperscript{14} Changing professional responsibilities emphasize the need for changes in pharmacy education to ensure pharmacists have the capacity to meet evolving standards of practice, which are based on competencies.\textsuperscript{4}

### 2.4 Competency Based Accreditation and Licensure

In North America, accreditation of pharmacy schools, licensing of pharmacists and thus pharmacists’ education is based on competencies. A discussion reviewing the definition of competency and how competencies are incorporated into accreditation of pharmacy schools and licensure of pharmacists’ follows and sets the stage for the subsequent discussion of pharmacists’ NHP-related education.

As discussed in section 2.0 Introduction and Definitions, core competencies are defined by NAPRA in Canada as: “significant job related knowledge, skills, attitudes, and/or judgments required for competent performance by members of the profession (p.16).”\textsuperscript{1} They are used to define what is minimally required of pharmacists at the point of licensure in Canada.\textsuperscript{1} Core competencies represent the minimum level below which individuals would not be considered competent to practice.\textsuperscript{4} Competencies are often created through extensive consultative processes,\textsuperscript{44} including deliberation, and ideally consensus.\textsuperscript{45} Thus in conducting this study, it was our goal to develop core NHP-related competencies that are consistent with existing documents including: the National Association of Pharmacy Regulatory Authorities’ (NAPRA) Model Standards of Practice for Canadian Pharmacist (2003),\textsuperscript{4} NAPRA’s Professional Competencies for Canadian Pharmacists at Entry to Practice (2007),\textsuperscript{1} and the Association of the Faculties of Pharmacy of Canada’s (AFPC) Educational Outcomes for Entry-Level Doctor of Pharmacy Graduates in Canada (2007).\textsuperscript{3} (Although only two Canadian pharmacy schools currently offer
entry level PharmD programs, I refer to the 2007 Doctor of Pharmacy AFPC document because it is the most recent. The 1996 AFPC baccalaureate educational outcomes are currently being revised, but were not available for this project). The core NHP-related competencies identified in the project would represent a minimum level of professional competence related specifically to NHPs that would be required of Canadian pharmacists at entry-to-practice.

“Accreditation is the public recognition accorded to a professional program that meets established professional qualifications and educational standards through initial and periodic evaluation (pg.i).” Accreditation is thus concerned with both quality assurance and program enhancement. In Canada, the Canadian Council for Accreditation of Pharmacy Programs (CCAPP) is responsible for the accreditation of all pharmacy programs, with the specific mission of evaluating the quality of pharmacy professional degree programs in Canadian universities and promoting continued improvement of such programs. (The parallel organization in the United States is the Accreditation Council for Pharmacy Education - ACPE). It is the view of the CCAPP that, “the educational outcomes established for a professional degree program in pharmacy should encompass the entrance-to-practice competencies specified by the appropriate licensing authority (pg.ii),” which are defined by each Province, but are based on NAPRA’s Professional Competencies for Canadian Pharmacists at Entry to Practice (2007). In addition, accreditation of schools of pharmacy requires that pharmacy curricula satisfy the AFPC educational outcomes.

2.4.1 Competency Based Licensure of Pharmacists

In Canada, the Pharmacy Examining Board of Canada (PEBC) is responsible for assessing the qualification of pharmacists on behalf of provincial pharmacy regulatory authorities, and ensuring that entry-level pharmacists have the necessary professional knowledge, skills and abilities to practice pharmacy competently. To become licensed to practice as a
pharmacist, an individual must: complete a BScPhm or PharmD degree from an accredited academic institution (or equivalent for foreign students) and pass the PEBC Qualifying Examination. The PEBC grants a certificate as evidence that an individual has successfully met evaluation criteria for entry level competency (knowledge, skills, abilities) to practice pharmacy safely and effectively. The Qualifying Exam is based on the practice competencies defined in NAPRA’s *Professional Competencies for Canadian Pharmacists at Entry to Practice* (1997), and involves both a written assessment and the performance based-assessment. Both components must be completed satisfactorily in order for an individual to be certified as competent.

In the United States, since 2004, passing the North American Pharmacists Licensure Examination (NAPLEX) has been a requirement of earning initial pharmacy licensure in all fifty states. State licensing of pharmacists is defined by state legislatures and based upon the measurement of competence that ultimately secures the protection of public health. In creating this exam careful attention is paid to reviewing and revising competence issues in response to changes in pharmacy practice and education with other interested pharmacy organization including: the American Association of Colleges of Pharmacists (AACP), and the Accreditation Council of Pharmacy Education (ACPE). The exam is designed according to a set of specific knowledge areas, practice functions and skills, which are the Competency Statements, or Competencies, published in the NAPLEX Blueprint. The NAPLEX is one of the primary outcome measures that can be utilized in formulating decisions regarding curriculum development and change.

Canadian and American pharmacists are expected to know certain information about NHPs/DS to become licensed. In Canada, the PEBC currently recommends that students planning to write the Qualifying Examination or the Evaluating Examination (if an international
pharmacy student) familiarize themselves on the subject of therapeutic considerations concerning alternative treatments, the category to which NHPs belong. In 2005, the NAPLEX added a competency specifically addressing knowledge of DS. With these requirements, clearly, it is imperative that pharmacists’ formal education be in line with licensing requirements.

2.5 Pharmacists’ NHP-related Education

Despite the pressure from consumers for pharmacists to take on an NHP-related professional role, the NHP Regulations and licensure requirements in formal testing and jurisdictions which appear to make NHPs a part of pharmacists’ scope of practice, research described below, demonstrates that pharmacists are not equipped by their formal education to meet standards of practice guidelines and consumer expectations related to NHPs as demonstrated by the following trends.

2.5.1 Trends in NHP-Related Pharmacy Education in North America

In theory, training in pathophysiology and pharmacology should provide pharmacists with the necessary background to interpret and evaluate scientific information about NHPs and place them in a position to determine if an NHP is a safe and appropriate therapeutic option. However, there exists substantial diversity in the extent of NHP education at schools of pharmacy. While content is increasingly presented in a formalized manner, it is often offered as an elective (as compared to a mandatory) course during the final years of schooling, and thus it is up to the individual student if they choose to take the course or not.

Researchers suggest that it is imperative that pharmacy education provide practitioners with evidence-based information on alternative therapies, especially with regards to NHPs, and give them the skills to recognize and analyze claims, evaluate sources of information, and communicate effectively with patients, particularly when patients are using both NHPs and conventional medicines. What is challenging for pharmacists is the need to assess the claims
made about NHPs while interacting with a population “educated” by sales persons, manufacturers, and anyone who has the ability to post information on the internet. \(^{49}\) Their education should equip pharmacists to meet these challenges. Reviews of pharmacists’ knowledge about NHPs have demonstrated that, in general, their knowledge is low. \(^{15}\) Given the lack of Canadian data in this area, the following sections will examine trends in both Canadian and American studies on pharmacists’ current NHP education. Themes to be discussed include: i) natural product content in pharmacy curricula, and ii) pharmacy students’ natural product knowledge.

Please note that the term “NHPs” is not used in the American literature. Products classified as NHPs in Canada are usually referred to as dietary supplements (DS) in the United States. Every effort has been made to clarify which types of natural products the primary authors were referring to in each of the studies mentioned.

### 2.5.2 Natural Product Content in Pharmacy Curricula

Studies conducted between 1998 and 2008 have measured the degree to which natural products have been included in pharmacists’ formal education. \(^{21,27,32}\) While many schools do offer courses on natural products, \(^{17,21,32}\) the information is quite often presented in elective (as compared to mandatory) courses during later years of formal education. \(^{21,32}\) A number of studies indicate that: pharmacy students believe they need more information on the subject of natural products, \(^{22,27,29,50}\) and that a majority of practicing pharmacists and pharmacy students believe that NHPs are part of their professional responsibility. \(^{27,29}\) Pharmacy students’ attitudes towards complementary and alternative medicine (CAM) have been demonstrated to change upon completion of a mandatory course. \(^{51}\)

Studies suggest that some NHP instruction is now found in the majority of North American schools of pharmacy. A 2008 study of five (out of nine in existence at the time of the
study) Canadian pharmacy schools reported that all five schools had natural product courses.\textsuperscript{17} Rowell and Kroll surveyed American pharmacy colleges in 2001 to assess the degree to which CAM instruction (defined by these authors as herbal medicines and homeopathic remedies) was included in pharmacists’ formal education.\textsuperscript{21} Of the 77 total schools surveyed, 50 responded and 72\% offered coursework in either herbal medicine or other areas of CAM. Similarly, Shields et al. surveyed 81 schools of pharmacy in 2003, the responses they received (from 79\% of the initial 81 surveyed) showed that 67\% of state institutions and 86\% of private institutions covered natural products in their curriculum.\textsuperscript{32} Most disconcerting to these authors was the fact that the number of schools with no CAM/natural product instructional offerings had not changed since a similar survey performed in 1997.\textsuperscript{32}

How natural product content is presented is also important. Courses on this subject are offered in two forms, as required courses or elective options. In the 2008 Canadian study by Johnson et al., two of the five pharmacy schools surveyed had stand alone elective NHP courses, another two had stand alone required courses, while the final school offered an integrated required course on this topic area.\textsuperscript{17} In 2001, Rowell and Kroll looked at the curriculum differences between Bachelor and PharmD pharmacy programs in the United States and found that while Bachelor program were slightly more likely to offer general CAM coursework, PharmD programs were more likely to present this information in required courses rather than electives.\textsuperscript{21} The most common category of natural products discussed in both Bachelor and PharmD curriculums (in terms of contact hours) was herbal medicines.\textsuperscript{21} Finally, Shields et al. reported in 2003 that natural products or CAM were still not consistently covered in curricula, and was most often offered as elective courses.\textsuperscript{32}

Rowell and Kroll (2001) found that most schools offered CAM coursework in the second or third professional year and content was most frequently delivered in a standard lecture
format. Shields et al. (2003) demonstrated that natural products were included more often as a component of a general CAM course than as an individual focused course, and included an average of 2.45 credit hours most commonly in the third professional year. Additionally, Shah et al. (2005) determined that curricular content on herbal supplements was not standardized or co-ordinated making it hard for students to identify when they were first exposed to this topic.

The best evidence that pharmacists’ formal education in the area of NHPs is lacking comes from reports that pharmacy students, pharmacy faculty and practicing pharmacists themselves saying that they need more information on this topic. In 2000, Chang et al. examined practicing pharmacists’ knowledge and attitudes towards herbal medicine in Virginia and North Carolina (n=164) and reported that the majority of pharmacists agreed that continuing education on herbal medications should be mandatory. In 2003, Clauson et al. found that approximately 57% of practicing pharmacists in the state of Missouri that responded to their survey (n=2921) indicated that they received natural product questions from their patients on a weekly basis, but only 2.4% felt that they could “always answer natural product questions.” This same study found that the most commonly used means for education on natural products in daily practice was printed continuing education materials (70.2%), while only 12.5% of pharmacists indicated that they had gained knowledge about natural products from their didactic pharmacy education. In a 2005 study by Shah et al., to assess students’ perspectives on including education about herbal supplements in the curriculum, 92% of students questioned perceived their own knowledge of herbal supplements to be inadequate, while 95% of students reported a need to learn more about herbal supplements. In 2006, Harris et al. found that students desired more training specifically in the areas of herbal medicines and nutritional supplements; while both faculty and students believed that CAM should be included in the curriculum.
In terms of the difference made in attitudes following a mandatory course on the subject of natural products, Evans and Evans (2006) found that 90% of PharmD students who took a required course addressing CAM either agreed or strongly agreed with the statement that they had developed the ability to discuss the scope of complementary medicine practices after taking the required course. Approximately, 93% of these same students agreed or strongly agreed that they had developed the ability to evaluate information available on herbal/natural products and make sound recommendations as to their use after taking this mandatory course. This confirms that knowledge does indeed empower pharmacists to take ownership of their professional NHP-related roles and responsibilities which practicing pharmacists and pharmacy students alike do believe to be a part of their scope of practice. As demonstrated by Chang et al. (2000), a strong majority of the practicing pharmacists surveyed believed that providing herbal medication information is a pharmacist’s responsibility. Similarly, Shah et al. (2005) in examining pharmacy student’s perceptions of their responsibilities towards natural products determined that 71% agreed or strongly agreed that pharmacists have a responsibility to provide information on herbal supplements to patients.

In their discussion section, all of these authors speak to an “education gap” related to natural products, and the importance of NHP-related competencies. Rowell and Kroll contend that, “…the majority of recent graduates are employed in…pharmacies where a large portion of herbal remedies … are sold … pharmacists have an ethical responsibility to the public to be as knowledgeable about herbal products …, as they would for any other conventional medicinal product (pg. 416).” Clauson et al. note, “[t]here is an educational gap of natural product knowledge that needs to be filled now for both future and practicing pharmacists if we are to offer optimal pharmaceutical care for all patients. Our results provide support for the addition or expansion of natural product education elements to existing pharmacy school curricula and for
the development of continuing education modules in the area of natural products (pg. 307).”

Shields et al. add, “[f]ailure to educate future practitioners about natural products does a great
disservice to patients and misses an opportunity for pharmacists to reclaim their niche as experts
in this area (pg. 47).” Shah et al. recommend, “…pharmacy associations should establish
guidelines for herbal education in pharmacy curricula, pharmacy schools should work towards
developing a structured approach to teaching about herbal supplements (pg.1).”

Evans and Evans state that their promising results seem to suggest materials similar to those offered in their
required course be mandatory in all PharmD curriculums and advocate wide-spread adaptation.

Lack of consistent natural product curriculum and pharmacy students’ perceptions that
their own knowledge regarding natural products is not sufficient based on the lack of formal
education on this topic is a key indicator for the need for NHP-related competencies and wide-
spread acceptance would ensure a minimum level of knowledge for all students regardless of the
specific institution they attend.

2.5.3 Pharmacy Students’ Natural Product Knowledge

The following section examines studies conducted in Canada and the United States in the
last decade that have tried to quantify pharmacy students’ as well as practicing pharmacists’
natural product knowledge. In Canada and the United States, both practicing pharmacists
and pharmacy students did poorly on objective tests, with the average test scores generally being
described as low in all three examples discussed.

In 2008 Johnson et al. conducted a study to determine fourth-year Canadian pharmacy
students’ knowledge of herbal medicine (at the end of their formal education), and whether that
knowledge was associated with mandatory instruction in herbal medicine. Standardized
multiple-choice tests were used to assess student’s herbal knowledge of the safety and efficacy of
common herbal products at five (of a total of nine existing at the time) pharmacy schools in
Canada. The overall mean test score across all five pharmacy schools was 65.9%. Higher test scores were positively associated with having previously taken a herbal medicine class. Overall, the scores were lower than the cumulative yearly grade averages. Johnson concludes that, “[p]harmacy students knowledge of herbal medicine varies depending on the school attended and higher herbal knowledge test scores appear to be most closely related to mandatory herbal instruction.”

A study by Chang et al. in 2000 of practicing pharmacists in Virginia and North Carolina (n=164) showed that the average score on a 15 item herbal medication knowledge test assessing the uses, adverse drug effects, and cautions (including drug interactions, precautions, and contraindications) of five herbal medications (four of which were among the top selling medications that year) was 6.3/15. While test scores were generally low, pharmacists were more likely to answer correctly about the uses of herbal medications than about adverse effects and cautions. Higher test scores were associated with prior continuing education, and the availability of herbal medication information sources at the pharmacist’s practice site. Surveyed pharmacists however, agreed that herbal medications should only be sold in pharmacies, providing herbal medication is a pharmacists’ responsibility and continuing education on herbal medications should be mandatory.

In 2001, Mackowiak et al. examined the extent of use and knowledge of herbal drugs by pharmacy students and used the data collected to revise an existing core course in non-prescription drugs to include basic information about herbal products. A convenience sample of students at Temple University (n=370) in Philadelphia, Pennsylvania completed a survey on the appropriate use of twelve popular herbal products. The average score was 32%, while individual results ranged from 0-92% and were affected by ethnicity, work experience, family tradition, and sources of information. Except for students who did personal research on herbal
remedies, all students’ mean scores were less than 50%. \textsuperscript{52} Mackowiak et al. conclude that their data demonstrates a need for herbal instruction in core curricula, “if students are expected to provide comprehensive pharmaceutical care in the area of self-care for their patients (pg.1).” \textsuperscript{52} They recommend that colleges of pharmacy include formal instruction on herbal products, and that such instruction should be included in an existing course or a separate course but it should not remain an elective option. \textsuperscript{52}

In summary, pharmacy students and practicing pharmacists alike in both Canada and the United States scored poorly on objective tests assessing their natural product knowledge. While the Chang et al. (2000) and Mackowiak et al. (2001) studies are almost ten years old, they are still commonly cited articles because they provide an actual test of natural product knowledge (as compared to perceived or self-reported knowledge). Johnson contends that her results demonstrate that graduates of some pharmacy schools have very little knowledge of NHPs, \textsuperscript{17} and Mackowiak confirms that pharmacy students’ formal education is not adequately preparing them to face questions about NHPs in daily practice. \textsuperscript{52} Chang argues that higher test scores by those with continuing education demonstrates the effectiveness of continuing education and the necessity of appropriate resources for pharmacists to access. \textsuperscript{29} Low test scores in all examples demonstrate just how little North American pharmacists really know as a result of their formal education about natural products. Formal education on the topics of NHPs must be brought in line with consumer expectations and professional responsibilities.

\textbf{2.6 Summary of Literature Review}

This chapter examined why it has become necessary for pharmacists to include NHPs in their professional scope of practice given the current policy environment in Canada, consumer usage trends, accreditation and licensure based on competence, and the educational issues that are preventing pharmacists from fulfilling their NHP-related professional responsibilities. It
presents an argument as to why the development of core NHP-related competencies that may better prepare pharmacists to fulfill their obligation to the Canadian public regarding the safe and effective use of NHPs are the focus of this study. In general, it appears that pharmacists do have NHP-related professional roles and responsibilities. Pharmacists agree about their need for additional training on NHPs especially in the areas of interactions, side effects/adverse events, patient counselling, therapeutic uses and dosing. However, as discussed, formal education does not match required professional responsibilities with respect to NHPs. A focus on incorporating more NHP-specific education into pharmacy curriculum will help to ensure that students will pass licensing examinations and ultimately enable pharmacists to fulfill their NHP-related professional responsibilities. Thus, it is imperative that NHP-related core competencies for pharmacy students be developed as a first step to bridging the gap between pharmacy education and the demands of daily pharmacy practice.11

2.7 References


Chapter 3
Methodology
3.0 Introduction

This chapter examines the specific methodology used to complete this study. This chapter will be arranged as follows: i) study design – the Delphi method, ii) study participants and recruitment, iii) the test instrument, iv) data collection, v) data analysis, vi) strengths and limitations of the study design, and vii) ethical issues. This project was approved by the University of Toronto Office of Research Ethics (Appendix 27 and 28).

3.1 Study Design – The Delphi Method

Our technique for achieving consensus was the use of a modified Delphi method. The Delphi method is a group facilitation technique that is used to obtain consensus on the opinions of “informed individuals” or “experts” (participants) through a series of structured questionnaires (or rounds). The questionnaires are completed anonymously by the participants and the responses from each round are fed back in summarized form to the participants. The Delphi method is therefore an iterative multi-stage process designed to combine opinion into group consensus. While the classic Delphi technique consisted of four rounds, more recent evidence suggests either two or three rounds are likely sufficient to reach consensus.

There are four features which characterize the Delphi method and distinguish it from other group decision making processes: i) anonymity, ii) iteration with controlled feedback, iii) statistical group response, and iv) expert input. Our Delphi method was considered to be “modified” for two reasons: i) traditionally the Delphi technique has been paper based, however, the use of electronic communication (i.e., email) is being used more frequently, which is the technique we employed, and ii) our participants were physically brought together, and were therefore known to each other. While the identities of our participants were not anonymous, their individual responses from each Delphi round (e.g., how each person answered during each
Delphi round) were kept anonymous. When one knows the participants of a Delphi method but not their individual responses, this is referred to as “quasi-anonymity” within the technique.¹,⁴,⁵

We used a modified Delphi method as we knew that physically bringing our participants together would allow for dialogue between Delphi rounds that would be potentially beneficial in leading us to consensus as views and opinions could be more easily expressed, thus allowing the opportunity for participants to change their opinions between Delphi rounds.¹ Bringing participants together for two of the four Delphi rounds also mitigated the common problems associated with traditional Delphi methods regarding the time commitment required by participants¹ (i.e., if all rounds were conducted using email, it takes time to not only complete each round but to complete all rounds which may take a period of months), and the tendency towards poor response rates in later rounds.² A consensus meeting has been used successfully in the literature during later rounds of a Delphi method to speed up the process of consensus.⁶

### 3.1.1 Uses of the Delphi Method

The name “Delphi” was initially used to characterize a research technique developed in the 1950s for the Rand Corporation in California as a means of predicting future trends in defense technology ⁷ and military strategic planning,⁸ in an attempt to eliminate interpersonal interactions in decision-making during the Cold War era.⁴ The technique was valued for its potential in avoiding some of the problems associated with group dynamics in unstructured, direct interactions, and was intended for use as a judgment tool or procedure involving a panel of anonymous experts to whom intensive questionnaires and feedback were given to obtain consensus on a particular topic.⁹

Since its origins in military strategy, the Delphi method has been described in a range of situations.⁸ The Delphi approach has been commonly adopted in medical, nursing and health services research,¹ and is noted for its ability to make effective decisions in situations where
there is contradictory or insufficient information.\textsuperscript{1} The Delphi’s popularity in health care research is largely because of its versatility in the collection and assimilation of data and its effectiveness in determining direction and development in practice and policy.\textsuperscript{4} Health researchers utilizing the Delphi have done so successfully in areas relating to: education (including the development of educational competencies and curriculum documents), practice, research and management.\textsuperscript{6,8} Several Delphis have been conducted within the field of complementary and alternative medicine (CAM) related to: developing educational standards, establishing CAM service provision, comparing views on different CAM therapies, and in setting general standards of clinical governance for CAM in primary care.\textsuperscript{10}

\textbf{3.2 Study Participants and Recruitment}

\textbf{3.2.1 Study Participants}

One faculty member from each of the ten Canadian pharmacy schools was invited to participate in this project (n=8). These individuals were primarily professors/instructors currently responsible for teaching NHP content at their respective institutions. Many were general therapeutics instructors who have developed a niche in the area of NHPs and some continue to practise pharmacy. In addition, we invited representatives from three American pharmacy schools who were identified because they had published about pharmacy dietary supplement (DS) education in the last decade (n=3), and representatives from as many Canadian pharmacy organizations as we could identify that were involved in developing or implementing NHP-related or educational policies in Canada (n=6), two of whom were pharmacy students. The total number of participants in the study was seventeen (n=17). A list of study participants and their affiliations is provided in Chapter 4 – Results (4.6 Acknowledgements).
3.3.2 Participant Recruitment

Generally, these participants were recruited using purposive sampling, in which the researchers’ knowledge about the population can be used to handpick participants who are thought to be the most likely to have the knowledge and skills appropriate to address the issue under investigation. This sampling technique is commonly used in the Delphi method. Specifically, participants were recruited through the vast contact networks of the research supervisor, suggestions from thesis advisory committee members, and recommendations from within each school or organization of an appropriate representative.

Representatives from Canadian pharmacy schools were identified through previous collaboration with the research supervisor or members of the thesis advisory committee because they were known to teach NHP-related material at their respective institutions. In cases when an appropriate individual was not known at a particular school of pharmacy, internet searches of school websites and in some cases emails to Deans or other known faculty members asking for suggestions of an appropriate individual who could best represent their schools occurred. Four participants had been involved with the data collection (i.e., focus groups of consumers and practicing pharmacists) from earlier stages of this program of research.

Representatives from American pharmacy schools were identified through literature searches, from previous collaboration with the research supervisor or thesis advisory members, and/or because they attended a round table discussion on teaching pharmacy students about NHPs/DS at the joint annual meeting of the American Association of Colleges of Pharmacy (AACP) and the Association of the Faculties of Pharmacy of Canada (AFPC) in July 2008.

Representatives from pharmacy organizations were identified by initially contacting a leader in the organization (usually the President or Executive Director) and asking them to
recommend an individual involved in developing or implementing practice, NHP-related or educational policies in Canada to represent their organization in this study.

All contact with potential participants was conducted via email. After identification of potential study participants was completed and ethics approval was obtained, emails were sent to potential participants beginning at the end of July 2008, inviting them to attend (or in the case of the pharmacy organization to identify an appropriate individual to contact) the invitational consensus building meeting. Included with the emails of invitation were registration forms which participants were asked to submit by September 30, 2008. The original invitation/identification and information emails were followed up with reminder emails; approximately every two weeks following initial contact, until the registration deadline of September 30, 2008, up to a maximum of four additional contacts. Email contact was limited to a maximum of five instances. Failure to respond to five contacts constituted refusal to participate.

Numerous efforts were made to ensure full participation from all identified key informants including: early notice of the meeting, offering to reimburse travel and accommodation expenses of one representative from each school and/or organization, scheduling the meeting immediately before a research symposium on the topic of CAM of which NHPs are an integral part, and inviting other individuals if first choices were unable to attend.

Appendices 1 through 9 chronicle the aforementioned recruitment process.

3. 3 The Test Instrument

3.3.1 The Delphi Questionnaire

The 1st Delphi round questionnaire was developed from N. Shanthakumar’s survey of 3356 practicing Canadian pharmacists, which focused on answering the question, “what do Canadian pharmacists perceive to be the scope of their responsibilities with respect to natural health products (NHPs)” Preliminary results of Shanthakumar’s survey indicated that
Canadian pharmacists identified several key roles and responsibilities related to NHPs as being part of their professional scope of practice. These roles and responsibilities were re-written into statements appropriate to our Delphi study and were broadly organized in the categories of attitudes, knowledge and skills toward NHPs. Attitudes, knowledge and skills are three of the major categories in the taxonomy of educational objectives commonly used in the educational outcomes literature to demonstrate competence.\textsuperscript{13, 14} After input from the thesis advisory committee, the statements were edited to better reflect the six major categories in the taxonomy of educational outcomes proposed by Bloom,\textsuperscript{13, 14} and the language, formatting and design of standards of practice documents (NAPRA) and competency-based educational outcomes documents (AFPC and CCAPP) discussed in Chapter 2 – Literature Review.\textsuperscript{15-18}

Study participants were asked to rank their level of agreement with the Delphi statements using a 5-point Likert scale (Figure 1). A Likert scale is a type of psychometric response scale that is an established method of attitudinal measurement in Delphi studies.\textsuperscript{4, 19} The typical test item is a statement, the respondent is asked to indicate his/her degree of agreement with the statement or any kind of subjective or objective evaluation of the statement.

The literature demonstrates that Likert scales can vary between 3-11 points. A recent study showed that data from 5, 7, and 10 point scales had very similar characteristics in terms of mean, variance, skewness, and kurtosis, suggesting that anyone of these scales render the desired result of gauging opinions.\textsuperscript{20} Additionally, studies of Likert scales have shown that reliability and validity are improved with scales with fewer points (either 5 or 7-point Likert scales).\textsuperscript{20} Another key argument related to the use of a 5-point Likert scale is whether the “mid-point” (3 on our scale) represents “half” (or 50% agreement) or a neutral position (i.e., no opinion).

Our Likert scale was developed from a needs assessment scale in which the five response categories were shown to be mutually exclusive and collectively exhaustive.\textsuperscript{3} Headings for each
of the five response categories of our Likert scale were edited to reflect our purpose of developing core competencies, and were reviewed, edited and approved by the thesis advisory committee. Ultimately, we chose a 5-point scale because it provided the simplest way to separate true and relatively strong agreement from either “luke warm” acceptance of the competency statement or true disagreement. The authors of the original scale justified the use of a mid-point because they felt that all responses required judgements to be made about the relative importance of the statement being assessed. They did not believe the mid-point represented no opinion. This argument applied to our situation as well. Our purpose was to create core competencies based only upon the items where there was strong agreement with the competency statements from our participants. In our case, the mid-point served as a line demarking the point at which agreement became strong enough to warrant identification of a statement as a core competency.

3.3.2 Piloting the Test Instrument

The Delphi questionnaire was piloted at the joint annual meeting of the American Association of Colleges of Pharmacy (AACP) and the Association of the Faculties of Pharmacy of Canada (AFPC) in Chicago, Illinois in July 2008, primarily by interested faculty members of American pharmacy schools (n=10) during a round table discussion session. Feedback from pilot participants helped to further clarify the 1st Delphi round questionnaire (i.e., to eliminate redundancies, and clarify the language of the statements) and reinforced the appropriateness of the headings of our 5-point Likert scale.

After this extensive process of developing both the Delphi questionnaire and the Likert scale, the statements used in the 1st Delphi round questionnaire (Appendix 16) were solidified. Finally, the online version of the 1st Delphi round, using Survey Monkey - an internet based survey generating program, was piloted by the thesis advisory committee to ensure the proper functioning of the technology as well as to complete a final check of the Delphi statements.
themselves before sending them to participants. Survey Monkey, was used to complete all Delphi rounds.

3.4 Data Collection

Data collection occurred at three distinct times: i) pre-invitational consensus building meeting, ii) at the invitational consensus building meeting, and iii) post-invitational consensus building meeting. Between each round, participants were provided with reports summarizing the results of the previous round (see section 3.5 Data Analysis for details).

3.4.1 Pre-Invitational Consensus Building Meeting

Study participants were given a limited number of readings summarizing previous research in order to provide adequate context for the study (Appendix 10). The 1st Delphi round took place via email using Survey Monkey in October 2008 and consisted of six competency statements and three supplementary questions (Appendix 16). During all Delphi rounds, participants were encouraged to add any competencies they felt were missing, amend wording or provide justification for their responses to all questions. Refer to Appendices 16, 18, 20 and 23 for the questionnaires of all four Delphi rounds.

3.4.2 Invitational Consensus Building Meeting

The 2nd Delphi round was conducted on the first day of the invitational consensus building meeting (Thursday November 6, 2008), again using Survey Monkey. The 2nd Delphi round was preceded by a general introduction to pharmacy education in Canada as well as presentations on previous qualitative research that included: 35 key informant interviews; 16 focus groups with practicing pharmacists and consumer; results from herbal knowledge testing of 4th year Canadian pharmacy students; and results from a survey of 3356 practicing Canadian pharmacists. These presentations were intended to provide participants with relevant information not only from this particular study, but also from the wider perspectives of this topic.
to better inform our participants while conducting the Delphi rounds deciding on the core NHP-related competencies. (Appendix 14 details the final agenda for the two-day invitational consensus building meeting). The 2\textsuperscript{nd} Delphi round contained eight competency statements to be ranked using the Likert scale and three supplementary questions (Appendix 18).

The 3\textsuperscript{rd} Delphi round was held on the second day of the invitational consensus building meeting (Friday November 7, 2008) and was preceded by presentations by participants representing both Canadian and American pharmacy schools who shared current practices at their respective schools, and a group discussion of participants (n=16) detailing the Delphi process thus far, clarifying terms and misconceptions arising from the participants’ qualitative comments during the first two Delphi rounds, and describing what we hoped to achieve in the coming day. The 3\textsuperscript{rd} Delphi round contained five competency statements to be ranked using the Likert scale and two supplementary questions (Appendix 20).

\textit{3.4.3 Post-invitational Consensus Building Meeting}

During the second week of November (five days after the end of the invitational consensus building meeting), all study participants were emailed anonymous summary results of the 3\textsuperscript{rd} Delphi round along with a link to the 4\textsuperscript{th} Delphi round and were asked to complete the questionnaire within a week (Appendix 22). The 4\textsuperscript{th} Delphi round contained all the same questions as the 3\textsuperscript{rd} Delphi round. The Likert scale was removed from two competency statements, as consensus had been achieved on these two statements since the 1\textsuperscript{st} Delphi round. However, participants were still encouraged to make comments regarding final wording in the comment box provided. Titles were added to each competency statement to be consistent with the format of competency statements utilized by NAPRA.\textsuperscript{16}
Four Delphi rounds were completed in total by all participants (n=17) during the course of data collection. To view the questionnaires and summaries from all four Delphi rounds refer to Appendices 16 through 24.

3.5 Data Analysis

Data analysis occurred simultaneously with data collection. The results (both qualitative and quantitative) of each of the four total Delphi rounds were reviewed, and written summaries, including number of responses and percentage, mode, range and mean for each Delphi statement, and all qualitative comments were provided (anonymously) to all participants between each Delphi round. Refer to Appendices 17, 19, 21 and 24 for summary results of all Delphi rounds.

Upon completion of the 4th Delphi round, all participants were sent a summary report (Appendix 25) identifying the final consensus based core competencies and were asked to provide approval and indicate if they wished for their names and affiliations to appear on the final report (Appendix 26).

3.5.1 Measurement of Consensus

When using the Delphi method, consideration must be given to the level of consensus to be employed. A universally agreed upon proportion does not exist for the Delphi, as the level used depends on sample numbers, aim of the research and resources. Moore’s work suggests that consensus should be equated with 51% agreement amongst respondents; Sumsion recommends 70%, while Green et al. opted for 80%. Williams and Webb define consensus as 100% agreement. In most studies, consensus levels have varied anywhere between 51% and 80%. Alternatively, some authors question the value of using percentage measures, suggesting that the stability of the response through a series of rounds is a more reliable indicator of consensus. Others base the definition of consensus on unanimity—unanimity minus one, unanimity minus two, unanimity minus three, or rough consensus. It is generally suggested that
a predetermined level of consensus can ensure rigor in the technique, preventing researcher subjectivity. However, many researchers do not attempt to set a level of consensus prior to the enquiry and instead make a decision after the data have been analyzed, this allows the data to dictate the level of participant agreement rather than making a judgment beforehand which may not be in line with the results of participants ranking, and also speaks to the importance of the stability of responses over the course of Delphi rounds. Our definition of consensus was developed through an iterative process during the Delphi rounds, as we believed that setting a cut-off for consensus prior to conducting the Delphi rounds may have negatively influenced our participants in their rankings (i.e, they may have focused on whether they were ranking a statement “in” or “out” of the core competency list rather than focusing on the Likert scale item labels). We also began to see a trend in the stability of responses as it became clear very early on in the process that certain competency statements were going to become core competencies (i.e. we achieved consensus during the 1st Delphi round and kept this consensus in subsequent rounds despite changes in wording). Ultimately, statements that had an average mean of >3 were continued onto the next Delphi round (participants were informed of this in the written summary of the 1st Delphi round – Appendix 17). Consensus was defined to have been reached when all participants ranked a given statement 4 (very important) or 5 (essential). Participants were informed of this definition of consensus in the written summary of the 2nd Delphi round (Appendix 19) and it was discussed during the group discussion on Friday November 7 prior to the 3rd and 4th Delphi rounds.

3.6 Strengths and Limitations of the Study Design

3.6.1 Strengths

The Delphi method is said to have many advantages, including: i) the avoidance of unnecessary side-tracking for the panellists and unnecessary analysis for the researcher, ii) a
strong claim to validity as nature and content of study are dictated by the panelists, iii) flexibility which allows considerable diversity in its application, iv) providing consensus of “expert” opinion without the bias that can occur in comparable techniques, v) the avoidance of the potentially destructive group dynamics of other techniques, vi) it is effective compared with personal interviews or committee meetings, and has the ability to guide a group towards consensus and a final decision, and vii) it is novel, interesting and motivating for participants and has the ability to obtain large quantities of information.

Specifically, our Delphi method has a strong claim to validity because it was based on the opinions of our “informed individuals” (participants), who are actively involved in the fields of NHP education and policy-making as well as the many key informants who participated in previous aspects of the project. It was flexible in that we used both remote (email) rounds and rounds at the invitational consensus building meeting. Ultimately we were successful in reaching consensus, and thus the method was effective. Based on the feedback received from our participants, they enjoyed the process and were pleased to see something tangible (the summary report) come from the method. The Delphi technique is becoming an increasingly popular method in health and social research, as when it is used correctly and rigorously, the Delphi can contribute significantly to broadening knowledge. Because of the Delphi’s usefulness in determining curriculum content, and developing educational standards, especially within the field of CAM, and its significant methodological advantages we believe it was well suited to our research objectives.

3.6.2 Limitations

The major limitations of the Delphi method can be summarized as criticisms relating to its lack of methodological rigour. However, it is recognized that regardless of how the method is used, a high degree of methodological precision is required on the part of the investigators. To
this end, we were diligent in following those guidelines that do exist for the Delphi method, documenting where our methodology diverges from those guidelines, and reporting what happened between Delphi rounds. We are confident in our choice to use the Delphi method to achieve consensus based on the method’s success within the field of CAM in developing educational standards, establishing CAM service provision, comparing views on different CAM therapies, and in setting general standards of clinical governance for CAM in primary care.¹⁰

The success of the Delphi method is contingent upon the type of statements that are circulated (both the wording of our questionnaire and Likert scale) and how the definition of consensus is interpreted.¹⁰ As detailed above, our Delphi questionnaire statements went through a rigorous process of development and review, and we are confident that they reflect the language and format used by NAPRA and the AFPC in their existing competency-based standards of practice and educational outcomes documents.¹⁵-¹⁷ Additionally, our definition of consensus was developed through an iterative process during Delphi rounds which better reflected our participants’ actual ranking of the competency statements.

Critiques of the Likert scale suggest that it is subject to distortion from several causes as respondents may: avoid using extreme response categories (central tendency bias), agree with statements as presented (acquiescence bias), try to portray themselves or their organizations in a more favourable light (social desirability bias), and distortions may be caused by the framing effect (an interaction between the wording of the question and that of the answers offered).¹⁹ To mitigate these concerns, we based our Likert scale on one that was previously validated³ to try to avoid the framing effect. We were sure to include all qualitative comments made during all Delphi rounds on summary reports (hoping to avoid the social desirability bias), and encouraged our participants to make comments, which they did (thus, avoiding the acquiescence bias). Finally, by giving clear instruction stressing the importance of appropriately ranking a statement
based on the level of agreement (either 4 – very important, or 5 – essential when in agreement or 1 – unimportant, or 2 – not important as a core competency, when not in agreement), we sought to avoid the central tendency bias. Most importantly, the responses of all participants during all Delphi rounds were kept anonymous through the use of Survey Monkey as is detailed in the next section.

3.7 Ethical Issues

This study involved very low risk to the participants since no invasive procedures or active interventions were involved. A proposal was submitted to the University of Toronto Office of Research Ethics on June 24, 2008 to ensure compliance with University research guidelines and approval was granted on July 8, 2008 (Appendix 27). Minor amendments related to the wording of the 1st Delphi round questionnaire of the original protocol were submitted on August 21, 2008 and were approved September 10, 2008 (Appendix 28). The key ethical issues relevant to this study were: confidentiality, the right to withdraw, and anonymity.

3.7.1 Confidentiality and the Right to Withdraw

Participants were informed that their participation in the consensus building process was voluntary and confidential through a Letter of Information (Appendix 3 or 4). Since we were attempting to create core competencies that we hope will be implemented at the Faculties of Pharmacy and pharmacy organizations across Canada, we wanted to be able to properly acknowledge the efforts of our contributors. As such, we included a consent form asking for each participant’s written consent to be included in a published list of the participants name and affiliations (Appendix 6). Additionally, in recognition that all parties may not be in total agreement with the core NHP-related competencies developed from the invitational consensus building meeting, participants were informed of their right to withdraw their name and affiliations from being published in our final report after having an opportunity to review the
final draft of the report within 14 days of receiving the draft simply via correspondence with the investigators (Appendix 25).

3.7.2 Anonymity

The final ethical consideration is anonymity. As participants were physically brought together for the invitational consensus building meeting, and therefore were known to each other, their identities were not anonymous, hence the use of a “modified” Delphi method. However, individual responses from each of the Delphi rounds (e.g., how each person answered the questionnaires) were kept anonymous through the use of an internet based survey generating program – SurveyMonkey.21 When one knows the participants but not their individual responses, this is referred to as “quasi-anonymity” within the Delphi method.1, 4, 5 Hard data (participant registration and consent forms) are stored in a locked filing cabinet in the student office of the research supervisor. Aggregate data files from the survey rounds of the Delphi are stored in an anonymized data base and will be kept for five years upon study completion and then destroyed.

3.8 Summary

This study used a modified Delphi method which culminated at an invitational consensus building meeting held in Toronto, Ontario, Canada on November 6 and 7, 2008. The goal was to develop core NHP-related competencies, consistent with existing competency-based educational outcomes and standards of practice documents 15-17 informed by previous qualitative research,11, 22, 24, 26, 27 and the opinions of our “expert” Delphi participants which consisted of pharmacy educators who currently teach NHP content from Canadian and American schools of pharmacy and representatives from Canadian pharmacy organizations interested in policy-making related to NHPs. Four Delphi rounds were necessary to reach consensus on selected NHP-related core competencies, which was defined through an iterative process to have been reached when all participants ranked a given statement 4 (very important) or 5 (essential).
3.9 References


Chapter 4
Results
This chapter describes the key findings that emerged from data collection/analysis. It is written as a paper to be submitted to the American Journal of Pharmaceutical Education.

Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies

4.0 Abstract

Objective: To reach consensus on entry-to-practice core natural health product (NHP)-related competency statements for Canadian pharmacy students.

Methods: Four rounds of a modified Delphi method were used to achieve consensus. Selected pharmacy educators from Canada and the United States, and representatives from Canadian pharmacy organizations (n=17) ranked their agreement, using a 5-point Likert scale, with competency statements derived from qualitative interviews with 35 key informants, 16 focus groups of Canadian pharmacists and consumers, and a survey of 3356 licensed Canadian pharmacists.

Results: Consensus was defined as occurring when all participants ranked a given competency statement 4 (very important) or 5 (essential). Consensus was achieved on 3 core NHP-related competency statements.

Conclusions: Canadian pharmacists need to be knowledgeable in the area of NHPs and if the 3 core NHP-related competency statements agreed upon are widely implemented, newly graduating Canadian pharmacists will be able to fulfill their professional responsibilities related to NHPs.

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4.1 Introduction

Pharmacists have a key role to play with respect to natural health products (NHPs), such as herbal medicines and vitamins according to Canadian consumers, pharmacy regulatory bodies, professional pharmacy associations, pharmacy examining boards, and pharmacists themselves. Previous research indicates that a range of stakeholders (including consumers, pharmacists, and other health care providers) believe that pharmacists have a key role to play in providing consumers with guidance regarding safe use of NHPs. The Natural Health Products Regulations (2004) legally categorize NHPs as “drugs” at the level of the Food and Drugs Act and thus technically make NHPs part of pharmacists’ scope of practice. Additionally, pharmacy regulatory authorities across Canada are establishing NHP-related standards of practice and policy guidelines amidst increased consumer usage. However, many pharmacists appear to have little knowledge of NHPs, as curricular content pertaining to NHPs varies widely across North America.

While pharmacists’ are increasingly being identified as important sources of information on NHPs and perhaps the health care practitioners most suitable to counsel consumers about NHPs, this role appears to be at odds with their actual education in the area of NHPs. The research described in this paper will attempt to bridge the gap between Canadian pharmacists’ formal education and their NHP-related professional responsibilities through identifying core NHP-related competencies that pharmacy educators and representatives from pharmacy organizations agree are important for pharmacy students to have when entering pharmacy practice in Canada. Incorporation of more NHP-specific education in the professional pharmacy program curriculum will help to enable pharmacists to fulfill their professional responsibilities with regards to NHPs.
4.1.1 Background

The goal of this study was to develop core NHP-related competencies for Canadian pharmacy students upon entry to practice in Canada using a modified Delphi method to achieve consensus on the competency statements. Thus, it is important to discuss the definition of NHPs and what is known about current NHP-related pharmacy policies to provide some context to the concept of core competencies.

For the purposes of this study, NHPs were defined according to Health Canada’s NHP Regulations (2004) as any substance found in nature:

...that is manufactured, sold or represented for use in: (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in 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 (p.42).22

By definition, NHPs must be suitable for self care and/or over-the-counter (OTC) use.9

In 2005, the Baseline NHP Survey found that 71% of Canadians have used a NHP at least once in their lifetime.23 Of this 71%, 1/3 reported that they use a NHP on a daily basis.5, 11, 23 Consumers appear to prefer buying NHPs/dietary supplements (DS) in pharmacies compared with other locations.24 A survey by the Non-prescription Drug Manufacturers Association of Canada (NDMAC) in 2000 found that 60% of consumers who buy herbal products purchase them in a pharmacy.25 Similarly, in the United States, half of the adults polled (n=1000) in a phone survey conducted for Reader’s Digest, preferred to shop for alternative health care products in a pharmacy.26

When patients seek expert advice in relation to NHPs, they view pharmacists as trustworthy and knowledgeable sources of information.5, 23 Additionally, the majority of consumers agree that pharmacists should be knowledgeable about NHPs and feel that
pharmacists should be able to help them manage drug-NHP interactions as well as identify and assess the range of information available to help consumers make informed decisions with regards to NHPs.1

4.1.2 Pharmacists’ and NHPs

As pharmacists are increasingly viewed as “front line” providers of information regarding the safety and efficacy of NHPs,16 regulatory associations in Canada and the United States have created specific policies for these products. The American College of Clinical Pharmacy (ACCP), the American Society of Health-System Pharmacists (ASHP), and the Canadian Society of Hospital Pharmacists (CSHP) have recommended that the profession of pharmacy actively embrace NHPs/DS as part of the pharmacist’s scope of practice.5, 27-29 The ACCP White Paper on Herbal Products argues that, “the basis for pharmacists’ involvement with herbal products is an extension of their established roles in pharmaceutical care...(p.883).”28 Since pharmaceutical care is defined as to, “accept responsibility for optimizing all of a patient’s drug therapy, regardless of source (prescription, non-prescription, alternative, or traditional medicines), to achieve better patient outcomes and to improve the quality of each patient’s life (pg.2-3),”30 it can be argued that there are expectations for pharmacists to have knowledge regarding NHPs, and yet the majority of pharmacists report feeling ill-equipped to meet these expectations.5

In Canada, pharmacy is a self-regulating profession, and each jurisdiction (province or territory) has a statute that sets out the scope and standards of practice for pharmacists.14 The majority of Canadian jurisdictions now include some explicit reference to NHPs.14 Also of importance is the message that Canadian regulatory bodies and associations are sending to patients, as they are increasingly advertising the role of pharmacists in advising patients about NHPs and state that pharmacists are “experts” in this area.14
Despite the pressure on pharmacists to take on a NHP-related professional role, research demonstrates that pharmacists are not equipped by their formal education to meet standards of practice guidelines or consumer expectations related to NHPs. In theory, training in pathophysiology, pharmacology and critical appraisal should provide pharmacists with the necessary background to interpret and evaluate scientific information about NHPs, and should place them in a position to determine if a NHP is a safe and appropriate option. However, there exists substantial diversity in the extent of NHP education at schools of pharmacy. While content is increasingly presented in a formalized manner, it is often as an elective (as compared to a mandatory) course offered during the final years of schooling, and thus it is up to the individual student if they choose to take the course or not. Research from both Canada and the United States regarding pharmacists’ NHP education reveals that there is an obvious lack of formal instruction regarding these products, as demonstrated with low test scores related specifically to NHP content, inconsistent curricula, proof that more training in NHPs resulted in higher test scores, and the repeated request of the need for mandatory teaching of this subject matter instead of elective options. Pharmacists themselves do not feel their knowledge of NHPs is adequate to make recommendations regarding use. A recent Canadian example of these educational trends is Johnson et al.’s 2008 study of 4th year pharmacy students’ knowledge of herbal medicine at five Canadian institutions. The overall mean test score was 65.9% which was lower than the overall yearly grade averages. Higher test scores appear to be most closely related to mandatory herbal instruction and were positively associated with having previously taken an herbal medicine class and completion of a pharmacy practicum.

However, both Canadian and American pharmacists are expected to know certain information about NHPs to become licensed. The Pharmacy Examining Board of Canada
(PEBC), the national certification body of Canadian pharmacists, currently recommends that students planning to write the Qualifying Examination or the Evaluating Examination (for foreign trained students) familiarize themselves on the subject of therapeutic considerations concerning alternative treatments, the category to which NHPs belong. In 2005, the North American Pharmacists Licensure Examination (NAPLEX) added a competency specifically addressing knowledge of dietary supplements (DS) (as NHPs are referred to in the United States). Also in the United States, in 2005, the Accreditation Council for Pharmacy Education (ACPE) Standards for Accreditation recommended instructive course work that focuses on patient use of DS, complementary and alternative medicine (CAM) treatments, safety/efficacy of CAM, and drug-herb interactions. Clearly, it is imperative that pharmacists’ formal education be in line with licensing requirements.

Core competencies are defined by the National Association of Pharmacy Regulatory Authorities (NAPRA) as, “significant job related knowledge, skills, attitudes, and/or judgments required for competent performance by members of the profession (p.16).” They define what is minimally required of pharmacists at the point of licensure in Canada, and are often created through extensive consultative processes, including deliberation, and ideally consensus. The NHP competencies identified in the project would represent a minimum level of professional competence related specifically to NHPs that would be required of Canadian pharmacists at entry-to-practice.

4.2 Methods

This study used a modified Delphi method which culminated at an invitational consensus building meeting held in Toronto, Ontario, Canada on November 6 and 7, 2008. The goal was to develop core NHP-related competencies, consistent with existing competency-based outcomes
and standards of practice documents, informed by previous qualitative research that included: a document analysis; 35 key informant interviews; 16 focus groups with practicing pharmacists and consumers; results from herbal knowledge testing of 4th year Canadian pharmacy students; and results from a survey of 3356 practicing Canadian pharmacists. The final step was to have “informed individuals” or “experts,” (e.g., those who are actively involved in teaching NHP content or setting/enforcing NHP-related pharmacy policies) make the final decision regarding core NHP-related competencies using an online questionnaire that asked the participants to rank their level of agreement with a statement being a core competency, using a 5-point Likert scale. This project was approved by the University of Toronto Office of Research Ethics.

4.2.1 The Test Instrument – the Delphi Method

Our technique for achieving consensus was the Delphi method, a group facilitation technique that seeks to obtain consensus on the opinions of “informed individuals” or “experts” (participants) through a series of structured questionnaires (or rounds). The questionnaires are completed anonymously by the participants and the responses from each round are fed back in summarized form to the participants. The Delphi method is therefore an iterative multi-stage process designed to combine opinion into group consensus and commonly consists of four rounds.

There are four features that characterize the Delphi method and distinguish it from other group decision making processes: i) anonymity, ii) iteration with controlled feedback, iii) statistical group response, and iv) expert input. Our Delphi method was considered to be “modified” as traditionally, the Delphi technique has been paper based. Increasingly, the use of electronic communication is employed, and as our participants were physically brought
together, and were therefore known to each other, their identities were not anonymous. However, individual responses from each Delphi round (e.g., how each person answered during each Delphi round) were kept anonymous. When one knows the participants but not their individual responses, this is referred to as “quasi-anonymity” within the Delphi method.38, 41, 42

4.2.2 Study Participants

One faculty member currently responsible for teaching NHP content at each Canadian pharmacy school was invited to participate in this project. In addition, we invited representatives from American pharmacy schools who were identified because they had published about pharmacy dietary supplement education in the last 10 years, and representatives from as many Canadian pharmacy organizations as we could identify that were involved in developing or implementing practice, NHP-related or educational policies in Canada.

4.2.3 Piloting the Test Instrument

The Delphi statements were developed from N. Shanthakumar’s survey of practicing Canadian pharmacists,10 and were edited to reflect the language and format used by NAPRA and the AFPC in their existing standards of practice and competency-based educational outcomes documents.33, 36, 37 The statements were then piloted at the joint annual meeting of the American Association of Colleges of Pharmacy (AACP) and the Association of the Faculties of Pharmacy of Canada (AFPC) Chicago, Illinois in July 2008 (n=10).

4.2.4 Data Collection/Analysis

Study participants (n=17) were asked to rank their level of agreement with the Delphi statements using a 5-point Likert scale (Figure 1). Survey Monkey, an internet based survey generating program,43 was used to complete all 4 Delphi rounds. During all Delphi rounds, participants were encouraged to add any competencies they felt were missing, amend wording or
provide justification for their responses to all statements during all rounds. The results (both qualitative and quantitative) of each Delphi round were analyzed and written anonymous summaries of all rounds, including number of responses and percentage, mode, range and mean, and all qualitative comments were provided to all participants between each Delphi round.

Statements that had a mean of >3 were carried forward to the next Delphi round and consensus was defined through an iterative process to have been reached when all participants ranked a given statement 4 (very important) or 5 (essential). Data collection/analysis occurred at three distinct times: i) pre-invitational consensus building meeting, ii) at the invitational consensus building meeting, and iii) post-invitational consensus building meeting.

Upon completion of the 4th Delphi round, all participants were sent a summary report identifying the final consensus based core competencies and were asked to provide approval and indicate if they wished for their names and affiliations to appear in the final report.

4.3 Results

All 4 Delphi rounds were completed by all study participants (n=17). Study participants included pharmacy educators responsible for NHP curriculum content at their respective institutions as well as academic administrators interested in curriculum development related to NHPs from 7 of 10 Canadian pharmacy schools (n=8), NHP content educators from American pharmacy schools (n=3), and representatives from Canadian pharmacy organizations interested in policies related to NHPs (n=6). A detailed summary of each Delphi round is provided below.

4.3.1 First Delphi Round

After the 1st Delphi round consensus was reached on 2 competency statements and all statements were carried forward to the 2nd Delphi round based on their mean of >3. Participant
feedback suggested the addition of 2 new competency statements as well as changes in wording to the original 6 competency statements.

4.3.2 Second Delphi Round

After the 2\textsuperscript{nd} Delphi round consensus was reached on 3 competency statements. A group discussion was held with study participants between the 2\textsuperscript{nd} and 3\textsuperscript{rd} Delphi rounds (after participants were given the summary results of the 2\textsuperscript{nd} Delphi round) regarding wording of the competency statements, justifications for ranking, and general discussion about core competencies for Canadian pharmacists. Participant comments (both from the 2\textsuperscript{nd} Delphi round summary and discussion) suggested dropping 3 competency statements for the 3\textsuperscript{rd} Delphi round (but incorporating elements of these statements into other competency statements), in other words, reorganizing the statements.

4.3.3 Third Delphi Round

Consensus was reached on 2 of the reorganized competency statements, and consensus was close on an additional 2 statements (e.g., mean \textgreater{}4, but not all participants had ranked these statements 4 - very important or 5 - essential). There was, however, 100\% agreement that no competency statements were missing from the questionnaire.

4.3.4 Fourth Delphi Round

Consensus was reached on 3 core NHP-related competency statements, and an additional 2 statements were close to consensus. Again there was 100\% agreement that no competencies were missing.

Therefore, after 4 Delphi rounds, with 100\% participation by all 17 participants, we concluded that we had consensus on the 3 core NHP-related competencies for Canadian pharmacy students upon entry-to-practice listed in Table 1. Two additional competencies
emerged from the Delphi method, and although consensus was not achieved (all participants ranking a given statement 4 or 5), the mean of both statements was >4. These additional competencies are summarized in Table 2.

4.4 Discussion

Consensus was achieved from the 1st Delphi round on core competency statements broadly related to providing NHP information and education, which became Professional NHP-related Competency statements #2- Provide NHP Information and #3 – Educate (Table 1). It is likely that consensus was achieved early with these statements because similar competency statements already exist in Canadian standards of practice documents for pharmacists relating to drugs (e.g., NAPRA’s Model Standards of Practice for Canadian Pharmacists (2003)). Thus, the idea of extending these competencies to include NHPs was easy for participants to see and endorse.1, 6 Consensus on Professional NHP-related Competency statement #1 – Practice Pharmaceutical Care was achieved after the 2nd Delphi round. Only 1 participant ranked this competency outside our definition of consensus (all participants ranking a statement 4 - very important or 5 - essential) during the 1st Delphi round, so it appears that for those statements on which consensus was possible, it was achieved quite quickly.

The 3 Professional NHP-related Competency statements that emerged from this consensus exercise are consistent with the results of previous research conducted by our research team. Kwan reported that focus groups of consumers and practicing pharmacists concluded that pharmacists should adopt a consultative role to help consumers integrate different sources of information related to NHPs.1 This is represented most prominently in Professional NHP-related Competency #3 – Educate. Additionally, Kwan demonstrated that pharmacists placed great emphasis on ensuring patient safety, especially with regard to potential NHP-drug interactions,1
which is captured in Professional NHP-related Competency #1 – Practice Pharmaceutical Care. Safety was also a key role identified by Olatunde from interviews of a range of stakeholders including: pharmacy leaders, consumer advocates, conventional and complementary health care practitioners, and NHP industry representatives, with respect to pharmacists’ NHP-related responsibilities. A lack of knowledge and reliable information on NHPs were identified as barriers to counseling patients on NHPs, which stresses the importance of creating NHP-related competencies, thus ensuring that all Canadian pharmacists are expected to be knowledgeable about NHPs. Finally, Shanthakumar found that Canadian pharmacists were more likely to endorse professional NHP-related responsibilities related to knowledge including: awareness of indications for use and expected outcomes, access to reliable references, and helping patients identify and access information, than any other types of NHP-related competencies (personal communication, December 2, 2008). These knowledge responsibilities are incorporated into all 3 of our core competency statements.

Consensus was not achieved on Additional Professional NHP-related Competency #4 – Understand NHP Regulations, and Additional Professional NHP-related Competency #5 – Report Suspected NHP Adverse Events (Table 2). These were the statements with the greatest range of responses throughout all 4 Delphi rounds. Previous research has also demonstrated that these topics received mixed reactions and levels of support from the pharmacy profession. For example, Olatunde found that many pharmacy leaders appeared to be unfamiliar with current pharmacy policies and guidelines concerning NHPs, thus our participants may have felt that demanding competency in the areas of understanding regulations and requirements to document and report adverse NHP reactions were not appropriate until education related to NHP content better matches pharmacists’ NHP-related professional responsibilities.
Shanthakumar also found that Canadian pharmacists were least likely to endorse professional responsibilities related to documentation of NHP usage, which included reporting adverse events to Health Canada and recording use in patients’ charts\textsuperscript{44} (personal communication, December 2, 2008). Lack of consensus on this item seems to be related to the existence of two distinct opinions: 1) reporting adverse events related to NHPs is vital and should be a core competency, in contrast to, 2) reporting adverse drug events to Health Canada is not required in current standards of practice documents, so we should not create a precedent by first requiring this for NHPs. Similarly, understanding the regulation of drugs is not identified as a core educational competency, although it is necessary for licensing. Thus, some participants argued that setting a precedent by first requiring this of NHPs was something they were not willing to do. In the end, we were able to incorporate general documentation responsibilities into Professional NHP-related Competency #1 – Practice Pharmaceutical Care in an attempt to bridge the gap on the two perspectives on NHP-related adverse event reporting.

This study, like all others, has limitations. The validity of this study was largely dependent on the active participation of all Canadian pharmacy schools, and pharmacy organizations, thus the constitution of the “expert” panel.\textsuperscript{45} In the end, 7/10 Canadian pharmacy schools were represented; however, there was no representation from either of the two French language pharmacy schools in the province of Quebec. Reasons for not sending a representative to the meeting included: prior commitments, lack of an appropriate individual to represent the institution, and no response to contact by the investigators. Lack of participation from the Quebec schools of pharmacy may have been due to the fact that all correspondence, and the Delphi rounds themselves were to be conducted in English. It is possible that representatives from the Province of Quebec may have had different perspectives on NHP-related core
competencies for pharmacists because a recent Canadian survey found use of NHPs to be seasonal and overall lower than the national average in Quebec compared with the rest of Canada, and curriculum content of NHPs in school of pharmacy varies across the country. However, results of a recent national survey of practising pharmacists’ opinions about NHP-related professional responsibilities suggest that location did not appear to influence practising pharmacists’ thoughts about NHP-related competencies. This suggests that our core NHP-related competency statements may be applicable nationally.

As NHPs represent a wide variety of products we purposely did not limit ourselves to certain categories (eg, vitamins/mineral, herbal medicines or homeopathy), and instead included the official definition of NHPs according to the NHP Regulations (2004) as a preface to our core NHP-related competency statements. However, it is not clear if our core NHP-competency statements are applicable to all categories of NHPs as we cannot know exactly what our participants were thinking about when they read the term “NHPs.” Furthermore, Shanthakumar concluded that generally pharmacists were more likely to endorse professional responsibilities associated with vitamins and minerals and herbal medicines than with homeopathy, thus we may assume that our participants may not agree that the developed core competency statements apply equally to all categories of NHPs.

This study also had several strengths. It is the culmination of a program of research that included key informant interviews, focus groups with pharmacists and consumers, and a survey of licensed Canadian pharmacists. Thus the Delphi process benefited from the input of a wide-range of stakeholders including consumers, practising pharmacists and pharmacy students, other health care providers, the NHP industry, policy makers, educators, and representatives from a variety of pharmacy organizations. Therefore, the creation of competency statements has been
inclusive and the resulting competencies are therefore likely to be extremely relevant to pharmacy practice in Canada. Additionally, this project stimulated much discussion among participants which resulted not only in something concrete – the creation of competency statements, but also a sense of true contribution to the advancement of pharmacy education in this area in Canada. This project represented the first time that NHP educators from pharmacy schools across North America have ever met to discuss NHP-specific curriculum.

These competency statements were never intended to stand alone, and we are in the process of sharing our results with the larger pharmacy community within North America, primarily through wide-spread dissemination of the competency statements. It is our hope that the core NHP-related competencies developed through this project will be incorporated into: existing provincially-and state-based standards of practice documents and the educational outcomes documents that form the basis for pharmacy education at individual educational institutions. In Canada this would be accomplished by working with the Canadian Council for Accreditation of Pharmacy Programs (CCAPP) and the Association of the Faculties of Pharmacy of Canada (AFPC) to explore how the competency statements developed may be incorporated into their educational outcomes documents. It is also imperative to work with organizations that foster or accredit continuing professional education amongst practicing pharmacists, for example, the Ontario Pharmacists’ Association (OPA), the offices of continuing education at Canadian Faculties of Pharmacy and the Canadian Council on Continuing Education in Pharmacy (CCCEP). It is important to widely disseminate these competency statements to pharmacy organizations, policy makers and pharmacy schools. Uptake by the pharmacy community at large will ensure that Canadian pharmacists can meet their professional
responsibilities with respect to NHPs upon entry to practice, ultimately for better patient outcomes.

4.5 Conclusions

After 4 Delphi rounds, 3 core NHP-related competencies for Canadian pharmacy students upon entry to practice were identified. An additional 2 NHP-related competency statements emerged as important, but consensus that they should be considered core competencies was not achieved. We recommend wide-spread implementation and adaptation of these core NHP-related competencies by Faculties of pharmacy, and pharmacy organizations across Canada to better equip today’s pharmacists with the skills they require when entering practice.

4.6 Acknowledgements

Funding for this study was provided by: the Canadian Institutes for Health Research (CIHR) Partnerships for Health System Improvement (PHSI) grant, the Advanced Foods & Materials Network (AFMNet) National Centres of Excellence (NCE). Special thanks to my colleagues: Kristine Hirschkorn, Teela Johnson, Natasha Kachan, Della Kwan, Shade Olatunde, Narmatha Shanthakumar, Teresa Tsui and Rishma Walji.

This study would not have been possible without the input of our Delphi participants:
Heather Boon – University of Toronto
Lana Dvorkin-Camiel – Massachusetts College of Pharmacy and Health Services
Lynda Ecott – University of British Columbia
Shirley Heschuk – University of Alberta
Derek Jorgenson – University of Saskatchewan
Tannis Jurgens – Dalhousie University
Rebecca Law – Memorial University of Newfoundland
Susan Mansour – Canadian Council for Accreditation of Pharmacy Programs (CCAPP)

Ken Potvin – University of Waterloo

John Pugsley – The Pharmacy Examining Board of Canada (PEBC)

Cynthia Richard – University of Guelph/University of Waterloo

Stephen Shalansky – Canadian Society of Hospital Pharmacists (CSHP)

Kelly Shields – Ohio Northern University

Saeed Tavakoli – Undergraduate Pharmacy Society – University of Toronto

Candy Tsourounis – University of California, San Francisco

Alexander Vuong – Canadian Association of Pharmacy Students and Interns (CAPSI)

Margaret Wong – Ontario Pharmacists’ Association (OPA)

4.7 References


Chapter 5
Discussion
5.0 Introduction

This chapter will provide: i) a discussion of the implications of the applicability of the developed NHP-related competency statements in Canada and beyond, ii) study limitations and strengths, iii) strategies for knowledge translation and implementation, iv) ideas for future research, and finally, v) conclusions.

5.1 Summary of Results

After four Delphi rounds, three core NHP-related competencies were identified, broadly summarized as providing NHP-related pharmaceutical care, information and education (Table 1). An additional two NHP-related competency statements emerged as important, relating to the understanding of NHP regulation, and documenting NHP-usage and reporting NHP-related adverse events, but consensus that they should be considered core competencies was not achieved (Table 2). These findings and their implications were discussed in-depth Chapter 4 – Results (4.4 Discussion).

5.2 Applicability of NHP-related Competencies

In creating core competency statements, it was our aim to develop statements that were widely applicable yet flexible enough that they will have relevance and longevity amongst inevitable change. Pharmacists’ scope of practice is changing and expanding (e.g., in Alberta and more recently Ontario) and it could be argued that such change presents a perfect opportunity to incorporate our NHP-related core competencies into education and practice documents that are being revised. The developed competency statements were never intended to stand alone and it is our intention that these statements will be incorporated into existing standards of practice documents such as NAPRA’s Model Standards of Practice for Canadian Pharmacists (2003).\(^1\)

In order for this incorporation to be achieved, we designed the competency statements so that
they were not overly specific, both in regards to the categories of NHPs to which we referred, and in the language choices made in the writing of the competencies. For example, the term “NHP or NHPs” was used to refer to the broad range of products captured by Health Canada’s definition of NHPs.\(^2\) Professional NHP-related Competency #1 – Practice Pharmaceutical Care contains competency element d) which reads, “document patients’ NHP usage when appropriate,” this statement could be interpreted in various ways depending on the context in which the educational competency is being taught and assessed. The words “when appropriate” were specifically intended to allow for flexibility to interpret this competency as including such things as: recording NHP use in patient files, and/or documenting and reporting suspected adverse events to Health Canada. Under the competency to practice pharmaceutical care, all of these interpretations would be considered appropriate.

NAPRA’s Model Standards of Practice for Canadian Pharmacists 2003\(^1\) (the format upon which our competencies are based), is currently under review and will be modified in the near future. In recognition that policy documents are often updated to better reflect current practices, we recognize that we need to be prepared to modify our core NHP-related competency statements to be more congruent with the new model standards when they are available. However, given the extensive background upon which these competencies were built, along with the consensus method used to identify them, we are confident that the essence of our core competencies can be incorporated into newly released documents over the next several years.

In a broader context, the developed NHP-related competency statements appear to be in line with suggestions for content to be included in pharmacists education related to NHPs in the United States. In Clauson et al.’s 2003 study, “Knowledge and Attitudes of Pharmacists in Missouri Regarding Natural Products,” the authors propose in their conclusions that the
following concepts should shape the development of natural product content in pharmacy education:

- encourage students to focus on avoidance of harm when natural products are used by patients,
- provide students with knowledge of reliable sources for quality information, provide students with current evidence on the efficacy of products with the skills necessary to evaluate new information as it becomes available,
- provide students with the skills to successfully communicate with patients about their use of natural products,
- provide students with a basic knowledge of the Dietary Supplement Health and Education Act of 1994 and other regulatory issues relevant to CAM and natural products (pgs.307-8).³

Arguably, all of these recommendations have been captured in our Professional NHP-related Competencies #1-3 and our Additional NHP-related Competencies #4-5, which may be attributed to a common vision shared by members of the pharmacy community across North America. Other researchers from the United States made similar recommendations for natural product content including: the incorporation of pharmacognosy into the pharmacy curriculum, promoting continuing education and self-education,⁴ teaching students about the top twenty-five best-selling natural products, how to critically evaluate the safety and efficacy of these compounds from a scientific perspective, and to analyze ethical issues and values relating to their advertisement, sale, regulation and recommendations.⁵ The congruity between the required curriculum content areas and our developed competencies suggest that these competencies are as applicable and relevant to the pharmacy context in the United States as they are to the Canadian situation.

Additionally, recent research in Australia by Tiralongo and Wallis (2008) found that an integrated approach to teaching CAM (which includes herbal medicines, their regulation, preparation, natural products, quality control and safety) over several years of pharmacy education increases student’s knowledge and application, and that students preferred having
CAM teaching integrated into the curriculum beginning in the first year rather than waiting until later in their education. Pharmacists in Australia, as in Canada and the United States rate their knowledge of CAM and their ability to answer patient questions about CAM as being inadequate. The results of this Australian research suggest that the problems facing the pharmacy community in North America in regards to pharmacists not being prepared by their formal education to take on NHPs in their daily practice appear to apply to Australia as well. Thus, I would argue that the competencies we have developed may also be relevant in Australia. In fact, Tiralongo and Wallis state that, “firm recommendations and required competencies from professional and educational bodies to assist CAM curriculum development are urgently needed (pg.8).” Our study has achieved the first part of this request through the creation of NHP-related competencies.

In light of evidence from the United States and Australia, our research is timely, relevant and likely to be applicable to jurisdictions outside of Canada. There is no clear consensus as to how natural product topics should best be incorporated into the education process. However, the development of these NHP-related core competencies will provide the first step to the larger process of exploring how NHP information should be taught, appropriate topics to cover as well as appropriate assessment tools.

5.3 Study Limitations and Strengths

5.3.1 Limitations

This study, like all others, has limitations. The validity of this study was largely dependent on the active participation of representatives from Canadian and American pharmacy schools, and Canadian pharmacy organizations, that is, our Delphi panel. In the end, seven of the ten Canadian pharmacy schools were represented. We were unable to recruit participants
from either of the two French language pharmacy schools in the province of Quebec, despite every effort by investigators to include them. Lack of participation from the Quebec schools of pharmacy may have been due to the fact that all correspondence and the Delphi rounds themselves were to be conducted in English. Additionally, one of the identified participants from a pharmacy school in Quebec was set to retire around the time of the invitational consensus building meeting and a replacement had not yet been named. Consumers from Quebec report slightly lower NHP usage (69% as compared to the national average of 71%), and it is the region most likely to report seasonal usage of NHPs, which may affect the amount and frequency of questions received by pharmacists in their daily practice about NHPs. In addition, comparably fewer complementary and alternative medicine practitioners (e.g., naturopathic practitioners, traditional Chinese medicine practitioners) that recommend NHPs are regulated in Quebec, thus pharmacists have less opportunity to collaborate with other HCPs in the management of NHP related issues. However, our success in recruiting participants from seven of ten Canadian pharmacy schools provided us with a variety of different experiences from across the country in terms of how NHP content is taught (i.e. stand alone or elective course, integrated or separate curriculum, and class size).

Secondly, although curriculum content related to NHP varies across the country, based on the results of Shanthakumar’s survey of licensed Canadian pharmacists, it appears that the province/territory in which pharmacists are located does not influence their attitudes and beliefs regarding NHP-related competencies. This again suggests that our core NHP-related competency statements may be applicable nationally.

Thirdly, NHPs include a wide variety of products (e.g., herbs, vitamins, and homeopathy). We purposely did not limit ourselves to certain categories. Instead, the official
definition of NHPs according to the Natural Health Products Regulations (2004),\(^2\) was included as a preface to our core NHP-related competency statements in the final summary report. However, this creates a limitation in that it is not clear if our core NHP-related competency statements are equally applicable to all categories of NHPs. Shanthakumar concluded that generally pharmacists were more likely to endorse professional responsibilities associated with vitamins and minerals and/or herbal medicines than with homeopathy.\(^{12}\) This is supported by earlier research which characterizes homeopathy as the most controversial type of NHPs, an area where pharmacists opinions differ widely regarding its place (if any) in pharmacy, and thus their professional responsibilities towards this category of NHPs.\(^{13-16}\) Thus we may assume that our participants may not agree that the developed core competency statements apply equally to all categories of NHPs.

However, our decision to develop core competencies related to a general NHP category was made in recognition of the diverse cultures across Canada (and beyond) who embrace various categories of NHPs. Patients will expect their community pharmacists to be knowledgeable about the products they sell, and this product set will vary across jurisdictions. This leaves room for individual pharmacy schools or organizations to focus on the NHP categories most relevant to their jurisdictions, making these competencies widely applicable.

Finally, we intentionally used language in the competency statements that both sets a specific minimum standard focused on skills and processes, while at the same time facilitates individual schools’ or organizations’ ability to individualize the specific NHP content that is most salient for their social and political context. This was done purposely in recognition of the diversity of the pharmacy organizations, Faculties of pharmacy and standards of practice documents into which these core competencies could potentially be incorporated. Since the NHP
competencies were never intended to stand alone, but instead be incorporated into existing
standards of practice and educational outcomes documents, it is important that those who wish to
incorporate them find them flexible enough to fit a variety of purposes. We believe that wide-
spread adaptation is most likely to occur with the use of language that has some room for
interpretation.

5.3.2 Strengths

This study also had its strengths. First and foremost, it is the culmination of a program of
research that included key informant interviews,\textsuperscript{17} focus groups with pharmacists and
consumers,\textsuperscript{18} a test of pharmacy students’ herbal knowledge,\textsuperscript{11} and a survey of licensed Canadian
pharmacists.\textsuperscript{12} As a result, our Delphi process benefited from the “informed” or “expert” input of
a wide-range of stakeholders including: consumers, practicing pharmacists and pharmacy
students, other health care providers, the NHP industry, policy makers, educators and
representatives from a variety of pharmacy organizations (from Canada and the United States
who are active in the teaching of NHP content or policy-making), both in the stages leading up to
the invitational consensus building meeting and during the Delphi rounds themselves. The
creation of the competency statements has thus been an inclusive and iterative process. We
therefore believe the resulting competencies are extremely relevant especially to pharmacy
practice in Canada.

Secondly, the Delphi method itself was novel approach to consensus building,\textsuperscript{19} and
stimulated much discussion among our participants, which resulted not only in something
concrete – the creation of competency statements, but also a sense of true contribution on the
part of our participants to the advancement of pharmacy education in Canada as demonstrated by
their active participation and positive feedback.
The invitational consensus building meeting represented the first time that this group of North American NHP educators and policy-makers were brought together for the specific purpose of discussing NHP curriculum, sharing current practices and networking. The culmination of the larger research project at the two-day invitational consensus building meeting in November 2008 provided an opportunity for our participants; and by extension the pharmacy schools and organizations that they represented, to “buy into” a common set of NHP-related expectations. The active participation by our participants for all four Delphi rounds, and review of the summary document, a process which spanned approximately six months from start to finish, speaks to the importance our participants placed on this project.

5.4 Knowledge Translation and Implementation

We are in the process of sharing our results (the core NHP-related competency statements) with the larger pharmacy community within North America. One key way to do this is through the wide-spread distribution of the summary report of the invitational consensus building meeting including the core NHP-related competency statements (Appendix 26).

It is our hope that the core NHP-related competencies will be incorporated into: existing provincial-and state-based standards of practice documents, and into the educational competency statements that form the basis for pharmacy education at individual educational institutions.

We believe that it is important to widely disseminate these competency statements to pharmacy organizations, policy makers and pharmacy schools as uptake by the pharmacy community at large will ensure that Canadian pharmacists can meet their professional responsibilities with respect to NHPs upon entry to practice, ultimately for better patient outcomes. Thankfully, many of the organizations we plan to work with have been directly
involved in this project, and thus we are confident in the success of our exercises in knowledge translation to disseminate the NHP-related core competencies widely.

In Canada, implementation of the developed NHP competencies will be accomplished by working closely with a number of pharmacy organization interested in pharmacy education and continuing professional education for pharmacists (as a follow up to the summary document that we have already sent to them). For example, future plans include discussions with the Canadian Council for Accreditation of Pharmacy Programs (CCAPP) to explore how the competency statements may be incorporated into their accreditation process for Canadian schools of pharmacy. Additionally, we have already sent the Deans, and the Chairs of the Curriculum Committees, at each of the ten Canadian pharmacy schools, the summary document of our research to promote “buy in” from those who provide pharmacists with their training. Working with the offices of continuing education and interprofessional curriculum committees at Canadian pharmacy schools will also help to ensure “buy in” from pharmacists already in practice and amongst other health care providers also involved in the management of NHPs. The principal investigator has given a presentation to the pharmacy practice Faculty at the University of Toronto and the research supervisor will continue to give such presentations should the opportunity arise in the future. The research supervisor was invited to give a presentation summarizing the results of this study at the Association of the Faculties of Pharmacy of Canada (AFPC) annual conference in June 2009, and this provided yet another opportunity for “buy in” from the larger Canadian pharmacy education community. There are also plans to work with the National Association of Pharmacy Regulatory Authorities (NAPRA) to ensure that they work with provincial and territorial regulatory and professional associations to require pharmacists to be more knowledgeable about NHPs. This may include the incorporation of the developed
competencies into any revisions which may be made to their Model Standards of Practice for Canadian Pharmacists (2003) document. As NAPRA was unable to send a formal representative to the invitational consensus building meeting, we are eager to schedule a meeting with them to discuss our results. Furthermore, it is imperative to work with organizations that foster continuing professional education amongst practicing pharmacists, for example, the Ontario Pharmacists’ Association, and the Canadian Council on Continuing Education in Pharmacy (CCCEP). Finally, we hope that the Pharmacy Examining Board of Canada (PEBC) will seek to ensure that graduating pharmacists are tested on their knowledge of NHP-related materials through the “buy in” we hope to achieve with pharmacy educational institutions and organizations described above, and feel that implementation in the PEBC exams will first require significant changes in pharmacy education and standards of practice documents.

5.5 Future Research

Future research is needed to promote the uptake of the developed competencies in Canada, and assess the impact of wide-spread implementation of the competencies. For example, it will be necessary to determine whether or not pharmacy students from schools that adopt the NHP competencies perform better on objective tests designed to measure their NHP content knowledge. Related to this, a conceptual measure to facilitate accurate assessment of pharmacists’ knowledge of herbal and dietary supplements in the United States was recently published.20 This measure may help to standardize how we assess what pharmacists actually know about NHPs leading to a better understanding of where gaps exist, and thus providing researchers with specific areas to target in providing solutions. This standardized approach to constructing a multiple-choice competency examination identifies eight specific criteria from which an item bank was created. Items were evaluated by herbal and dietary supplement experts
based on specific criteria. A such tool could be piloted in Canadian pharmacy schools, once the competencies have been implemented, to assess if schools did in fact adapt the competencies, and more importantly, better equip their students with NHP-related knowledge. A possible research question is: do Canadian pharmacy students score better on a standardized NHP-knowledge test after implementation of NHP-related core competencies in the pharmacy curriculum? This proposed project could not occur immediately as the implementation of the NHP-related competencies will take a few years.

Another important avenue in dissemination may involve collaborating with pharmacy educators worldwide to promote creation or adoption of similar competencies. Additionally, the competencies could be shared with other health care professionals such as doctors and nurses which may lead to the development of similar competencies for NHPs for incorporation into their curricula. An example of a potential collaboration would be with the CAM in UME project (Complementary and Alternative Medicine in Undergraduate Medical Education), which has already completed a survey of all sixteen Canadian medical schools to determine what education is being provided in the area of CAM. Potential research questions for such endeavours include: can the NHP-related core competencies developed in Canada be implemented in the United States? Or Australia? And, how can NHP-related core competencies developed for Canadian pharmacist be adapted for Canadian doctors and nurses?

It will be important that the competency statements developed for this study be updated every five to ten years to better reflect current practices in pharmacy practice. I would suggest reviewing these competencies using a similar Delphi process in five years to assess their continued applicability, relevance and potential for complete integration with existing standards of practice and educational outcomes document.
5.6 Conclusions

After four Delphi rounds, three core NHP-related competencies for Canadian pharmacy students upon entry to practice were identified relating to: i) integrating NHPs into the practice of pharmaceutical care, ii) providing NHP information, and iii) educating patients and other health care providers about NHPs (Table 1). An additional two NHP-related competency statements, relating to: iv) understanding of NHP regulations, and v) documenting and reporting NHP usage and adverse events, emerged as important, but consensus that they should be considered core competencies was not achieved.

The development of these competencies has been informed by a large body of research and has involved the input of a diverse group of stakeholders with key interest in the area of pharmacists’ NHP-related education, and it is our sincere hope that with wide-spread implementation and adaptation of these core NHP-related competencies tomorrow’s pharmacists will be better equipped with the skills they require when entering practice to best serve the needs of their patients.

5.7 References


Tables
Table 1: Core NHP-related Competencies for Canadian Pharmacy Students upon Entry to Practice in Canada

<table>
<thead>
<tr>
<th>Professional NHP-related Competency #1 – Practice Pharmaceutical Care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Competency Unit</strong></td>
</tr>
</tbody>
</table>
| Pharmacy graduates demonstrate the ability to incorporate NHP knowledge when providing pharmaceutical care, including the ability to: | a) create the opportunity for open dialogue with patients about NHPs  
b) inquire about patient NHP usage  
c) consider patient NHP usage when identifying potential and/or actual drug therapy problems  
d) integrate knowledge of NHPs into patients’ individualized care plans and,  
e) document patients’ NHP usage when appropriate. |

<table>
<thead>
<tr>
<th>Professional NHP-related Competency #2 – Provide NHP Information</th>
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<tbody>
<tr>
<td><strong>Competency Unit</strong></td>
</tr>
</tbody>
</table>
| Pharmacy graduates demonstrate the ability to access and critically appraise sources of information related to NHPs, including the ability to: | a) find and access credible NHP references  
b) identify evidence-based indications for use and expected outcomes for NHPs and,  
c) identify clinically relevant potential and/or actual interactions with drugs or disease states, as well as adverse effects and precautions associated with NHPs. |

<table>
<thead>
<tr>
<th>Professional NHP-related Competency #3 – Educate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Competency Unit</strong></td>
</tr>
</tbody>
</table>
| Pharmacy graduates demonstrate the ability to provide appropriate education to patients and other health care providers on the effectiveness, potential adverse effects and drug interactions of NHPs. To accomplish this, they must have the ability to: | a) integrate knowledge of NHPs into routine education when appropriate and,  
b) educate patients and other health care providers about appropriate NHP information sources. |
### Table 2: Additional NHP-related Competencies for Canadian Pharmacy Students upon Entry to Practice in Canada

#### Additional Professional NHP-related Competency #4 – Understand NHP Regulations

<table>
<thead>
<tr>
<th>Competency Unit</th>
<th>Competency Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy graduates demonstrate the ability to describe the Canadian NHP Regulations, including the ability to:</td>
<td>a) explain the significance of a NPN or DIN-HM on a product and,</td>
</tr>
<tr>
<td></td>
<td>b) explain the difference between a traditional use claim label and a label claim based on scientific evidence.</td>
</tr>
</tbody>
</table>

#### Additional Professional NHP-related Competency #5 – Report Suspected NHP Adverse Events

<table>
<thead>
<tr>
<th>Competency Unit</th>
<th>Competency Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy graduates demonstrate the ability to report adverse events suspected to be related to the use of NHPs to Health Canada. This includes the ability to:</td>
<td>a) integrate knowledge of NHPs when investigating suspected adverse events and,</td>
</tr>
<tr>
<td></td>
<td>b) report suspected NHP-related adverse events to Health Canada.</td>
</tr>
</tbody>
</table>
Figures
**Figure 1: Likert Scale**

<table>
<thead>
<tr>
<th>Not important as a core competency</th>
<th>Important, but other core competencies may take priority</th>
<th>Very important</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unimportant</td>
<td></td>
<td>Essential</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

*Adapted from Endacott et al. 1999*
Appendices
Appendix 1: Letter of Invitation (for pharmacy school participants)

UNIVERSITY OF TORONTO
LEASE DAN FACULTY OF PHARMACY

Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies

We are writing to invite you to participate in a two-day invitational consensus building meeting and collaborative session to identify NHP-related core competencies for Canadian pharmacy students. We are inviting representatives from each Canadian school of pharmacy as well as guests from U.S. schools of pharmacy, Canadian pharmacy associations, the National Association of Pharmacy Regulatory Authorities (NAPRA) and the Pharmacy Examining Board of Canada (PEBC). You have been invited because of your interest pharmacy education and/or policy, and natural health products (NHPs).

The meeting will take place at the Leslie Dan Faculty of Pharmacy at the University of Toronto in Toronto, ON on **Thursday November 6 and Friday November 7, 2008**, and coincides with the 5th Annual IN-CAM Research Symposium (Friday November 7 – Sunday November 9, 2008) to encourage your participation in both events! More information for the IN-CAM event is available at [http://www.incamresearch.ca](http://www.incamresearch.ca).

This invitational consensus building meeting is the final stage of the project Natural Health Products (NHPs) and Pharmacy Practice funded by CIHR which many of you have already contributed to, and is being conducted as part of an MSc thesis project at the Leslie Dan Faculty of Pharmacy at the University of Toronto.

**Your participation is completely voluntary** and you will be **reimbursed for your expenses** in attending this meeting.

Attached you will find:

i) A letter of information

ii) A registration form

iii) An informed consent form, and

iv) A tentative agenda for the two-day meeting

We appreciate your consideration of our request and hope to see you in November!

If you have questions or concerns about the study, please do not hesitate to contact us!

We can be reached at (telephone): 416-946-5859, (fax): 416-978-1833, (email): heather.boon@utoronto.ca or ani.byrne@utoronto.ca.

Sincerely,
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Fax: (416) 978-1833  
heather.boon@utoronto.ca
Appendix 2: Letter of Identification (for identification of pharmacy organization participants)

Thursday July 24, 2008

Dear (Association Contact name here):

**Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies**

We are writing to ask for your assistance in identifying a representative from (insert name of organization here) who might be interested in participating in a two-day invitational consensus building meeting and collaborative session to identify NHP-related core competencies for Canadian pharmacy students. Our goal is to invite representatives from each Canadian school of pharmacy as well as guests from U.S. schools of pharmacy, Canadian pharmacy associations, the National Association of Pharmacy Regulatory Authorities (NAPRA) and the Pharmacy Examining Board of Canada (PEBC). We wish to invite an individual from (insert organization name here) who is interested in pharmacy education and/or policy, and natural health products (NHPs).

The meeting will take place at the Leslie Dan Faculty of Pharmacy at the University of Toronto in Toronto, ON on **Thursday November 6 and Friday November 7, 2008**, and coincides with the 5th Annual IN-CAM Research Symposium (Friday November 7 – Sunday November 9, 2008) to encourage participation in both events! More information for the IN-CAM event is available at [http://www.incamresearch.ca](http://www.incamresearch.ca).

This invitational consensus building meeting is the final stage of the project **Natural Health Products (NHPs) and Pharmacy Practice** funded by CIHR, and is being conducted as part of an MSc thesis project at the Leslie Dan Faculty of Pharmacy at the University of Toronto.

**Participation is completely voluntary** and participants will be **reimbursed for expenses** in attending this meeting.

Please contact Ani Byrne at [ani.byrne@utoronto.ca](mailto:ani.byrne@utoronto.ca) with the name and email address of the identified participant so that we might be able to send an official invitation and further information about this study including:

i) A letter of information
ii) A registration form
iii) An informed consent form, and
iv) A tentative agenda for the two-day meeting

We appreciate your consideration of our request and hope to hear from you soon!
If you have questions or concerns about the study, please do not hesitate to contact us!

We can be reached at (telephone): 416-946-5859, (fax): 416-978-1833, (email): heather.boon@utoronto.ca or ani.byrne@utoronto.ca.

Sincerely,

Ani Byrne, BAS (Hons)                                      Heather Boon, BScPhm, PhD
MSc Candidate                                              Principal Investigator
Leslie Dan Faculty of Pharmacy                             Associate Professor
144 College Street                                         Leslie Dan Faculty of Pharmacy
Toronto, ON M5S 3M2                                        144 College Street
Ph: (416) 946-5859                                         Toronto, ON M5S 3M2
Fax: (416) 978-1833                                         Ph: (416) 946-5859
ani.byrne@utoronto.ca                                      Fax: (416) 978-1833
                                                   heather.boon@utoronto.ca
Appendix 3: Letter of Information (presenters)

Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies

Investigators:
Ani Byrne, BAS (Hons) MSc Candidate Leslie Dan Faculty of Pharmacy 144 College Street Toronto, ON M5S 3M2 Ph: (416) 946-5859 Fax: (416) 978-1833 ani.byrne@utoronto.ca

Heather Boon, BScPhm, PhD Principal Investigator Associate Professor Leslie Dan Faculty of Pharmacy 144 College Street Toronto, ON M5S 3M2 Ph: (416) 946-5859 Fax: (416) 978-1833 heather.boon@utoronto.ca

Funding: This study is funded by CIHR Partnerships for Health System Improvement (PHSI) grant and AFMNet.

You have been invited to participate in a two-day invitational consensus building meeting and collaborative session to identify NHP-related core competencies for Canadian pharmacy students.

What is the purpose of the study?
The purpose of this study is to develop core NHP-related competencies for Canadian pharmacy students using three rounds of the Delphi method.

When and where will the study take place?
The two-day invitational consensus building meeting is scheduled for Thursday November 6 and Friday November 7, 2008. Specifically, the 1st Delphi round will be conducted via email in October 2008. The 2nd and 3rd Delphi rounds will be conducted at the meeting to be held in November 2008. If consensus is not reached by the end of the two-day meeting additional rounds will be held via email.

Who is being asked to participate and what will they do?
We are inviting representatives from each Canadian school of pharmacy as well as guests from U.S. schools of pharmacy, Canadian pharmacy associations, the National Association of Pharmacy Regulatory Authorities (NAPRA) and the Pharmacy Examining Board of Canada (PEBC). You have been invited because of your interest in pharmacy education and/or policy, and natural health products (NHPs). During the rounds of the Delphi method, you will be asked to identify your level of agreement or disagreement with statements related to possible NHP-related roles and responsibilities for pharmacists using a Likert scale.
We are also hoping that you will agree to give a brief presentation (10 mins + 5 mins for questions/comments) on current NHP-related education initiatives at your institution (e.g., how NHPs are incorporated into curriculum, course outline etc.) during the two-day meeting to inform the Delphi rounds and facilitate national sharing of educational materials and ideas.

As a presenter at the invitational consensus building meeting, power-point presentations (if applicable) must be sent to ani.byrne@utoronto.ca by Monday October 20, 2008 (ensure a back-up USB copy is also brought). The final presentation schedule will be sent to you after October 20, 2008.

**What are the risks and benefits of the study?**
This study has minimal risks. Participation is voluntary. A potential benefit of this study is to provide you with a forum to discuss your views on pharmacists’ NHP-related educational competencies and to share current NHP practices and materials from your institution. Your willingness to participate will contribute to changes in undergraduate pharmacy curriculum.

**Is the study confidential?**
Since this will be a face-to-face meeting, your identity will be known by the other participants. However, all individual responses to the Delphi rounds will be kept anonymous and confidential. As we wish to give credit to all our participants, we are asking for your permission to publish your name and affiliation as part of the consensus statement that emerges from the meeting. If you do not provide your consent to publish your name on the attached consent and registration forms, then the study team will not release your name; however, it is impossible to insure complete confidentiality if you attend the meeting because you will be known to the other participants. We will circulate a draft report of the core NHP-related competencies developed from the meeting and you will have the right to withdraw your name from the final publication for up to 14 days after the draft report is circulated prior to it being made public.

**Will I be compensated for participating in this study?**
Your direct travel and accommodation expenses will be reimbursed while in Toronto for the invitational consensus building meeting.

Please be sure to keep all receipts.

**NOTE: You cannot be reimbursed for flights without your boarding pass**

Hotel accommodations will be pre-arranged for Thursday November 6, 2008 and confirmations will be emailed to you. If you are staying for IN-CAM or require an additional night’s stay, please indicate this on the registration form provided as we will be able to obtain the University of Toronto rate on your behalf.

Please note your credit card will be required at the hotel for incidental purposes.

Accommodation information is as follows:
**Delta Chelsea Downtown**
33 Gerrard St. W.
Toronto, ON
Tel. 1-800-243-5732

Directions to the Leslie Dan Faculty of Pharmacy from the Delta Chelsea Downtown (144 College Street, Toronto, ON)
Start address: 33 Gerrard St. W Toronto, ON
End address: 144 College St. Toronto, ON
1. Head west on Gerrard St. W toward Bay St. - 0.1 km
2. Turn right at La Plante Ave - 0.3 km
3. Turn left at College St - 0.4 km
Arrive at: 144 College St. Toronto, ON

http://maps.google.ca/maps?f=d&hl=en&geocode=&saddr=33+gerrard+street+West,+Toronto,+ON&daddr=144+College+St,+Toronto,+Ontario+M5S,+Canada&mra=pe&mrcr=0&sll=43.659188,-79.387535&sspn=0.009128,0.023432&ie=UTF8&z=17

What are my rights as a participant?
If you have any questions about your rights as a participant, please contact Jill Parsons, Health Sciences Ethics Review Officer, Ethics Review Office, University of Toronto at, telephone: (416) 946-5806 or by email: jc.parsons@utoronto.ca.

Your participation is very important to the development of NHP-related core competencies for Canadian pharmacy students and we hope that you will agree to take part!

Please fill out the attached registration form and RSVP via email or fax to ani.byrne@utoronto.ca (fax 416-978-1833) by Tuesday September 30, 2008. If you cannot attend, but can suggest someone else from your institution/association that may be available, please let us know.

Please remember to bring a copy for the consent form with you in November or fax it to (416) 978-1833 and keep a copy for yourself.

We look forward to seeing you in November!

Sincerely,
Ani Byrne, BAS (Hons) Heather Boon, BScPhm, PhD
MSc Candidate Principal Investigator
Leslie Dan Faculty of Pharmacy Associate Professor
144 College Street Leslie Dan Faculty of Pharmacy
Toronto, ON M5S 3M2 144 College Street
Ph: (416) 946-5859 Ph: (416) 946-5859
Fax: (416) 978-1833 Fax: (416) 978-1833
ani.byrne@utoronto.ca heather.boon@utoronto.ca

Research Team Members:
Lynda Eccott, University of British Columbia
Glenn Greiner, University of Alberta
Shirley Heschuk, University of Alberta
Kristine Hirschkorn, University of Toronto
Tannis Jurgens, Dalhousie University
Della Kwan, University of Toronto
Shade Olatunde, University of Toronto
Narmatha Shanthakumar, University of Toronto
Nola Reis, University of Victoria
Sandy Welsh, University of Toronto

National Association of Pharmacy Regulatory Authorities (NAPRA)
Natural Health Products Directorate (NHPD)
Ontario College of Pharmacists
Ontario Ministry of Health and Long-Term Care (OMHLTC)

**Thesis Committee Members:**
Zubin Austin, University of Toronto
Tannis Jurgens, Dalhousie University
Lalitha Raman-Wilms, University of Toronto
Appendix 4: Letter of Information (non-presenter)

UNIVERSITY OF TORONTO
LESLIE DAN FACULTY OF PHARMACY

Wednesday July 23, 2008

Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies

Investigators:
Ani Byrne, BAS (Hons)  Heather Boon, BScPhm, PhD
MSc Candidate         Principal Investigator
Leslie Dan Faculty of Pharmacy  Associate Professor
144 College Street  Leslie Dan Faculty of Pharmacy
Toronto, ON M5S 3M2  144 College Street
Ph: (416) 946-5859  Ph: (416) 946-5859
Fax: (416) 978-1833  Fax: (416) 978-1833
ani.byrne@utoronto.ca  heather.boon@utoronto.ca

Funding: This study is funded by CIHR Partnerships for Health System Improvement (PHSI) grant and AFMNet.

You have been invited to participate in a two-day invitational consensus building meeting and collaborative session to identify NHP-related core competencies for Canadian pharmacy students.

What is the purpose of the study?
The purpose of this study is to develop core NHP-related competencies for Canadian pharmacy students using three rounds of the Delphi method.

When and where will the study take place?
The two-day invitational consensus building meeting is scheduled for Thursday November 6 and Friday November 7, 2008. Specifically, the 1st Delphi round will be conducted via email in October 2008. The 2nd and 3rd Delphi rounds will be conducted at the meeting to be held in November 2008. If consensus is not reached by the end of the two-day meeting additional rounds will be held via email. The meeting will be scheduled for Thursday November 6 and Friday November 7, 2008.

Who is being asked to participate and what will they do?
We are inviting representatives from each Canadian school of pharmacy as well as guests from U.S. schools of pharmacy, Canadian pharmacy associations, the National Association of Regulatory Authorities (NAPRA) and the Pharmacy Examining Board of Canada (PEBC). You have been invited because of your interest in pharmacy education and/or policy, and natural health products (NHPs). During the rounds of the Delphi method, you will be asked to identify your level of agreement or disagreement with statements related to possible NHP-related roles and responsibilities for pharmacists using a Likert scale.
What are the risks and benefits of the study?
This study has minimal risks. Participation is voluntary. A potential benefit of this study is to provide you with a forum to discuss your views on pharmacists’ NHP-related educational competencies and to share current NHP practices and materials from your institution. Your willingness to participate will contribute to changes in undergraduate pharmacy curriculum.

Is the study confidential?
Since this will be a face-to-face meeting, your identity will be known by the other participants. However, all individual responses to the Delphi rounds will be kept anonymous and confidential. As we wish to give credit to all our participants, we are asking for your permission to publish your name and affiliation as part of the consensus statement that emerges from the meeting. If you do not provide your consent to publish your name on the attached consent and registration forms, then the study team will not release your name; however, it is impossible to insure complete confidentiality if you attend the meeting because you will be known to the other participants. We will circulate a draft report of the core NHP-related competencies developed from the meeting and you will have the right to withdraw your name from the final publication for up to 14 days after the draft report is circulated prior to it being made public.

Will I be compensated for participating in this study?
Your direct travel and accommodation expenses will be reimbursed while in Toronto for the invitational consensus building meeting.

Please be sure to keep all receipts.

**NOTE: You cannot be reimbursed for flights without your boarding pass**

Hotel accommodations will be pre-arranged for Thursday November 6, 2008 and confirmations will be emailed to you. If you are staying for IN-CAM or require an additional night’s stay, please indicate this on the registration form provided as we will be able to obtain the University of Toronto rate on your behalf.

Please note your credit card will be required at the hotel for incidental purposes.

Accommodation information is as follows:

**Delta Chelsea Downtown**
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Toronto, ON
1-800-243-5732

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Arrive at: 144 College St. Toronto, ON

http://maps.google.ca/maps?f=d&hl=en&geocode=&saddr=33+gerrard+street+West,+Toronto,+ON&daddr=144+College+St,+Toronto,+Ontario+M5S,+Canada&mra=pe&mrcr=0&sll=43.659188,-79.387535&sspn=0.009128,0.023432&ie=UTF8&z=17

What are my rights as a participant?
If you have any questions about your rights as a participant, please contact Jill Parsons, Health Sciences Ethics Review Officer, Ethics Review Office, University of Toronto at, telephone: (416) 946-5806 or by email: jc.parsons@utoronto.ca.

Your participation is very important to the development of NHP-related core competencies for Canadian pharmacy students and we hope that you will agree to take part!

Please fill out the attached registration form and RSVP via email to ani.byrne@utoronto.ca by Tuesday September 30, 2008. If you cannot attend, but can suggest someone else from your institution/association that may be available, please let us know.

Please remember to bring a copy for the consent form with you in November or fax it to (416) 978-1833 and keep a copy for yourself.

We look forward to seeing you in November!

Sincerely,
Ani Byrne, BAS (Hons) MSc Candidate
Leslie Dan Faculty of Pharmacy
144 College Street
Toronto, ON M5S 3M2
Ph: (416) 946-5859
Fax: (416) 978-1833
ani.byrne@utoronto.ca

Heather Boon, BScPhm, PhD
Principal Investigator
Associate Professor
Leslie Dan Faculty of Pharmacy
144 College Street
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Ph: (416) 946-5859
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Shade Olatunde, University of Toronto
Narmatha Shanthakumar, University of Toronto
Nola Reis, University of Victoria
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National Association of Pharmacy Regulatory Authorities (NAPRA)
Natural Health Products Directorate (NHPD)
Ontario College of Pharmacists
Ontario Ministry of Health and Long-Term Care (OMHLTC)

**Thesis Committee Members:**
Zubin Austin, University of Toronto
Tannis Jurgens, Dalhousie University
Lalitha Raman-Wilms, University of Toronto
Appendix 5: Registration Form

Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies

Invitational Consensus Building Meeting
Thursday November 6 and Friday November 7, 2008
Leslie Dan Faculty of Pharmacy, University of Toronto
144 College Street, Toronto, ON

Name: ___________________________________________________________

Email: __________________________________________________________

Affiliation (University or Association): _______________________________

May we add your contact information (name, email address and affiliations) to our list of participants for this event? Please note this list will be circulated to all event participants only.

YES                  NO

Please indicate which nights (if any) you will require hotel accommodation:

_________________________________________________________________

Hotel accommodation will be pre-paid for Thursday November 6, 2008 and confirmations will be emailed to you. If you are staying for the IN-CAM Symposium or require additional nights accommodation, we will be able to obtain the University of Toronto rate on your behalf. However, you will be responsible to pay for the additional nights of accommodation.

Do you have any special/serious dietary restrictions that we should be aware of?

_________________________________________________________________

Please return via email to ani.byrne@utoronto.ca or fax (416) 978-1833 by Tuesday September 30, 2008
Appendix 6: Informed Consent Form

Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies

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 my name and affiliations may be published unless I indicate in writing to the study authors two weeks (14 days) after receiving the draft report that I wish to have my name removed from the list of contributors. All questions have been answered to my satisfaction.

I understand that my individual responses to the Delphi questions will be kept anonymous and confidential by the research team.

I understand that my participation in this study is voluntary and that I have the right to withdraw at any time prior to the publication of the consensus statements from the meeting.

DATE (dd/mm/yy): _____/_____/______ (to be dated by participant)

SIGNATURE OF PARTICIPANT:________________________________________

PRINTED NAME OF PARTICIPANT:_____________________________________

**Please remember to bring a copy of this completed consent form with you to Toronto in November or fax it to (416) 978-1833 and keep a copy for your records**
## Appendix 7: Invitational Consensus Building Meeting Tentative Agenda

**UNIVERSITY OF TORONTO**  
**LESLIE DAN FACULTY OF PHARMACY**

**Invitational Consensus Building Meeting Tentative Agenda**

**Thursday November 6, 2008**

<table>
<thead>
<tr>
<th>Event</th>
<th>Time</th>
<th>Facilitated by</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opening remarks and Dean’s welcome</td>
<td>3:30</td>
<td>Heather, Ani, Dean Hindmarsh (TBC)</td>
<td>PB 850</td>
</tr>
<tr>
<td>Introductions (all participants)</td>
<td>3:45</td>
<td>Heather, Ani</td>
<td>PB 850</td>
</tr>
<tr>
<td>Introduction to pharmacy education (20-30 mins)</td>
<td>4:00</td>
<td>Zubin Austin and/or Lalitha Raman-Wilms</td>
<td>PB 850</td>
</tr>
<tr>
<td>Introductory presentations by co-investigators (10 mins each @ 6)</td>
<td>4:30</td>
<td>Kristine, Teela, Della, Shade, Narmatha</td>
<td>PB 850</td>
</tr>
<tr>
<td>U.S. schools presentations (15 mins each @ 3)</td>
<td>5:30</td>
<td>U.S. participants</td>
<td>PB 850</td>
</tr>
<tr>
<td>Summary of 1st Delphi round</td>
<td>6:15</td>
<td>Heather, Ani</td>
<td>PB 850</td>
</tr>
<tr>
<td>Complete 2nd Delphi round</td>
<td>6:30</td>
<td>Heather, Ani</td>
<td>PB 850</td>
</tr>
<tr>
<td>Dinner</td>
<td>6:45</td>
<td>N/A</td>
<td>PB 850</td>
</tr>
<tr>
<td>Day wrap up/preview of day 2</td>
<td>7:30</td>
<td>Heather, Ani</td>
<td>PB 850</td>
</tr>
<tr>
<td>Event</td>
<td>Time</td>
<td>Facilitated by</td>
<td>Location</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-------</td>
<td>--------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Participant arrival and breakfast</td>
<td>9:00</td>
<td>N/A</td>
<td>PB 850</td>
</tr>
<tr>
<td>Summary of 2\textsuperscript{nd} Delphi round</td>
<td>9:30</td>
<td>Ani, Heather</td>
<td>PB 850</td>
</tr>
<tr>
<td>Canadian schools presentations (5 @ 15 mins each)</td>
<td>9:45</td>
<td>Canadian participants</td>
<td>PB 850</td>
</tr>
<tr>
<td>Break</td>
<td>11:00</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Canadian schools presentations continued (5 @ 15 mins)</td>
<td>11:30</td>
<td>Canadian participants</td>
<td>PB 850</td>
</tr>
<tr>
<td>Complete 3\textsuperscript{rd} Delphi round</td>
<td>12:45</td>
<td>Heather, Ani</td>
<td>PB 850</td>
</tr>
<tr>
<td>Lunch</td>
<td>1:00</td>
<td></td>
<td>PB 850</td>
</tr>
<tr>
<td>Summary of 3\textsuperscript{rd} Delphi round, and decision on if additional rounds need</td>
<td>2:00</td>
<td>Heather, Ani</td>
<td>PB 850</td>
</tr>
<tr>
<td>Adjourn</td>
<td>2:30</td>
<td>Heather, Ani</td>
<td>PB 850</td>
</tr>
<tr>
<td>Optional tour of the Leslie Dan Faculty of Pharmacy</td>
<td>2:45 to 3:45</td>
<td></td>
<td>PB</td>
</tr>
<tr>
<td>5\textsuperscript{th} Annual IN-CAM Research Symposium</td>
<td>Begins at 6:00</td>
<td></td>
<td>PB</td>
</tr>
</tbody>
</table>
Appendix 8: Reminder Notice (for pharmacy school participants)

Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies

Dear (Participant’s name here):

On (insert date of original invitation here), we emailed you a letter of invitation for our study to develop NHP-related core competencies for Canadian pharmacy students using a modified Delphi method at a consensus meeting taking place in Toronto, ON on Thursday November 6 and Friday November 7, 2008. The information package is attached here again.

As of today’s date, we have not received your RSVP. We kindly ask that you RSVP as soon as possible so that we can make alternative arrangements to invite another participant if you are unable to attend. If you cannot attend, but can suggest someone else from your institution that may be available, please let us know.

The deadline to register is Tuesday September 30, 2008. Your participation will make an important contribution to the development of educational standards for pharmacists related to NHPs.

If you have questions about the study, we can be reached at (telephone): 416-946-5859, (fax) 416-978-1833, (email): ani.byrne@utoronto.ca or heather.boon@utoronto.ca.

Thank you very much for your time and assistance.

Sincerely,

Ani Byrne, BAS (Hons) MSc Candidate
Leslie Dan Faculty of Pharmacy
144 College Street
Toronto, ON M5S 3M2
Ph: (416) 946-5859
Fax: (416) 978-1833
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Heather Boon, BScPhm, PhD Principal Investigator
Associate Professor
Leslie Dan Faculty of Pharmacy
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Shirley Heschuk, University of Alberta
Kristine Hirschkorn, University of Toronto
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National Association of Pharmacy Regulatory Authorities (NAPRA)
Natural Health Products Directorate (NHPD)
Ontario College of Pharmacists
Ontario Ministry of Health and Long-Term Care (OMHLTC)

**Thesis Committee Members:**
Zubin Austin, University of Toronto
Tannis Jurgens, Dalhousie University
Lalitha Raman-Wilms, University of Toronto
Appendix 9: Reminder Notice (for pharmacy organization participants)

Date

Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies

Dear (Participant’s name here):

On (insert date of original invitation here), we emailed you a request to identify someone from (inset organization name here) who might be interested in participating in our study to develop NHP-related core competencies for Canadian pharmacy students using a modified Delphi method at a consensus meeting taking place in Toronto, ON on Thursday November 6 and Friday November 7, 2008.

As of today’s date, we have not received a response. We kindly ask that you respond as soon as possible as the deadline for participants to register is Tuesday September 30, 2008. Your assistance will make an important contribution to the development of educational standards for pharmacists related to NHPs.

We have included as an attachment the letter of invitation and complete information package with registration form to this email in the hope that it can be sent to an interested member of (insert organization here).

If you have questions about the study, we can be reached at (telephone): 416-946-5859, (fax) 416-978-1833, (email): ani.byrne@utoronto.ca or heather.boon@utoronto.ca.

Thank you very much for you time and assistance.

Sincerely,

Ani Byrne, BAS (Hons)                                Heather Boon, BScPhm, PhD
MSc Candidate                                         Principal Investigator
Leslie Dan Faculty of Pharmacy                          Associate Professor
144 College Street                                   Leslie Dan Faculty of Pharmacy
Toronto, ON M5S 3M2                                    144 College Street
Ph: (416) 946-5859                                    Toronto, ON M5S 3M2
Fax: (416) 978-1833                                    Ph: (416) 946-5859
ani.byrne@utoronto.ca                                 Fax: (416) 978-1833
                                                        heather.boon@utoronto.ca

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Narmatha Shanthakumar, University of Toronto
Nola Reis, University of Victoria
Sandy Welsh, University of Toronto

National Association of Pharmacy Regulatory Authorities (NAPRA)
Natural Health Products Directorate (NHPD)
Ontario College of Pharmacists
Ontario Ministry of Health and Long-Term Care (OMHLTC)

**Thesis Committee Members:**
Zubin Austin, University of Toronto
Tannis Jurgens, Dalhousie University
Lalitha Raman-Wilms, University of Toronto
Appendix 10: Supplementary Information for Meeting Participants and Link to 1st Delphi Round

Thursday October 2, 2008
Dear Participants

Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies

Thank you for agreeing to attend our two-day invitational consensus building meeting taking place on Thursday November 6 and Friday November 7, 2008 at the Leslie Dan Faculty of Pharmacy at the University of Toronto.

Your participation is very important to the development of NHP-related core competencies for Canadian pharmacy students!

Below you will find a link to the 1st round of the Delphi survey.

http://www.surveymonkey.com/s.aspx?sm=ZgsvBf6z7tEL7N_2f51hvBqA_3d_3d

We would ask that you please complete the survey by Monday October 20, 2008. The survey has 9 questions and will take approximately 10 minutes to complete.

The objective of the survey portion of this study is to identify NHP-related core competencies for Canadian pharmacy students upon entry to practice. There is no limit to how many or how few statements can be identified as core competencies.

We have also attached some supplementary readings from earlier parts of our NHPs and Pharmacy research project to inform your first Delphi round. Do not feel obligated to read all materials – they are provided for your interest only.

READINGS


If you have any questions or concerns do not hesitate to contact us!

We look forward to seeing you in November!

Sincerely,
Ani Byrne, BAS (Hons)  
MSc Candidate  
Leslie Dan Faculty of Pharmacy  
144 College Street  
Toronto, ON M5S 3M2  
Ph: (416) 946-5859  
Fax: (416) 978-1833  
ani.byrne@utoronto.ca

Heather Boon, BScPhm, PhD  
Principal Investigator  
Associate Professor  
Leslie Dan Faculty of Pharmacy  
144 College Street  
Toronto, ON M5S 3M2  
Ph: (416) 946-5859  
Fax: (416) 978-1833  
heather.boon@utoronto.ca
Appendix 11: Reminder – 1st Delphi Round

October 9, 2008
Dear Participants

Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies

Just a reminder that the first round of the Delphi survey is to be completed by Monday October 20, 2008.

Here is the link to the survey.
http://www.surveymonkey.com/s.aspx?sm=ZgsvBf6z7tEL7N_2f51hvBqA_3d_3d

If you have already completed the survey please ignore this email.

If you have any questions or concerns do not hesitate to contact us!

We look forward to seeing you in November!

Sincerely,
Ani Byrne, BAS (Hons) Heather Boon, BScPhm, PhD
MSc Candidate Principal Investigator
Leslie Dan Faculty of Pharmacy Associate Professor
144 College Street Leslie Dan Faculty of Pharmacy
Toronto, ON M5S 3M2 144 College Street
Ph: (416) 946-5859 Toronto, ON M5S 3M2
Fax: (416) 978-1833 Ph: (416) 946-5859
ani.byrne@utoronto.ca Fax: (416) 978-1833
heather.boon@utoronto.ca
Appendix 12: Participant Hotel Confirmation

Tuesday October 14, 2008
Dear (Participant’s Name here),

Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies

We want to thank you again for agreeing to attend our two-day invitational consensus building meeting on November 6 & 7, 2008 at the Leslie Dan Faculty of Pharmacy - University of Toronto.

A few housekeeping items:

1) Hotel reservations have been made for you for the following night(s):
   At:
   The Delta Chelsea Downtown
   33 Gerrard St. W.
   Toronto, ON
   Tel. 1-800-243-5732

   Your confirmation number is:
   If any changes are required to your reservation, please let me know ASAP.

2) As a presenter at the meeting (if applicable), we would ask that power-point presentations (if applicable) be sent to Ani at ani.byrne@utoronto.ca by Monday October 20, 2008. Please bring a back-up copy on a memory stick if at all possible.

3) We will be offering an optional tour of the Leslie Dan Faculty of Pharmacy on Friday November 7 (most likely between 2-3PM), please rely whether or not you might be interested to give us an idea of how many tour guides we may require.

4) Finally, we require all consent forms to be signed before the meeting begins. It has been re-attached here - please fax it to (416) 978-1833 ASAP.

If you have any questions or concerns do not hesitate to contact us.
We look forward to seeing you in November!

Sincerely,

Ani Byrne, BAS (Hons) MSc Candidate
Leslie Dan Faculty of Pharmacy
144 College Street
Toronto, ON M5S 3M2
Ph: (416) 946-5859
Fax: (416) 978-1833
ani.byrne@utoronto.ca

Heather Boon, BScPhm, PhD Principal Investigator
Associate Professor
Leslie Dan Faculty of Pharmacy
144 College Street
Toronto, ON M5S 3M2
Ph: (416) 946-5859
Fax: (416) 978-1833
heather.boon@utoronto.ca
Appendix 13: Final Reminder – Invitational Consensus Building Meeting

Monday November 3
Dear Participants,

**Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies**

Our two-day invitational consensus building meeting is taking place this week on Thursday November 6 and Friday November 7, 2008 at the Leslie Dan Faculty of Pharmacy at the University of Toronto.

A few housekeeping reminders:

1) The 1st Delphi round summary of results is attached, a hardcopy will be provided when you arrive as well.

2) A reading regarding model standards of practice for Canadian pharmacists (NAPRA’s *Model Standards of Practice for Canadian Pharmacists (April 2003)*) has been attached to provide additional background for the development of core competency statements. This reading should provide the context several participants asked for in the comments section of the 1st Delphi round.

3) Please be sure to keep ALL receipts, including boarding passes for your expense claims. Please note that you will NOT be reimbursed for flights without boarding passes. A hardcopy will be given out on Thursday and has also been attached for your convenience.

4) Your hotel confirmations were provided on Tuesday October 14, 2008 (if applicable). Please contact me if you require this information again. General hotel information is as follows:
   Delta Chelsea Downtown
   33 Gerrard St. W.
   Toronto, ON
   Tel. 1-800-243-5732

5) The invitational consensus building meeting will take place at the:
   Leslie Dan Faculty of Pharmacy – University of Toronto
   144 College St
   Toronto, ON
   (corner of College Street and University Avenue)
   Room #850 (elevators to 8th floor, 850 is straight ahead)

6) Directions are as follows:
   Directions to the Leslie Dan Faculty of Pharmacy from the Delta Chelsea Downtown (144 College Street, Toronto, ON)
   Start address:
   33 Gerrard St. W Toronto, ON
   End address:
   144 College St. Toronto, ON
1. Head west on Gerrard St. W toward Bay St. - 0.1 km
2. Turn right at La Plante Ave - 0.3 km
3. Turn left at College St - 0.4 km Arrive at: 
144 College St. Toronto, ON
http://maps.google.ca/maps?f=d&hl=en&geocode=&saddr=33+gerrard+street+West,+Toronto,+ON&daddr=144+College+St,+Toronto,+Toronto,+Ontario+M5S,+Canada&mra=pe&mrcr=0&sl=43.659188,-79.387535&sspn=0.009128,0.023432&ie=UTF8&z=17

It is approximately a 5 minute walk from the Delta Chelsea Downtown to the Leslie Dan Faculty of Pharmacy.

7) A finalized agenda of the two-day meeting is attached for your reference.

8) If you wish, you are more than welcome to bring your own laptops – internet connections will be provided free of charge during the meeting.

9) If you need to contact us while in Toronto do not hesitate to call Ani’s cell phone at: (416) 660-2394.

If you have any questions or concerns do not hesitate to contact us!

We look forward to seeing you all later this week!

Sincerely,
Ani Byrne, BAS (Hons) MSc Candidate
Leslie Dan Faculty of Pharmacy
144 College Street
Toronto, ON M5S 3M2
Ph: (416) 946-5859
Fax: (416) 978-1833
ani.byrne@utoronto.ca

Heather Boon, BScPhm, PhD
Principal Investigator
Associate Professor
Leslie Dan Faculty of Pharmacy
144 College Street
Toronto, ON M5S 3M2
Ph: (416) 946-5859
Fax: (416) 978-1833
heather.boon@utoronto.ca
### Invitational Consensus Building Meeting Final Agenda

**Thursday November 6 and Friday November 7, 2008**

Leslie Dan Faculty of Pharmacy, University of Toronto
144 College Street, Toronto, ON
Room 850

**Thursday November 6, 2008**

<table>
<thead>
<tr>
<th>Event</th>
<th>Presented by</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Welcome and Opening Remarks</td>
<td>Heather Boon, Dean Wayne Hindmarsh – <em>Leslie Dan Faculty of Pharmacy University of Toronto</em> Rickey Yada - <em>AFMNet</em></td>
<td>3:30</td>
</tr>
<tr>
<td>Participant Introductions</td>
<td></td>
<td>3:45</td>
</tr>
<tr>
<td>Introduction to Pharmacy Education</td>
<td>Lalitha Raman-Wilms</td>
<td>4:00</td>
</tr>
</tbody>
</table>

**Introductory Presentations by Co-investigators**

<table>
<thead>
<tr>
<th>Event</th>
<th>Presented by</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Della Kwan</td>
<td></td>
<td>4:30</td>
</tr>
<tr>
<td>Teela Johnson</td>
<td></td>
<td>4:45</td>
</tr>
<tr>
<td>Shade Olatunde</td>
<td></td>
<td>5:00</td>
</tr>
<tr>
<td>Narmatha Shanthakumar</td>
<td></td>
<td>5:15</td>
</tr>
<tr>
<td>Break</td>
<td></td>
<td>5:30</td>
</tr>
</tbody>
</table>

**Presentations by U.S. Pharmacy School Participants**

<table>
<thead>
<tr>
<th>Event</th>
<th>Presented by</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lana Dvorkin-Camiel – <em>Mass College of Pharmacy and Health Sciences</em></td>
<td></td>
<td>5:45</td>
</tr>
<tr>
<td>Kelly Shields – <em>Ohio Northern University</em></td>
<td></td>
<td>6:00</td>
</tr>
<tr>
<td>Candy Tsournousis – <em>University of California, San Francisco</em></td>
<td></td>
<td>6:15</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event</th>
<th>Presented by</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary of 1st Delphi round</td>
<td>Ani Byrne</td>
<td>6:30</td>
</tr>
<tr>
<td>Complete 2nd Delphi round</td>
<td></td>
<td>6:45</td>
</tr>
<tr>
<td>and Dinner</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Friday November 7, 2008

<table>
<thead>
<tr>
<th>Event</th>
<th>Presented by</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant arrival and breakfast</td>
<td></td>
<td>9:00</td>
</tr>
<tr>
<td>Summary of 2\textsuperscript{nd} Delphi round</td>
<td>Ani Byrne</td>
<td>9:30</td>
</tr>
</tbody>
</table>

**Presentations by Canadian Pharmacy School Participants**

<table>
<thead>
<tr>
<th>Name</th>
<th>University</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heather Boon</td>
<td>University of Toronto</td>
<td>9:45</td>
</tr>
<tr>
<td>Lynda Eccott</td>
<td>University of British Columbia</td>
<td>10:00</td>
</tr>
<tr>
<td>Shirley Heschuk</td>
<td>University of Alberta</td>
<td>10:15</td>
</tr>
<tr>
<td>Derek Jorgenson</td>
<td>University of Saskatchewan</td>
<td>10:30</td>
</tr>
</tbody>
</table>

**Break**

**Presentations by Canadian Pharmacy School Participants Continued**

<table>
<thead>
<tr>
<th>Name</th>
<th>University</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tannis Jurgens</td>
<td>Dalhousie University</td>
<td>11:00</td>
</tr>
<tr>
<td>Rebecca Law</td>
<td>Memorial University of Newfoundland</td>
<td>11:15</td>
</tr>
<tr>
<td>Ken Potvin</td>
<td>University of Waterloo</td>
<td>11:30</td>
</tr>
</tbody>
</table>

3\textsuperscript{rd} Delphi round (if necessary). If consensus already reached Brainstorming Session (Where to go from here?) and Resource Sharing Discussion

Lunch

Summary of 3\textsuperscript{rd} Delphi round, and decision on if additional rounds need (if necessary) or Brainstorming Session and Resource Sharing Discussion continued

Adjourn

Optional tour of the Leslie Dan Faculty of Pharmacy

5\textsuperscript{th} Annual IN-CAM Research Symposium

Begin at 6:00
Appendix 15: Expense Claim Form

Please Read Carefully Before Completing Your Expense Claim Account

In order to process expense claims in an expedient manner and to maintain a proper accounting system, we ask that you please adhere to the following:

Please include original receipts, e.g. airline ticket showing the cost, boarding passes, taxis, parking, meals with your expense claim form. Please note that when paying by credit card, both parts of meal receipts are required to process your expense claim. This means the itemized receipt that shows what you ate/drank as well as the payment receipt showing how you paid, and the total amount including any tip. The only exception to this is if you pay for your meal by cash. If you pay by cash, and you also pay gratuity, you will need to handwrite in the tip amount and SIGN the bottom of each meal receipt, indicating that that is the amount you actually paid.

Please also note that we will pay for your room and taxes, local phone calls and meals in your room, and hotel parking but not for long distance calls, video rentals, etc.

Please mail the signed ‘Travel Expense Claim’ form to the following address:

Ani Byrne  
Leslie Dan Faculty of Pharmacy  
University of Toronto  
144 College Street  
Toronto, ON, Canada M5S 3M2

Email: ani.byrne@utoronto.ca  
Telephone: (416) 946-5859  
Fax: (416) 978-1833

We thank you for your co-operation.
Expense Claim Sheet
Invitational Consensus Building Meeting
November 6 & 7, 2008
Leslie Dan Faculty of Pharmacy
University of Toronto

NAME: ______________________________________________________

ADDRESS (where cheque is to be sent): ______________________________________

____________________________________

____________________________________

E-MAIL: __________________________________________________________

TELEPHONE: ______________________________________________________

Please record your applicable expenses below:
Airfare (if applicable) $___________

Ground Transportation $___________

Meals $___________

Other (please specify and attach itemized receipts)
1. $___________

2. $___________

3. $___________

4. $___________

TOTAL: $___________

Claimant’s Signature _____________________________________________

FUND: __________________________________________________________

Authorized Signature _________________________________________
Appendix 16: 1st Delphi Round Questionnaire

**1st DELPHI ROUND QUESTIONNAIRE**
(Administered using Survey Monkey)

Please indicate how important it is that the following competency units and element(s) be identified as a core NHP-related competency pharmacy students should have upon entry to practice in Canada:

**Likert Scale used for Questions 1 – 6**

<table>
<thead>
<tr>
<th>Level of Importance</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranking</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates recognize that knowledge related to NHPs is important in providing pharmaceutical care, including the ability to:
   a) inquire about patient NHP usage
   b) interpret drug therapy problems to include NHP-related problems
   c) critically assess NHPs as therapeutic options and,
   d) integrate knowledge of NHPs into patients' individualized care plans.

Comments, justification for ranking, suggestions for rewording Competency #1:

2. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates use appropriate and effective strategies to access current and reliable information related to NHPs, including the ability to:
   a) find and access reliable NHP references
   b) identify evidence-based indications for use and expected outcomes for NHPs and,
   c) identify clinically relevant possible side-effects, drug interactions, and cautions associated with NHPs.

Comments, justification for ranking, suggestions for rewording Competency #2:

3. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates enable patients to identify and assess appropriate and reliable information on NHPs, including the ability to:
   a) create the opportunity for open dialogue with patients about NHPs
   b) educate patients about appropriate NHP information sources and,
c) help patients to critically assess NHP information.

Comments, justification for ranking, suggestions for rewording Competency #3:

<table>
<thead>
<tr>
<th>Comments, justification for ranking, suggestions for rewording Competency #3:</th>
</tr>
</thead>
</table>

4. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates provide appropriate education to patients on the effectiveness, potential adverse effects and drug interactions of NHPs, including the ability to:
   a) integrate knowledge of possible NHP adverse effects into routine patient education when appropriate
   b) identify possible NHP-drug combinations which are contraindicated and,
   c) inform patients of suspected NHP-drug interactions where applicable.

Comments, justification for ranking, suggestions for rewording Competency #4:

<table>
<thead>
<tr>
<th>Comments, justification for ranking, suggestions for rewording Competency #4:</th>
</tr>
</thead>
</table>

5. COMPETENCY UNIT AND ELEMENT
Pharmacy graduates document the use of NHPs in patients' computer profiles or medical records, including the ability to:
   a) routinely document patient usage of NHPs.

Comments, justification for ranking, suggestions for rewording Competency #5:

<table>
<thead>
<tr>
<th>Comments, justification for ranking, suggestions for rewording Competency #5:</th>
</tr>
</thead>
</table>

6. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates report suspected adverse drug reactions or drug interactions related to the use of NHPs to Health Canada, including the ability to:
   a) integrate knowledge of NHPs when investigating suspected adverse drug reactions and/or drug interactions and,
   b) routinely report NHP-related suspected adverse drug reactions and/or drug interactions.

Comments, justification for ranking, suggestions for rewording Competency #6:

<table>
<thead>
<tr>
<th>Comments, justification for ranking, suggestions for rewording Competency #6:</th>
</tr>
</thead>
</table>

7. MISSING COMPETENCIES?
Are there any competencies that you believe are missing from the above listing?

| Yes | No |

If Yes, please add them below:

<table>
<thead>
<tr>
<th>If Yes, please add them below:</th>
</tr>
</thead>
</table>

8. ADJUNCT QUESTION
Pharmacists' practice standards for NHPs should be the same as those for other unscheduled over-the-counter (OTC) medications (eg. Tylenol).

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If you would like to explain your reasoning, please do so below:

9. **ADDITIONAL COMMENTS?**

If you have any additional comments/suggestions, please include them below:
Appendix 17: 1st Delphi Round Summary

1st DELPHI ROUND – SUMMARY

The following is a summary of the responses gathered from the 1st Delphi round survey as of October 21, 2008 (n=17).
A mean of >3 ensures that the competency will continue onto the 2nd Delphi round.

1. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates recognize that knowledge related to NHPs is important in providing pharmaceutical care, including the ability to:
   a) inquire about patient NHP usage
   b) interpret drug therapy problems to include NHP-related problems
   c) critically assess NHPs as therapeutic options and,
   d) integrate knowledge of NHPs into patients' individualized care plans.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of response (%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (5.9%)</td>
<td>5 (29.4%)</td>
<td>11 (64.7%)</td>
</tr>
<tr>
<td>Mode</td>
<td>Essential (5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>Important, but other core competencies may take priority (3) – Essential (5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>4.59</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments and suggestions(all)</td>
<td>Important to provide a definition of natural health product. Is the expectation that graduates have a comprehensive knowledge base to recommend NHPs as a therapeutic option? d. is not clear as to what is intended. To what end is the knowledge being integrated? a and b are most important, c and d may influence ratings I would reword it as: Pharmacy graduates will need to demonstrate an ability to incorporate NHP knowledge when providing pharmaceutical care, including... There are probably more NHP or other 'natural' products on the pharmacy shelf than typical pharmacologicals. Even if almost all of these products do not have any evidence regarding efficacy, pharmacists should at least know about the indications, safety, interactions, etc. Even though you would not recommend such a product, the patient may end up buying it anyway so it is crucial to tell them about it even if you do not recommend it - otherwise there would be no 'patient-centered care’ Excellent wording as is Pharmacists need to be aware of the potential for interactions so that NHPs are</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

assessed as a drug. Goes by the "do no harm" philosophy.
the only portion I could see as less critical is section c. Due to the product
goodness differences between NHP and other meds that may make assessing as a
therapeutic option more difficult.
Since people are using NHPs, you can't really provide complete
pharmaceutical care without including NHPs
I would reword b) as something like: "consider patient NHP usage when
identifying drug therapy problems"

Competency #1 moving onto 2nd Delphi round? YES

2. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates use appropriate and effective strategies to access current and reliable
information related to NHPs, including the ability to:
   a) find and access reliable NHP references
   b) identify evidence-based indications for use and expected outcomes for NHPs and,
   c) identify clinically relevant possible side-effects, drug interactions, and cautions
      associated with NHPs.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>4 (23.5%)</td>
<td>13 (76.5%)</td>
</tr>
<tr>
<td>Mode</td>
<td>Essential (5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>Very Important (4) – Essential (5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>4.76</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Comments and suggestions(all)    | Pharmacy graduates will demonstrate an ability to access appropriate sources of information, including....
It's essential and is VERY easy to learn where to look. It will take an hour to teach.
absolutely critical as this lays the groundwork for all the other skills a pharmacist should demonstrate
I don't expect that pharmacy students will have memorized everything, but
they need to know how to access the information when it is relevant |

Competency #2 moving onto 2nd Delphi round? YES

3. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates enable patients to identify and assess appropriate and reliable information
on NHPs, including the ability to:
a) create the opportunity for open dialogue with patients about NHPs
b) educate patients about appropriate NHP information sources and,
c) help patients to critically assess NHP information.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>0 (0%)</td>
<td>1 (5.9%)</td>
<td>9 (52.9%)</td>
<td>7 (41.2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Mode</td>
<td>Important, but other core competencies may take priority (3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>Not important as a core competency (2) – Very Important (4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>3.35</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments and suggestions(all)</td>
<td>This core competency relates more to communication skills, which should be of high priority in skills courses. It is relevant to any pharmacy topic or disease condition (i.e. can substitute NHP with asthma, acne, oral contraceptives, drug use in children.....) not sure how 'a)' fits in as a detractor to some extent opening dialogue should follow normal pharmacists/patient communications This one needs some rewording for clarity-the first sentence talks about the pharmacist enabling the patient to do... but a -c seems more about what the pharmacist does...the content is fine-it just needs to be reworded. How about....Pharmacy graduates enable (or foster the ability of) patients to identify and assess appropriate and reliable information on NHPs. This will be a result of the pharmacist being able to: I think pharmacists will be seen by patients as effective health educators only if they can help them with NHPs as well as drugs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Competency #3 moving onto 2nd Delphi round? YES

4. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates provide appropriate education to patients on the effectiveness, potential adverse effects and drug interactions of NHPs, including the ability to:
   a) integrate knowledge of possible NHP adverse effects into routine patient education when appropriate
   b) identify possible NHP-drug combinations which are contraindicated and,
   c) inform patients of suspected NHP-drug interactions where applicable.
### Comment 4: Pharmacy graduates document the use of NHPs in patients' computer profiles or medical records, including the ability to:

- a) routinely document patient usage of NHPs.

<table>
<thead>
<tr>
<th><strong>Levels of Importance (weighting)</strong></th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of responses (%)</strong></td>
<td>1 (5.9%)</td>
<td>2 (11.8%)</td>
<td>5 (29.4%)</td>
<td>7 (41.2%)</td>
<td>2 (11.8%)</td>
</tr>
<tr>
<td><strong>Mode</strong></td>
<td>Very important (4)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Range</strong></td>
<td>Unimportant (1) – Essential (5)</td>
<td></td>
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</tr>
<tr>
<td><strong>Mean</strong></td>
<td>3.41</td>
<td></td>
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<tr>
<td><strong>Comments and suggestions(all)</strong></td>
<td>Documentation should be taught as a pharmacy skill in a skills lab, not as part of an NHP course. (The NHP course could just refer to the skills course). Pharmacists often do not documenting OTC use in profiles (they should be)</td>
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</tbody>
</table>
but current practice models does not facilitate this. Important but can't do this without knowing anything about the products. At this stage there are a lot more important nonprescription drugs in use that are not documented in patients' records. As NHPs are considered to be safe for self-selection to a greater extent than many of these other OTCs, documentation of their use must be considered a lower relative priority. If there are individual agents that have major interaction potential, they probably shouldn't be regulated as NHPs in the first place.

in general pharmacists tend to be poor documenters I think wording of the lead in sentence....put period where comma is and start new sentence- or maybe (a) is redundant with the lead in sentence I'd love to know that this was happening, but I don't think the current structure of community practice will realistically allow this to happen yet

### Competency #5 moving onto 2nd Delphi round? YES

#### 6. COMPETENCY UNIT AND ELEMENTS

Pharmacy graduates report suspected adverse drug reactions or drug interactions related to the use of NHPs to Health Canada, including the ability to:

a) integrate knowledge of NHPs when investigating suspected adverse drug reactions and/or drug interactions and,

b) routinely report NHP-related suspected adverse drug reactions and/or drug interactions.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>0 (0%)</td>
<td>2 (11.8%)</td>
<td>4 (23.5%)</td>
<td>4 (23.5%)</td>
<td>7 (41.2%)</td>
</tr>
<tr>
<td>Mode</td>
<td>Essential (5)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Range</td>
<td>Not important as a core competency (2) – Essential (5)</td>
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<tr>
<td>Mean</td>
<td>3.94</td>
<td></td>
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</tr>
<tr>
<td>Comments and suggestions(all)</td>
<td>The skills relating to adverse drug reporting or drug interaction reporting should be taught in a skills lab, where ADR reporting regarding more conventional drug therapies is being taught. Reporting an ADR from an NHP is no different from reporting an ADR from a conventional medication, and it would be more important for pharmacy students to consider and investigate the possibility of an NHP-related event while documenting ANY ADR. We don't place ADR reporting of drugs as a core competency in our program. Essential - an important way to gather information on adverse effects of NHPs This should be encouraged, but I find it difficult to call this a core competency. If prescription drug and OTC ADR reporting isn't taking place</td>
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</table>
(whether or not those are listed as core competencies), then it seems too great a stretch to require this for NHPs.
For me the lead in sentence is not grammatically correct (as in the last few comments)
I see this as a core part of pharmacy practice even though I suspect AE reporting is not routinely happening with either drugs or NHPs

Competency #6 moving onto 2nd Delphi round? YES

7. MISSING COMPETENCIES?
Are there any competencies that you believe are missing from the above listing?

<table>
<thead>
<tr>
<th>Options</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>8 (47.1%)</td>
<td>9 (52.9%)</td>
</tr>
</tbody>
</table>

If Yes, please add them below:
The main areas of competence should center around 1) effectiveness 2) safety 3) information retrieval and evaluation 4) patient counseling and 5) regulation. I did not see anything that discusses regulation. Although in the US, regulation is different than in Canada, I think that this would be a good component to consider in that NHP, including homeopathic medicines are different than prescription or over-the-counter medications. Pharmacy graduates are able to outline the regulatory differences and similarities between NHPs and prescription medications. In addition, you may even want to include a competency that relates to knowledge regarding botanical cultivation, harvesting etc. For the average graduate they should have an appreciation for the plant parts that are most associated with the greatest efficacy and fewest adverse effects (encompassing both). Pharmacy graduates are able to identify the ingredients or plant parts of NHP associated with increased efficacy and fewest adverse effects. Finally, although this is not in my domain it may be worth while to incorporate cultural diversity and philosophy regarding NHPs. This may fit within the "creating an opportunity for dialogue". Basic understanding of manufacturing practices related to NHP Basic understanding of national and international regulations related to NHP Critical assessment of NHP literature is touched on in competency #1 and implied in competency #2. Does it need to be more explicitly addressed as a core competency?
Knowledge of current lack of appropriate Quality Control of NHP products - variability in reported label contents - lack of manufacturing standards
Need to have a little bit of knowledge about the manufacturing sector of NHP's (i.e. pharmaceutics, how they extract things, etc --> this is not as important but something to consider. The socio-economics behind NHPs (i.e. regulation, marketing, general public spending) --> also not as important, probably taught within an hour class. - Perhaps an optional short session about compounding certain herbal --> also not as important as other competencies helping a patient choose a product - there are many eg. ginkgo products on the market - which one is best?
I don't know if it's a competency, but in the interests of encouraging interprofessional collaboration and the most efficient/effective use of limited health resources, there might be something to be said for pharmacists understanding the role and expertise of naturopathic doctors and/or other disciplines that are legitimate and regulated. That way they may find it appropriate
to refer patients for more intensive evaluation or instruction if they are primarily interested in CAM approaches to their care.

Ability to educate other health providers about the rational usage, effectiveness, safety, and interactions with COMMON NHPs...especially in clinical situaations where patients are found to be taking mutlipkle NHPs that the other health providers care not aware of.

8. ADJUNCT QUESTION
Pharmacists' practice standards for NHPs should be the same as those for other unscheduled over-the-counter (OTC) medications (eg. Tylenol).

<table>
<thead>
<tr>
<th>Options</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>13 (76.5%)</td>
<td>4 (23.5%)</td>
</tr>
</tbody>
</table>

If you would like to explain your reasoning, please do so below:
I think that there are more factors at play with NHP. I feel that NHPs have more issues that need to be discussed. It has to do with holistic care and what that may mean for a patient. There is so much more to be said on this.
Different regulatory bodies
Define what is intended by practice standards
In general, NHP's are not as hazardous as normal OTC meds. Perhaps you could group some, such as St. john's wort in the OTC med section (no reason not to)
As NAPRA has decided that NHPs are beyond the scope of the NDS, and that their conditions of sale are not going to be regulated by the Colleges of Pharmacists, I don't think that pharmacists can be held to the same practice standards for these products (that are deemed to be safe for self-selection). If a pharmacist provides advice and guidance on NHPs that they sell, as they should, they have a professional and ethical responsibility to make sure it is sound advice. They may, however, sell products that they know relatively little about. I don't think the same can or should be said about Schedule II or Schedule III medications.
I believe that any products used for therapeutic purpose should be held to the same standards in terms of patient education.
I am actually not sure what the practice standards are for OTCs-that could influence my answer if I knew

9. ADDITIONAL COMMENTS?

If you have any additional comments/suggestions, please include them below:
We have to teach our students to think about the whole patient and not in segmented and fragmented parts. This has to be emphasized with NHPs and also it serves an important role in getting the patient to talk to the provider.
I think it is great that you are integrating this into the program. Main thing is identifying key NHPs, increasing awareness, and directing to reputable resources to search for this information
Appendix 18: 2nd Delphi Round Questionnaire

2nd DELPHI ROUND QUESTIONNAIRE
(Administered using Survey Monkey)
Please indicate how important it is that the following competency units and element(s) be identified as a core NHP-related competency pharmacy students should have upon entry to practice in Canada:

Likert Scale used for Questions 1 – 8

<table>
<thead>
<tr>
<th>Level of Importance</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
</table>

Ranking

1. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates demonstrate an ability to incorporate NHP knowledge when providing pharmaceutical care, including the ability to:
   a) inquire about patient NHP usage
   b) consider patient NHP usage when identifying drug therapy problems and,
   c) integrate knowledge of NHPs into patients' individualized care plans.

Comments, justification for ranking, suggestions for rewording Competency #1:

2. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates demonstrate an ability to describe the regulation of NHPs based on Health Canada’s NHP Regulations, including the ability to:
   a) explain the significance of a NPH or DIN-HM on a product
   b) explain the difference between a traditional use label claim and a label claim based on scientific evidence
   c) describe basic manufacturing standards for NHPs and,
   d) identify the regulatory status of common CAM practitioners that regularly use NHPs.

Comments, justification for ranking, suggestions for rewording Competency #2:

3. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates demonstrate an ability to access appropriate sources of information related to NHPs, including the ability to:
   a) find and access reliable NHP references
   b) identify evidence-based indications for use and expected outcomes for NHPs and,
c) identify clinically relevant possible side-effects, drug interactions, and cautions associated with NHPs.

Comments, justification for ranking, suggestions for rewording Competency #3:

4. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates demonstrate an ability to critically assess reliable scientific evidence with respect to the safety and efficacy of NHPs, including the ability to:
   a) critically assess evidence-based indications for use and expected outcomes for NHPs and,
   b) integrate knowledge of clinically relevant possible side-effects, drug interactions, and cautions associated with NHPs in patient care plans when appropriate.

Comments, justification for ranking, suggestions for rewording Competency #4:

5. COMPETENCY UNIT AND ELEMENT
Pharmacy graduates enable patients to identify and assess appropriate and reliable information on NHPs. This will be a result of being able to:
   a) create the opportunity for open dialogue with patients about NHPs
   b) educate patients about appropriate NHP information sources and,
   c) help patients to critically assess NHP information.

Comments, justification for ranking, suggestions for rewording Competency #5:

6. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates provide appropriate education to patients on the effectiveness, potential adverse effects and drug interactions of NHPs. To accomplish this, they must have the ability to:
   a) integrate knowledge of possible NHP adverse effects into routine patient education when appropriate
   b) identify possible NHP-drug combinations which are contraindicated and,
   c) inform patients of suspected NHP-drug interactions where applicable.

Comments, justification for ranking, suggestions for rewording Competency #6:

7. COMPETENCY UNIT
Pharmacy graduates routinely document the use of NHPs into patients’ computer profiles or medical records.

Comments, justification for ranking, suggestions for rewording Competency #7:
8. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates report suspected adverse drug reactions or drug interactions related to the use of NHPs to Health Canada. This includes the ability to:
   a) integrate knowledge of NHPs when investigating suspected adverse drug reactions and/or drug interactions and,
   b) routinely report NHP-related suspected adverse drug reactions and/or drug interactions.

Comments, justification for ranking, suggestions for rewording Competency #8:

9. MISSING COMPETENCIES?
Are there any competencies that you believe are missing from the above listing?

Yes  No

If Yes, please add them below:

10. ADJUNCT QUESTION
Pharmacists' practice standards for NHPs should be the same as those for other unscheduled over-the-counter (OTC) medications (eg. Tylenol).

Yes  No

If you would like to explain your reasoning, please do so below:

11. ADDITIONAL COMMENTS?
If you have any additional comments/suggestions, please include them below:
Appendix 19: 2nd Delphi Round Summary

2nd DELPHI ROUND – SUMMARY

The following is a summary of the responses gathered from the 2nd round of the Delphi survey as of November 6, 2008 (n=17).
A mean of >3 ensures that the competency will continue onto the next round of the Delphi. Consensus achieved when all participants rank a statement 4 or 5.

1. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates demonstrate an ability to incorporate NHP knowledge when providing pharmaceutical care, including the ability to:
   a) inquire about patient NHP usage
   b) consider patient NHP usage when identifying drug therapy problems and,
   c) integrate knowledge of NHPs into patients' individualized care plans.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of response (%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>4 (23.5%)</td>
<td>13 (76.5%)</td>
</tr>
<tr>
<td>Mode</td>
<td>Essential (5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>Very important (4) – Essential (5)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>4.76</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments and suggestions(all)</td>
<td>I'm not clear what c means.... recommendation or management suggestions? Need to be able to &quot;Do no harm&quot; and identify potential for harm. is WHEN APPROPRIATE necessary?</td>
<td></td>
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</tbody>
</table>

Competency #1 moving onto 3rd Delphi round? Yes
Consensus Achieved? Yes

2. COMPETENCY UNIT AND ELEMENT
Pharmacy graduates demonstrate an ability to describe the regulation of NHPs based on Health Canada’s NHP Regulations, including the ability to:
   a) explain the significance of a NPH or DIN-HM on a product
   b) explain the difference between a traditional use label claim and a label claim based on scientific evidence
   c) describe basic manufacturing standards for NHPs and,
   d) identify the regulatory status of common CAM practitioners that regularly use NHPs.
<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>4 (23.5%)</td>
<td>7 (41.2%)</td>
<td>6 (35.3%)</td>
</tr>
<tr>
<td>Mode</td>
<td></td>
<td></td>
<td></td>
<td>Very important (7)</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td></td>
<td>Important, but other core competencies may take priority (3) – Essential (5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td>4.12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments and suggestions(all)</td>
<td></td>
<td>I am less concerned about &quot;c&quot; as I don't know what specific competency elements pertain to pharmacy students' knowledge about manufacturing standards for conventional meds. I think this is critical, though as a US person I'm not sure the details of this. Had trouble answering the same for all 4 selections. a and b seem essential-the rest are important but not essential. Not sure that regulatory status of CAM practitioners fits into regulation of NHPs.</td>
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</table>

**Competency #2 moving onto 3\textsuperscript{rd} Delphi round? Yes**

**3. COMPETENCY UNIT AND ELEMENTS**
Pharmacy graduates demonstrate an ability to access appropriate sources of information related to NHPs, including the ability to:
   a) find and access reliable NHP references
   b) identify evidence-based indications for use and expected outcomes for NHPs and,
   c) identify clinically relevant possible side-effects, drug interactions, and cautions associated with NHPs.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>2 (11.8%)</td>
<td>15 (88.2%)</td>
</tr>
<tr>
<td>Mode</td>
<td></td>
<td></td>
<td></td>
<td>Essential (5)</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td></td>
<td></td>
<td></td>
<td>Very important (4) – Essential (5)</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>4.88</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments and suggestions(all)</td>
<td>Identifying and providing advice concerning interactions between traditional medications and NHPs is the most essential component of this competency. It seems that being able to access information also includes primary literature (which is the next competency). Therefore, there seems to be a bit of an overlap between the two.</td>
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</table>

**Competency #3 moving onto 3rd Delphi round? Yes**
**Consensus achieved? Yes**

4. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates demonstrate an ability to critically assess reliable scientific evidence with respect to the safety and efficacy of NHPs, including the ability to:
- a) critically assess evidence-based indications for use and expected outcomes for NHPs and,
- b) integrate knowledge of clinically relevant possible side-effects, drug interactions, and cautions associated with NHPs in patient care plans when appropriate.

| Levels of Importance (weighting) | Unimportant (1) | Not important as a core competency (2) | Important, but other core competencies may take priority (3) | Very important (4) | Essential (5) |
| Number of responses (%) | 0 (0%) | 1 (5.9%) | 2 (11.8%) | 4 (23.5%) | 10 (58.8%) |
| Mode | Essential (5) |
| Range | Important, but other core competencies may take priority (3) – Essential (5) |
| Mean | 4.35 |
| Comments and suggestions(all) | If this is talking about looking through primary sources and critically compare evidence then this is a 2. If it's general, then I would rate it as 4 (but that would make it similar to the previous question). The reason I don't think looking at primary sources for NHPs with regards to efficacy, DI's, and safety should be a primary competency is because I feel the evidence behind NHPs are extremely varied and that it will take a substantial amount of time to fully look at all the evidence; this should be expected from someone whose primary job is to assess scientific evidence and publish a conclusive article (i.e. tertiary sources), and should not be expected of the pharmacist. For example, for a busy community pharmacist, one should not expect him/her to be able to look at hundreds of unreliable primary sources in order to find safety, efficacy, DI's, etc; this is useless since it is an unrealistic expectation. Since the science behind NHP approvals is not as robust as that for conventional pharmaceuticals, I don't think that pharmacy students are likely going to be able to think in the paradigm of many CAM practitioners. Thus, |
part a) may not be a realistic expectation. Part b), on the other hand, is important as it relates to the prescribed drugs, and overall drug therapy management.

I think #3 is probably good enough and make this one not completely necessary...it would nice to expect students to be capable of "critically appraising or assessing literature" it may be somewhat unrealistic since we struggle to teach pharmacists to do this for regular meds.

**Competency #4 moving onto 3rd Delphi round? Propose to drop**

### 5. COMPETENCY UNIT AND ELEMENT
Pharmacy graduates enable patients to identify and assess appropriate and reliable information on NHPs. This will be a result of being able to:

- a) create the opportunity for open dialogue with patients about NHPs
- b) educate patients about appropriate NHP information sources and,
- c) help patients to critically assess NHP information.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
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<tr>
<td>Number of responses (%)</td>
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<td>2 (11.8%)</td>
<td>5 (29.4%)</td>
<td>9 (52.9%)</td>
<td>1 (5.9%)</td>
</tr>
<tr>
<td>Mode</td>
<td>Very important (4)</td>
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<tr>
<td>Range</td>
<td>Not important as a core competency (2) – Essential (5)</td>
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<tr>
<td>Mean</td>
<td>3.53</td>
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</table>
| Comments and suggestions(all)    | Pharmacists should be responsible for telling patients to talk to the appropriate people before taking any NHP's. They should not be responsible for teaching patients how to assess info since this is extremely unrealistic. That's what pharmacists are there for.

It should be kept in mind that not all patients will want to seek their own information, or will not be capable of finding/interpreting the available information.

Since patients are likely to have a stronger opinion or inclination regarding NHPs (based on advice from family/friends) than pharmacists, one of the key roles pharmacists have to play is directing patients to sources of information and guiding them on the reliability/cautions with the info sources. As with many of the other competency elements, this one could probably be a modification or addendum to an existing competency statement.

This is a lofty goal and would be wonderful in a perfect world - but is not really achievable.

**Competency #5 moving onto 3rd Delphi round? Propose to drop**
6. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates provide appropriate education to patients on the effectiveness, potential adverse effects and drug interactions of NHPs. To accomplish this, they must have the ability to:
   a) integrate knowledge of possible NHP adverse effects into routine patient education when appropriate
   b) identify possible NHP-drug combinations which are contraindicated and,
   c) inform patients of suspected NHP-drug interactions where applicable.

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<th>Essential (5)</th>
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<td>0 (0%)</td>
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<tr>
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<td>Essential (5)</td>
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<tr>
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<tr>
<td>Comments and suggestions(all)</td>
<td>This ones seems to overlap with #5 do no harm</td>
<td></td>
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Competency #6 moving onto 3rd Delphi round? Yes
Consensus achieved? Yes

7. COMPETENCY UNIT
Pharmacy graduates routinely document the use of NHPs into patients’ computer profiles or medical records.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>2 (11.8%)</td>
<td>1 (5.9%)</td>
<td>7 (41.2%)</td>
<td>6 (35.3%)</td>
<td>1 (5.9%)</td>
</tr>
<tr>
<td>Mode</td>
<td>Very important (4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>Unimportant (1) – Essential (5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Only document the important ones with a significant amount of case reports. Not only is documentation important for clinical practice, but it is also important for building evidence to use in clinical decision-making. Part of the reason we know so little about the safety and efficacy of NHPs is because epidemiological research is very difficult to conduct. This documentation should be by exception, and will likely happen rarely in reality.

I find this to be critical because of the potential risk for drug interactions. Documenting use is the first step.

This is a problem for ALL OTCs...including herbals. do not do it with OTCs, but should Work on documentation of other meds (OTC, etc) first.

Competency #7 moving onto 3rd Delphi round? Yes

8. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates report suspected adverse drug reactions or drug interactions related to the use of NHPs to Health Canada. This includes the ability to:
   a) integrate knowledge of NHPs when investigating suspected adverse drug reactions and/or drug interactions and,
   b) routinely report NHP-related suspected adverse drug reactions and/or drug interactions.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>0 (0%)</td>
<td>1 (6.3%)</td>
<td>5 (29.4%)</td>
<td>8 (47.1%)</td>
<td>3 (17.6%)</td>
</tr>
<tr>
<td>Mode</td>
<td>Very important (4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>Not important as a core competency (1) – Essential (5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>3.76</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments and suggestions(all)</td>
<td>all pharmacists will &quot;have the ability to&quot; do these things. Reporting of ADRs is very unlikely, at large, as many patients will buy these products from other venues and/or self-select and purchase in a pharmacy. Routine report won't happen, and would be less important than the reporting for ADRs for Rx drugs or conventional OTCs. Important for patient safety.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Competency #8 moving onto 3rd Delphi round? Yes
9. **MISSING COMPETENCIES?**
Are there any competencies that you believe are missing from the above listing?

<table>
<thead>
<tr>
<th>Options</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>1 (5.9%)</td>
<td>16 (94.1%)</td>
</tr>
</tbody>
</table>

If Yes, please add them below:
Effective communication skills to be able to convey the information to their patients or to other health care professionals.

10. **ADJUNCT QUESTION**
Pharmacists' practice standards for NHPs should be the same as those for other unscheduled over-the-counter (OTC) medications (eg. Tylenol).

<table>
<thead>
<tr>
<th>Options</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>11 (64.7%)</td>
<td>6 (35.3%)</td>
</tr>
</tbody>
</table>

If you would like to explain your reasoning, please do so below:
Evidence based, it should be similar. But as mentioned in the presentations, pharmacists should be more open-minded and admit that there is a lack of evidence and the patient may use it based on their belief of 'evidence', as long as it's safe.
NHPs are regulated based on a different paradigm and system than other OTCs licensed with a DIN. If the licensing bodies (Health Canada and colleges of pharmacy) aren't considering them to be on the same level as OTCs, then why should the professional standards be the same?
Patient safety is always cited as one of the paramount concerns for pharmacists. Surely, when one considers the spectrum of Rx drugs, conventional OTCs, and NHPs, from a risk-management perspective NHPs must be (in general) of least concern.
I think that NHPs represent more variables than do OTC drugs.

11. **ADDITIONAL COMMENTS?**
If you have any additional comments/suggestions, please include them below:
Appendix 20: 3rd Delphi Round Questionnaire

3rd DELPHI ROUND QUESTIONNAIRE
(Administered using Survey Monkey)

Please indicate how important it is that the following competency units and element(s) be identified as a core NHP-related competency pharmacy students should have upon entry to practice in Canada:

**Likert Scale used for Questions 1-5**

<table>
<thead>
<tr>
<th>Level of Importance</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ranking</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. **COMPETENCY UNIT AND ELEMENTS**
Pharmacy graduates demonstrate an ability to incorporate NHP knowledge when providing pharmaceutical care, including the ability to:
   a) create the opportunity for open dialogue with patients about NHPs
   b) inquire about patient NHP usage
   c) document patients’ NHP usage when appropriate
   d) consider patient NHP usage when identifying potential drug therapy problems and,
   e) integrate knowledge of NHPs into patients' individualized care plans.

Comments, justification for ranking, suggestions for rewording Competency #1:

2. **COMPETENCY UNIT AND ELEMENTS**
Pharmacy graduates demonstrate an ability to describe the regulation of NHPs based on Health Canada’s NHP Regulations, including the ability to:
   a) explain the significance of a NPN or DIN-HM on a product and,
   b) explain the difference between a traditional use label claims and a label claim based on scientific evidence.

Comments, justification for ranking, suggestions for rewording Competency #2:

3. **COMPETENCY UNIT AND ELEMENTS**
Pharmacy graduates demonstrate an ability to access and critically appraise sources of information related to NHPs, including the ability to:
   a) find and access credible NHP references
b) identify evidence-based indications for use and expected outcomes for NHPs and,
c) identify clinically relevant potential side-effects, drug interactions, and cautions
associated with NHPs.

Comments, justification for ranking, suggestions for rewording Competency #3:

4. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates provide appropriate education to patients and other health care providers on
the effectiveness, potential adverse effects and drug interactions of NHPs. To accomplish this,
they must have the ability to:
a) integrate knowledge of NHPs into routine education when appropriate and,
b) educate patients and other health care providers about appropriate NHP information
sources.

Comments, justification for ranking, suggestions for rewording Competency #4:

5. COMPETENCY UNIT AND ELEMENT
Pharmacy graduates demonstrate an ability to report suspected adverse drug reactions and/or
drug interactions related to the use of NHPs to Health Canada. This includes the ability to:
a) integrate knowledge of NHPs when investigating suspected adverse drug reactions and/or
drug interactions and,
b) report NHP-related suspected adverse drug reactions and/or drug interactions.

Comments, justification for ranking, suggestions for rewording Competency #5:

6. MISSING COMPETENCIES?
Are there any competencies that you believe are missing from the above listing?

| Yes | No |

If Yes, please add them below:

7. ADDITIONAL COMMENTS?
If you have any additional comments/suggestions, please include them below:
Appendix 21: 3rd Delphi Round Summary

3rd DELPHI ROUND – SUMMARY

The following is a summary of the responses gathered from the 3rd round of the Delphi survey as of November 7, 2008 (n=17).
A mean of >3 ensures that the competency will continue onto the next round of the Delphi. Consensus achieved when all participants rank a statement 4 or 5.

1. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates demonstrate an ability to incorporate NHP knowledge when providing pharmaceutical care, including the ability to:
a) create the opportunity for open dialogue with patients about NHPs
b) inquire about patient NHP usage
c) document patients’ NHP usage when appropriate
d) consider patient NHP usage when identifying potential drug therapy problems and,
e) integrate knowledge of NHPs into patients' individualized care plans.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of response (%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (5.9%)</td>
<td>16 (94.1%)</td>
</tr>
<tr>
<td>Mode</td>
<td>Essential (5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>Very important (4) – Essential (5)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>4.94</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments and suggestions(all)</td>
<td>&quot;c&quot; might be a good place to put &quot;document NHP use and report potential problems if necessary&quot;. I would also move it the last position. for 'd' - could we include actual DRPs as well as potential - I believe these are the terms used in the PC model - a patient may already be taking an NHP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Consensus had been achieved, thus on the 4th Delphi round this question will not have a Likert scale – just a box for any additional wording suggestions

2. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates demonstrate an ability to describe the regulation of NHPs based on Health Canada’s NHP Regulations, including the ability to:
a) explain the significance of a NPN or DIN-HM on a product and,
b) explain the difference between a traditional use label claims and a label claim based on scientific evidence.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (5.9%)</td>
<td>9 (52.9%)</td>
<td>7 (41.2%)</td>
</tr>
<tr>
<td>Mode</td>
<td>Very important (4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>Important, but other core competencies may take priority (3) – Essential (5)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>4.35</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments and suggestions(all)</td>
<td>delete phrase &quot;based on Health Canada's NHP Regulations&quot; and replace with &quot;describe the Canadian regulation of NHPs.... could we also address advertising claims or is this beyond the scope??</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Competency #2 moving onto 4th Delphi round? Yes**

3. **COMPETENCY UNIT AND ELEMENTS**
Pharmacy graduates demonstrate an ability to access and critically appraise sources of information related to NHPs, including the ability to:
   a) find and access credible NHP references
   b) identify evidence-based indications for use and expected outcomes for NHPs and,
   c) identify clinically relevant potential side-effects, drug interactions, and cautions associated with NHPs.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>2 (11.8%)</td>
<td>15 (88.2%)</td>
</tr>
<tr>
<td>Mode</td>
<td>Essential (5)</td>
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<td></td>
</tr>
<tr>
<td>Range</td>
<td>Very important (4) – Essential (5)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>4.88</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments and suggestions(all)</td>
<td>for part C maybe add disease interactions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
*Consensus had been achieved, thus on the 4th Delphi round this question will not have a Likert scale – just a box for any additional wording suggestions

4. COMPETENCY UNIT AND ELEMENTS
Pharmacy graduates provide appropriate education to patients and other health care providers on the effectiveness, potential adverse effects and drug interactions of NHPs. To accomplish this, they must have the ability to:
   a) integrate knowledge of NHPs into routine education when appropriate and,
   b) educate patients and other health care providers about appropriate NHP information sources.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (5.9%)</td>
<td>6 (35.3%)</td>
<td>10 (58.8%)</td>
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<tr>
<td>Mode</td>
<td>Essential (5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>Important, but other core competencies may take priority (3) – Essential (5)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>4.53</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments and suggestions(all)

Competency #4 moving onto 4th Delphi round? Yes

5. COMPETENCY UNIT AND ELEMENT
Pharmacy graduates demonstrate an ability to report suspected adverse drug reactions and/or drug interactions related to the use of NHPs to Health Canada. This includes the ability to:
   a) integrate knowledge of NHPs when investigating suspected adverse drug reactions and/or drug interactions and,
   b) report NHP-related suspected adverse drug reactions and/or drug interactions.
<table>
<thead>
<tr>
<th>Number of responses (%)</th>
<th>0 (0%)</th>
<th>1 (5.9%)</th>
<th>4 (23.5%)</th>
<th>10 (58.8%)</th>
<th>2 (11.8%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode</td>
<td>Very important (4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>Not important as a core competency (2) – Essential (5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>3.76</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments and suggestions(all)</td>
<td>b) needs to say &quot;report.....to Health Canada please check terminology - adverse reaction reporting?? I would actually remove the DI stuff...as we don't actually report drug interactions to Health Canada...just ADRs...at least I THINK this but I COULD be wrong.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Competency #5 moving onto 4th Delphi round? Yes**

6. **MISSING COMPETENCIES?**

Are there any competencies that you believe are missing from the above listing?

<table>
<thead>
<tr>
<th>Options</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>0 (0%)</td>
<td>17 (100%)</td>
</tr>
</tbody>
</table>

If Yes, please add them below:

7. **ADDITIONAL COMMENTS?**

If you have any additional comments/suggestions, please include them below:

Integrating a life-long learning component was identified and this is an important aspect to incorporate and integrate. Knowledge about these products will change and including this as a competency will allow the sustainability of one's competence in this area.

Thanks - it’s been fun and educational!
Appendix 22: 4th Delphi Round Email

Wednesday November 12, 2008
Dear Participants,

**Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies**

Thank you all again for your participation in our invitational consensus building meeting last week. I think we all learned a lot and benefitted from each other’s unique expertise and experience in this area!

Attached are the 3rd round summary results. Based on these results we have decided to do one final Delphi round via email – as we are very close to reaching consensus on two additional statements.

As consensus has been achieved on statements #1 and 3, on the 4th Delphi round these questions will not have a Likert scale - just a box for any additional wording suggestions. Minor wording changes have been made to most statements and have been capitalized to make them easier to see.

Additionally, proposed titles for each competency have been given based on the wording used in NAPRA’s *Model Standards of Practice for Canadian Pharmacists (April 2003)*. Please feel free to add your comments on these titles as well.

Here is the link to the 4th Delphi round – please complete it by **Wednesday November 19, 2008** if at all possible.


Thank you all again!

Sincerely,

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MSc Candidate  
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144 College Street  
Toronto, ON M5S 3M2  
Ph: (416) 946-5859  
Fax: (416) 978-1833  
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HEATHER BOON, BScPhm, PhD  
Principal Investigator  
Associate Professor  
Leslie Dan Faculty of Pharmacy  
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Ph: (416) 946-5859  
Fax: (416) 978-1833  
heather.boon@utoronto.ca
Appendix 23: 4th Delphi Round Questionnaire

4th DELPHI ROUND QUESTIONNAIRE
(Administered using Survey Monkey)

Professional NHP-related Competency #1 – Practice Pharmaceutical Care
Pharmacy graduates demonstrate the ability to incorporate NHP knowledge when providing pharmaceutical care, including the ability to:

a) create the opportunity for open dialogue with patients about NHPs
b) inquire about patient NHP usage
c) consider patient NHP usage when identifying potential and/or actual drug therapy problems and,
d) integrate knowledge of NHPs into patients’ individualized care plans and,
e) document patients’ NHP usage when appropriate.

Comments and suggestions for rewording competency unit/elements and title:

Professional NHP-related Competency #2 – Understand Regulations
Pharmacy graduates demonstrate the ability to describe the Canadian NHP Regulations, including the ability to:

a) explain the significance of a NPH or DIN-HM on a product and,
b) explain the difference between a traditional use claim label and a label claims based on scientific evidence.

Please indicate how important it is that this competency be identified as a core NHP-related competency pharmacy students should have upon entry to practice in Canada:

<table>
<thead>
<tr>
<th>Level of Importance</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranking</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments, justification for ranking, suggestions for rewording Competency #2:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Professional NHP-related Competency #3 – Provide NHP Information
Pharmacy graduates demonstrate the ability to access and critically appraise sources of information related to NHPs, including the ability to:

a) find and access credible NHP references
b) identify evidence-based indications for use and expected outcomes for NHPs and,
c) identify clinically relevant potential and/or actual interactions with drugs or disease states, as well as adverse effects and cautions associated with NHPs.
Professional NHP-related Competency #4 – Educate
Pharmacy graduates provide appropriate education to patients and other health care providers on the effectiveness, potential adverse effects and drug interactions of NHPs. To accomplish this, they must have the ability to:
   a) integrate knowledge of NHPs into routine education when appropriate and,
   b) educate patients and other health care providers about appropriate NHP information sources.
Please indicate how important it is that this competency be identified as a core NHP-related competency pharmacy students should have upon entry to practice in Canada:

<table>
<thead>
<tr>
<th>Level of Importance</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
</table>

Ranking

Comments, justification for ranking, suggestions for rewording Competency #4:

Professional NHP-related Competency #5 – Report Suspected NHP Adverse Events
Pharmacy graduates demonstrate the ability to report adverse events suspected to be related to the use of NHPs to Health Canada. This includes the ability to:
   a) integrate knowledge of NHPs when investigating suspected adverse events and,
   b) report suspected NHP-related adverse events to Health Canada.
Please indicate how important it is that this competency be identified as a core NHP-related competency pharmacy students should have upon entry to practice in Canada:

<table>
<thead>
<tr>
<th>Level of Importance</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
</table>

Ranking

Comments, justification for ranking, suggestions for rewording Competency #5:
6. **MISSING COMPETENCIES?**
Are there any competencies that you believe are missing from the above listing?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If Yes, please add them below:

7. **ADDITIONAL COMMENTS?**
If you have any additional comments/suggestions, please include them below:


Appendix 24: 4th Delphi Round Summary

4th DELPHI ROUND – SUMMARY

The following is a summary of the responses gathered from the 4th round of the Delphi survey as of November 20, 2008 (n=17).

Consensus achieved when all participants rank a statement 4 or 5.

Professional NHP-related Competency #1 – Practice Pharmaceutical Care

Pharmacy graduates demonstrate the ability to incorporate NHP knowledge when providing pharmaceutical care, including the ability to:
   a) create the opportunity for open dialogue with patients about NHPs
   b) inquire about patient NHP usage
   c) consider patient NHP usage when identifying potential and/or actual drug therapy problems and,
   d) integrate knowledge of NHPs into patients’ individualized care plans and,
   e) document patients’ NHP usage when appropriate.

Comments and suggestions for rewording competency unit/elements and title:

No need for the "and" at the end of statements c and d
If this becomes a general competency relating to providing pharmaceutical care, then what would also need to be added, as part of the pharmaceutical care process, would be: f) monitor patients using NHPs appropriately and as the need arises g) counsel patients about NHPs when appropriate and as the need arises
This competency reads very well-I like it! Only comment is on e) why did we decide to put "when appropriate"? I think that could be left out-why would it not be appropriate? -it says they have the ability to document-doesn't mean they always have to....
This looks good.
remove "and" from c)
no changes
no additional comments

Consensus achieved

Will appear as a core competency in the final summary document

Professional NHP-related Competency #2 – Understand Regulations

Pharmacy graduates demonstrate the ability to describe the Canadian NHP Regulations, including the ability to:
   a) explain the significance of a NPH or DIN-HM on a product and,
   b) explain the difference between a traditional use claim label and a label claims based on scientific evidence.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
</table>


Consensus not achieved

Professional NHP-related Competency #3 – Provide NHP Information
Pharmacy graduates demonstrate the ability to access and critically appraise sources of information related to NHPs, including the ability to:

a) find and access credible NHP references
b) identify evidence-based indications for use and expected outcomes for NHPs and,
c) identify clinically relevant potential and/or actual interactions with drugs or disease states, as well as adverse effects and cautions associated with NHPs.

Comments and suggestions for rewording competency unit/elements and title:

in 'c' does the first phrase capture the positive interactions?
for c) instead of "drugs", change to "drugs/herbs"
c is very wordy.
could a be changed to say find, access and interpret
I think c) is getting too wordy. In my opinion, "drug interactions" includes all of "drug-drug", "drug-NHP", "NHP-NHP", "drug-disease", "NHP-disease", etc. Since this element is about information sources, I don't think we need to include "potential or actual" in this bullet. I would be happy with "identify clinically relevant adverse effects, drug interactions, and cautions associated with NHP use."
Drug Interactions usually refer to drug-drug, drug-disease and drug-laboratory interactions
Suggest either using only drug interactions or referring to all, including laboratory interactions
Use "precautions" rather than "cautions" in part c
Consensus achieved
Will appear as a core competency in the final summary document

Professional NHP-related Competency #4 – Educate
Pharmacy graduates provide appropriate education to patients and other health care providers on the effectiveness, potential adverse effects and drug interactions of NHPs. To accomplish this, they must have the ability to:
   a) integrate knowledge of NHPs into routine education when appropriate and,
   b) educate patients and other health care providers about appropriate NHP information sources.

<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>4 (23.5%)</td>
<td>13 (76.5%)</td>
</tr>
<tr>
<td>Mode</td>
<td>Essential (5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>Very important (4) – Essential (5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>4.76</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments and suggestions(all)
I believe this is already an expectation on the part of the general public anyway. i.e. our graduates will be forced into situations where they have to provide these services. So how can our schools NOT include "Educate" as a core competency?
I almost think that the term "when appropriate" could be removed from a Suggest "Pharmacy graduates demonstrate the ability to provide ..."
Suggest using the NAPRA entry-to-practice competencies 2007 description of Communicate and Educate - Effective communication is needed to educate appropriately

Consensus achieved
Will appear as a core competency in the final summary document

Professional NHP-related Competency #5 – Report Suspected NHP Adverse Events
Pharmacy graduates demonstrate the ability to report adverse events suspected to be related to the use of NHPs to Health Canada. This includes the ability to:
   a) integrate knowledge of NHPs when investigating suspected adverse events and,
   b) report suspected NHP-related adverse events to Health Canada.
<table>
<thead>
<tr>
<th>Levels of Importance (weighting)</th>
<th>Unimportant (1)</th>
<th>Not important as a core competency (2)</th>
<th>Important, but other core competencies may take priority (3)</th>
<th>Very important (4)</th>
<th>Essential (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>4 (23.5%)</td>
<td>8 (47.1%)</td>
<td>5 (29.4%)</td>
</tr>
</tbody>
</table>

**Mode**
Very important (4)

**Range**
Important, but other core competencies may take priority (3) – Essential (5)

**Mean**
4.06

**Comments and suggestions (all)**
this is very important as it is a major avenue in obtaining data on safety of NHPs

**Consensus not achieved**

6. **MISSING COMPETENCIES?**
Are there any competencies that you believe are missing from the above listing?

<table>
<thead>
<tr>
<th>Options</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of responses (%)</td>
<td>0 (0%)</td>
<td>17 (100%)</td>
</tr>
</tbody>
</table>

If Yes, please add them below:

7. **ADDITIONAL COMMENTS?**

If you have any additional comments/suggestions, please include them below:
Thank you for the opportunity to participate in this very important initiative.
Good job Ani!
Thanks for all your work on this!
This is great stuff!
Appendix 25: NHPs and Canadian Pharmacy Students: Core Competencies – Review of Final Document

Thursday November 27, 2008
Dear Participant,

**Natural Health Products (NHPs) and Pharmacy Practice: Core Competencies**

We are pleased to be sending you the final document from our invitational consensus building meeting complete with the agreed upon core competencies, along with the 4th Delphi round summary. Please send any feedback or suggestions **before December 15, 2008**.

As a stipulation of our ethics approval we need you all to consent to attaching your name and affiliation to the final document. Please see page 3 of the “Consensus document Nov 27 revised” to review your involvement and please feel free to remove yourself from the list if you do not wish to be identified as a participant for any reason.

We will require your written approval (via email) to attach your name and affiliation to the final report which will be widely distributed beginning **Monday December 15, 2008**. Please do not distribute this version. If you have any questions please do not hesitate to ask.

Additionally, at the end of our meeting some individuals were inquiring about the distribution of all PowerPoint presentations to all participants. Again, please let me know **in writing my Monday December 15, 2008** if I can distribute your Powerpoint slides (if applicable).

Once I have received feedback from all of you I will re-send the final document in PDF form which you will then be welcome to share (hopefully before Christmas).

Thank you again for all your assistance in making this project a success.

Sincerely,

Ani Byrne, BAS (Hons)
MSc Candidate
Leslie Dan Faculty of Pharmacy
144 College Street
Toronto, ON M5S 3M2
Ph: (416) 946-5859
Fax: (416) 978-1833
ani.byrne@utoronto.ca

Heather Boon, BScPhm, PhD
Principal Investigator
Associate Professor
Leslie Dan Faculty of Pharmacy
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Ph: (416) 946-5859
Fax: (416) 978-1833
heather.boon@utoronto.ca
Appendix 26: NHPs and Canadian Pharmacy Students: Core Competencies Summary Report

January 2009

Natural Health Products (NHPs) and Pharmacy Practice: Core Competencies

Since 2005, Dr. Heather Boon and her students have been working on the a series of projects to explore pharmacists’ roles and responsibilities with respect to natural health products. After stakeholder interviews with 35 stakeholder leaders, 16 focus groups with practicing pharmacists and consumers, and a survey of more than 3300 licensed Canadian pharmacists, the project culminated in a consensus meeting to identify NHP-related core competencies for Canadian pharmacy students upon entry to practice.

Because of your involvement or interest in this research, please find attached the final summary report containing the consensus-based NHP-related core competency statements.

Please feel free to disseminate this document widely and if you have any questions or comments do not hesitate to contact us.

Sincerely,

Ani Byrne, BAS (Hons)  
MSc Candidate  
Leslie Dan Faculty of Pharmacy  
144 College Street  
Toronto, ON M5S 3M2  
Ph: (416) 946-5859  
Fax: (416) 978-1833  
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Heather Boon, BScPhm, PhD  
Principal Investigator  
Associate Professor  
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Fax: (416) 978-1833  
heather.boon@utoronto.ca
Natural Health Products (NHPs) and Canadian Pharmacy Students:

Core Competencies Report
from an Invitational Consensus Building Meeting

(November 2008)

Ani Byrne BAS(Hons) (ani.byrne@utoronto.ca)
MSc Candidate - Leslie Dan Faculty of Pharmacy, University of Toronto

Heather Boon BScPhm, PhD (heather.boon@utoronto.ca)
Associate Professor – Leslie Dan Faculty of Pharmacy, University of Toronto

Zubin Austin BScPhm, MBS, MIS, PhD
Associate Professor – Leslie Dan Faculty of Pharmacy, University of Toronto

Tannis Jurgens BScPhm, MSc, PhD
Associate Professor – College of Pharmacy, Dalhousie University

Lalitha Raman-Wilms BScPhm, PharmD
Associate Professor – Leslie Dan Faculty of Pharmacy, University of Toronto
Background and Objectives

More than 70% of Canadians report using natural health products (NHPs) (1). As of 2004, NHPs in Canada are defined as:

any substance found in nature “...that is manufactured, sold or represented for use in: (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in 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 (p.42).”(2)

By definition, NHPs must be suitable for self care and over-the-counter (OTC) use (3). Previous research indicates that a range of stakeholders (consumers, pharmacists, and other health care providers) believe that pharmacists have a key role to play in providing consumers with guidance regarding the safe and effective use of NHPs.(3-8) In addition, pharmacy regulatory authorities are establishing NHP-related standards of practice amidst increased consumer usage (9). However, many pharmacists have little knowledge of NHPs, as undergraduate curricula content varies widely (10). The objective of this project was to identify core NHP-related competencies that pharmacy educators and representatives of pharmacy organizations agree are important for pharmacy students to have when entering pharmacy practice in Canada.

Methodology

This study used a modified Delphi method which culminated at an invitational consensus building meeting held in Toronto on November 6 & 7, 2008. The goal was to develop core NHP-related competencies, consistent with existing competency-based outcomes documents (11-13). The process began with qualitative research that included: a document analysis (4); 35 key informant interviews (6); 16 focus groups with practicing pharmacists and consumers (5), testing of Canadian 4th year pharmacy students’ herbal knowledge (10); and a survey of 3356 licensed Canadian pharmacists (7). The final step was to have “experts,” (i.e., those who are actively involved in teaching about NHPs or setting/enforcing NHP-related pharmacy policies) make the final decision regarding core NHP-related competencies. Study participants (total n=17) including: pharmacy educators from seven of the ten Canadian pharmacy schools (n=8), pharmacy educators from selected U.S. pharmacy schools (n=3), and representatives from Canadian pharmacy organizations (n=6), ranked their agreement with possible core competency statements on a 5-point Likert scale (1=Unimportant, 2= Not important as a core competency, 3= Important, but other core competencies may take priority, 4 =Very important, and 5 =Essential). Four Delphi rounds were completed by all participants and consensus was defined through an iterative process to have been reached when all participants ranked a given statement 4 or 5.

Results

The following statements emerged as core NHP-related competencies for Canadian pharmacy students upon entry to practice:
### Professional NHP-related Competency #1 – Practice Pharmaceutical Care

<table>
<thead>
<tr>
<th>Competency Unit</th>
<th>Competency Elements</th>
</tr>
</thead>
</table>
| Pharmacy graduates demonstrate the ability to incorporate NHP knowledge when providing pharmaceutical care, including the ability to: | f) create the opportunity for open dialogue with patients about NHPs  
g) inquire about patient NHP usage  
h) consider patient NHP usage when identifying potential and/or actual drug therapy problems  
i) integrate knowledge of NHPs into patients’ individualized care plans and,  
j) document patients’ NHP usage when appropriate. |

### Professional NHP-related Competency #2 – Provide NHP Information

<table>
<thead>
<tr>
<th>Competency Unit</th>
<th>Competency Elements</th>
</tr>
</thead>
</table>
| Pharmacy graduates demonstrate the ability to access and critically appraise sources of information related to NHPs, including the ability to: | d) find and access credible NHP references  
e) identify evidence-based indications for use and expected outcomes for NHPs and,  
f) identify clinically relevant potential and/or actual interactions with drugs or disease states, as well as adverse effects and precautions associated with NHPs. |

### Professional NHP-related Competency #3 – Educate

<table>
<thead>
<tr>
<th>Competency Unit</th>
<th>Competency Elements</th>
</tr>
</thead>
</table>
| Pharmacy graduates demonstrate the ability to provide appropriate education to patients and other health care providers on the effectiveness, potential adverse effects and drug interactions of NHPs. To accomplish this, they must have the ability to: | c) integrate knowledge of NHPs into routine education when appropriate and,  
d) educate patients and other health care providers about appropriate NHP information sources. |

### Funding
Funding for this study was provided by: the Canadian Institutes for Health Research (CIHR) Partnerships for Health System Improvement (PHSI) grant, as well as the Advanced Foods & Materials Network (AFMNet) National Centre of Excellence (NCE).

### Delphi Participants
The following individuals were participants of this study and have consented to have their names and affiliations appear on the final document:
Heather Boon – University of Toronto  
Lana Dvorkin-Camiel – Massachusetts College of Pharmacy and Health Services  
Lynda Eccott – University of British Columbia
Shirley Heschuk – University of Alberta
Derek Jorgenson – University of Saskatchewan
Tannis Jurgens – Dalhousie University
Rebecca Law – Memorial University of Newfoundland
Susan Mansour – Canadian Council for Accreditation of Pharmacy Programs (CCAPP)
Ken Potvin – University of Waterloo
John Pugsley – Pharmacy Examining Board of Canada (PEBC)
Cynthia Richard – University of Guelph/University of Waterloo
Stephen Shalansky – Canadian Society of Hospital Pharmacists (CSHP)
Kelly Shields – Ohio Northern University
Saeed Tavakoli – Undergraduate Pharmacy Society – University of Toronto
Candy Tsourounis – University of California, San Francisco
Alexander Vuong – Canadian Association of Pharmacy Students and Interns (CAPSI)
Margaret Wong – Ontario Pharmacists’ Association (OPA)

References
Appendix 27: Ethics Approval (July 8, 2008)

University of Toronto
Office of the Vice-President, Research
Office of Research Ethics

PROTOCOL REFERENCE #23084

July 8, 2008

Dr. Heather Boon  Ms. Ani Byrne
Faculty of Pharmacy  Faculty of Pharmacy
144 College St.  144 College St.
Toronto, ON M5S 3M2  Toronto, ON M5S 3M2

Dear Dr. Boon and Ms. Byrne:

Re: Your research protocol entitled “Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies”

ETHICS APPROVAL  Original Approval Date: July 8, 2008
Expiry Date: July 7, 2009
Continuing Review Level: 1

We are writing to advise you that a member of the Health Sciences Research Ethics Board has granted approval to the above-named research study, for a period of one year, under the REB’s expedited review process. Ongoing projects must be renewed prior to the expiry date.

The following consent documents (received June 24, 2008) have been approved for use in this study: Letter of Invitation, Letter of Information, Consent Form and Reminder Notice.

Any changes to the approved protocol or consent materials must be reviewed and approved through the amendment process prior to its implementation. Any adverse or unanticipated events should be reported to the Office of Research Ethics as soon as possible.

Best wishes for the successful completion of your project.

Yours sincerely,

Jenny Peto
Research Ethics Coordinator

xc: Mr. W. Maurice (Grants Officer, Health Sciences)
Appendix 28: Ethics Approval – Amendments (September 10, 2008)

University of Toronto
Office of the Vice-President, Research
Office of Research Ethics

PROTOCOL REFERENCE #23084 September 10, 2008

Dr. Heather Boon
Faculty of Pharmacy
144 College St.
Toronto, ON M5S 3M2

Ms. Ani Byrne
Faculty of Pharmacy
144 College St.
Toronto, ON M5S 3M2

Dear Dr. Boon and Ms. Byrne:

Re: Your research protocol entitled “Natural Health Products (NHPs) and Canadian Pharmacy Students: Core Competencies” (Amendment received August 21, 2008) by Dr. H. Boon (supervisor), Ms. A. Byrne (Master’s student)

We are writing to advise you that a member of the Health Sciences Research Ethics Board has granted approval to an amendment to the above referenced research study under the REB’s expedited review process. This amendment involves minor wording changes to the Survey Questionnaire.

The following documents has been approved for use in this study: Delphi Round 1 Version Date: June 24, 2008 (Appendix 1).

Any changes to the approved protocol or consent materials must be reviewed and approved through the amendment process prior to its implementation. Any adverse or unanticipated events should be reported to the Office of Research Ethics as soon as possible.

Best wishes for the successful completion of your project.

Yours sincerely,

Marianna Richardson
Research Ethics Coordinator