

# **Traditional Chinese Medicine Products Research at Canadian Universities: Capacity and Challenge.**

Prepared for NHPRP, Health Canada

By EMK Lui, PhD

Associate Professor

Department of Physiology and Pharmacology

University of Western Ontario

and

President of the Canadian Institute of Chinese Medicinal Research

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## Summary

This overview document is concerned with identifying current research capacity in Traditional Chinese Medicine (TCM) products at Canadian universities and challenges faced by researchers in this area of research. Information was collected by an electronic survey, telephone interviews, research on internet web-sites and publications.

There are at least a total of 30 scientists/researchers from universities and associated research institutes across Canada who are currently involved in TCM products research. The majority of them are considered as part of a multi-disciplinary team, engaging in broader NHPs- or CAM-based research programs. A few of them do have collaboration with the industrial sector, TCM practitioners, and with researchers from Hong Kong/China.

Preclinical and clinical studies on the efficacy of TCM products represent the strength of the research community. Since products classified for traditional and non-traditional uses normally carry health claims that are based on TCM principles; this may pose a challenge for regulators and researchers, who are more familiar with the biomedical systems of health and disease. However, research evaluating modification of organ structure/function and adaptogenic effects of TCM products may be appropriate for dealing with this difficulty. A new CIHR-funded research initiative which is designed to examine the efficacy of TCM treatments using a combination of conventional and TCM principle-based strategies in both diagnosis and outcome measurement will have a strong impact on our understanding of TCM products. Research on treatment of or risk reduction for diseases classified under *Schedule A* would have less direct relevance to the regulatory function of NHPD, which has a specific mandate for self care products.

The research effort in the area of product quality and safety is less intense; however, these are important areas of research that would support NHPD's role in the regulation of TCM products.

Currently, there is very limited research activity on information resources and health services; most of the information available comes from larger studies dealing with CAM use. Consequently, there is very limited information re the utilization, demographics and cultural determinants of TCM product use as well as consumer attitude towards the use of TCM products. However, we do have excellent potential resources in this area of research that could be called upon if funding is made available.

With regard to challenges faced by researchers, lack of "funding" and "leadership and research priority" were the obvious top two concerns. Other expressed challenges were related to issues concerning human resources, lack of critical mass in specific research areas, reliable sources of good quality products for research and a lack of recognition of significance of TCM research by peers as well as limited availability of competent TCM practitioners with interest in collaboration. The role of funding agencies and several organizations (NHPR Society, Canadian Institute for Chinese Medicinal Research, In-CAM) in the promotion and support of TCM products research was discussed.

The relevance of current research to the regulatory function of NHPD was discussed, emphasizing the importance of effective knowledge transfer to the consumers for the promotion of safe and responsible use of TCM products. Some of the strategies

for translating TCM-based health claims and possible side effects into terminologies that would make sense to the average Canadian consumers were discussed. Finally, recommendations for priority setting in research were presented.

## **I. Objective**

To prepare an overview document concerning the current research capacity in Traditional Chinese Medicine (TCM) products at universities and related research institutes/organizations in Canada and to identify challenges faced by researchers in this area of research. The information provided by this document will be used by the discussants at a small consultation meeting sponsored by the NHPD to develop an agenda for a larger meeting later this year to identify what types of research the NHPs Research Program (NHPRP) should fund to support Health Canada's regulatory function. Because of this reason the relevance and implications of the present findings in TCM products research will be discussed in the context of the regulatory function of Health Canada.

### **Definition of TCM products**

In this document "TCM products" are taken to mean "finished TCM products and proprietary products". A finished product is one that has undergone all stages of production, including packaging in its final container and labeling. A single TCM formula or product may contain between six to twenty different ingredients; a recent survey on natural substances used as Chinese medicinal materials showed that 86.8%, 12.5%, and 0.7% of the products examined could be classified as herb, animal, and mineral, respectively (Way forward for Chinese medicines. Editor K. Chan and H. Lee, Taylor and Francis, 2002).

## **II. Historical perspectives**

Research in TCM products in Canadian universities has a relatively short history. Over the last ten years, there has been a shift in the attitude of Canadians in managing their health: increase awareness of holism and better sense of self-control of one's health, and the belief in freedom of choice in health-related matters. Moreover, there has been a significant increase in popularity of complementary and alternative medicine (CAM); and its use among Canadians. The consumers have expressed their desire for freedom of choice in selecting CAM and in obtaining safe effective and good quality natural health products (NHPs), including TCM products.

Recent advances in TCM education and research in China has led to a revitalization and modernization of this traditional system of health. This movement has brought about the concept and practice of integrative medicine as well as the introduction of many new TCM products. These products have been made available to Canadian, directly for self care or under the supervision of TCM practitioners or naturopathic doctors. It should be pointed out that there is a paucity of information regarding the prevalence, patterns of use as well as population and cultural determinants of TCM products use among Canadians.

Product quality is particularly important to TCM products because of published reports of adulteration, contamination, inappropriate use and labeling as well as wrongful substitutions of products that have resulted in occurrence of adverse events associated with their use. Low compliance to good manufacturing practices (GMP) in the manufacturing of TCM products in China has raised concern about the quality, safety, and efficacy of TCM products that are currently available in the Canadian market place.

Despite of long history of traditional use of many TCM products and documentation of their use in classical medical literatures, there is paucity of good quality clinical trials that support their purported use. In addition, significant numbers of these TCM products have been marketed with health claims that are based primarily on TCM principles and in most cases have no apparent correlation to the conventional biomedical model of health and disease that most Canadian consumers and conventional health care practitioners are accustomed to.

### **III. Methodology of this report: collection of information**

1. Survey by email (Appendix 1) distributed by Board of Directors of Canadian Institute of Chinese Medicinal Research (CICMR) and via the Canadian Interdisciplinary Network for CAM Research (In-CAM).
2. Telephone/personal interviews with Canadian researchers engaged in TCM research.
3. Independent search: internet website of Canadian universities and associated health research network; publications by Canadian researchers in peer-reviewed journals in last five years (Pub Med and SciFinder Scholar) using TCM or Chinese herbal medicines as key words; conference proceedings.
4. Consultation with Board of Directors of CICMR.

### **IV. Current capacity of research in TCM products**

#### **Results of information collection**

Because of the time constraint and limited level of financial support /resource, a relatively small scale survey was accomplished. Most of the information presented was derived from the electronic survey, interviews with researcher and consultation with Board of Directors of CICMR. Research services department/research office of major Canadian universities and health research networks were not able to provide much data relating to TCM products research, while search on university research web sites did provide some useful information. Search of peer-reviewed publications by Canadian researchers yielded only limited numbers of manuscripts in the last five years; it is not certain whether use of more specific search strategy relating to TCM products would give better results.

Review of proceedings from the First and Second Annual NHPR Conference showed that there were 19-22 presentations that were related to TCM research (Table 1). Preclinical studies were most popular among university-based researchers, clinical studies and health services research had a better participation in the 2<sup>nd</sup> meeting. Reports on quantitative/qualitative chemical analytical studies were provided by the industry sector and government agency (RNC), though the work of a few academic researchers were related to product contaminations and safety (drug-NHP interactions) issues. With regards to the products involved, ginseng was the most commonly cited one.

Table 1. Number of TCM-related presentation at the NHP Research Conferences.

NHPR conference	Qualitative/quantitative chemical analysis	Product contamination	Safety	Preclinical	Clinical	Health Services
First	4(industry/govt)	3	2	11	1	1*
Second	1 (govt)	0	2	9	3	4*

\* including studies that were relevant to TCM products research

Results obtained from the survey and consultations/interviews are summarized in Table 2 and will be discussed below. As shown in Table 2, there are at least a total of 30 scientists/researchers (the number in bracket) from universities and associated research centers across Canada who is currently involved in TCM products research. Although the majority of them are basic scientists who hold appointments in the Faculties of Science, Health Science or Medicine, significant numbers of researchers with clinical and social science expertise are also making significant contribution.

### **Preclinical study**

Currently there are at least 18 preclinical studies that examine the beneficial effects of TCM products on clinically significant conditions or diseases, such as cancer, inflammatory diseases, loss of various organ structure and function (Table 2). The focus on these disease categories is likely due to the training/experience of the researchers involved in this type of research as well as the competitiveness for funding from major granting agencies, which generally give higher priority to research projects that would yield more “clinically significant” results. Most of the current preclinical research is based on state-of-art biomedical and molecular methodologies and techniques; these are not likely to have any apparent relevance, with our current knowledge base, to health claims of TCM products that are often based on TCM principles. However, for products that could be classified as adaptogens or modulators of organ structure-function in the context of TCM principles, biomedical research may have useful applications.

In addition, preclinical studies may provide further evidence on purported biological activity (mechanism of action) of TCM products (specifically Chinese medicines herbs) that will contribute to the overall evidence on safety and efficacy of these products.

**Table 2. Capacity of research involving TCM products** (# in brackets represent number of principal researcher involved in a specific field of study)

Nature of research	Field of study	Study endpoints and TCM correlates
<b>i) QUALITY</b>		
Descriptive Standardization Dosage form, extraction	Markers for standardization (3) Quantitative analysis (3) Product development- arthritis, cancer, infection (5)	
<b>ii) EFFICACY</b>		
<u>Preclinical (biomedical) :</u> Descriptive Methodology development Mechanism/biological plausibility	Anti-cancer (4) Anti-inflammatory (4) Immuno-modulatory (3) Cardiovascular protective (3) Hepato-protective (2) Neuropharmacological (1) Pulmonary-protective (1) Pharmacological markers (4)	Adaptogen, modulator of organ structure-function (relevance to concept of tonics and modulator of Qi)
<u>Clinical</u> Research methodology, study design  Product trials	-Conventional trial (4) -Integration with TCM principles (2)  -Cancer, chemo-prevention (1), -Mental health (2) -Pediatrics health (2)	Quality of life Conventional clinical and TCM-based outcomes.
<b>iii) SAFETY</b>		
Product quality	Contaminations, adulteration (2)	
Preclinical	Herb-drug interactions (3) Predictive modeling (1)	Pharmacodynamics Pharmacokinetics
Clinical	Monitoring, adverse event reporting, evaluation (3)	
<b>iv) INFORMATION RESOURCE AND OUTREACH</b>	<u>Health services</u> Utilization, attitude, psychosocial and cultural determinants.(4) Education of consumers and practitioners (2)  <u>Health economic analysis</u> (1)	Use and misuse; Monitoring, case reporting

### **Clinical study**

There are basically two types of clinical research that are currently conducted in Canada: methodology/study design and clinical trials (Phase I and II) of TCM products. There is an on-going phase II trial of ACAPHA in former smokers with IEN, which is headed by Dr S. Lam and is funded by the National Cancer Institute of the USA from 10/01/2002 to - 09/30/2007 for a total project award of \$4,710,376 USF. In addition to this type of conventional clinic trial design, there is a novel, multi-disciplinary approach being initiated. A one year funding of \$309,810 from the Canadian Institutes of Health Research (CIHR) was announced in Jan 2005 ([www.cihr-irsc.gc.ca/e/26139.html](http://www.cihr-irsc.gc.ca/e/26139.html)) to support a pilot randomized clinical trial to study the effect of traditional Chinese herbal medicine, acupuncture, massage and qigong on improving quality of life of cancer patients. According to Dr. Collet, a combination of conventional and TCM principle-based strategy in both diagnosis and outcome measurements will be used to examine the efficacy of TCM treatments in cancer; and TCM practitioners are an integral part of this research project. Studies like this will help to validate TCM principles or tradition in clinical medicine. Although this type of study will focus on cancer treatment, other TCM syndromes will also be examined. In this and other clinical trials (on-going or pending), quality of life as a treatment outcome has been emphasized. Recent progress in quantitative quality of life measurement has been made, including clinical studies concerning the use of TCM modalities.

Current areas of clinical research focus on cancer, pediatrics, and mental health. The quality of the major Canadian clinical trials on TCM products are of high caliber as reflected from the agencies that fund these major Canadian studies as indicated in the above.

### **Safety**

Safety and product quality issues have received less attention from Canadian researchers. Safety aspects of TCM products are normally addressed as a component of most clinical trials, but there is limited expertise in conducting toxicological studies, particularly with respect to testing in laboratory animals. Although the potential adverse consequence of herb-drug interactions are generally ranked very high in priority by physicians, researchers and regulators, up to now there has not been any organized and focused effort in this area of research. Lack of funding and absence of strategic research plans as well as limited availability of appropriate experimental models could be the contributing factors to the paucity of this type of research.

### **Product quality**

Although the quality of TCM products has been recognized as the one of the most critical factors in determining the safety and efficacy of NHPs, Canadian researchers employed in academic centers are less concerned with this issue as compared with their counterpart from industry. There are three university-based laboratories that have the capability of carrying out chemical standardization; more recently two initiatives have been established to study the use of pharmacological markers for product standardization.

### **Information resources and health services research**

Currently, there is very limited research of this nature directed at TCM products; most of information available comes from larger studies dealing with CAM use (H. Boon et al. 2000. Use of complementary/alternative medicines by breast cancer survivors in Ontario: prevalence and perceptions. *J Clinical Oncology*. 18: 2515-2521). Consequently, there is very limited information about utilization, demographics and cultural determinants to select TCM products as well as consumer attitude towards TCM products. There are, however, initiatives being considered to deal with the education of TCM practitioners and particularly in case reporting of adverse events.

### **Educational programs**

Although there is no formal graduate program in TCM research, researchers with membership at the Faculty of Graduate Studies of their respective university do supervise graduate students in their areas of expertise. International graduate students exchange program has been under discussion/negotiation between universities in Hong Kong and some Canadian universities.

In some medical schools, TCM products are covered as part of the CAM curriculum for undergraduate medical education and more specifically under NHPs. The National Working Group in Undergraduate Medical Education (UME) was formed under the leadership of Dr. M. Verhoef two years ago; it currently has representatives from most if not all medical schools in Canada. It is expected that there will be a national curriculum in CAM for UME in the near future. With the seed funding from NHPRP, a NHPs curriculum for UME is being established as part of this larger initiative; and TCM as well as TCM products are included in this curriculum development effort.

### **Organization, infrastructure, and impact of national networks on TCM products research**

Although the principal investigators who have been identified in this project are recognized as independent researcher, the majority of them are considered part of a multi-disciplinary team, engaging in broader NHPs- or CAM-based research programs. A few of them do have collaboration with the industrial sector (5), TCM practitioners (4), and with researchers from Hong Kong/China (6).

The formation of **NHP Research Society**, which was recommended by previous consultation sponsored by NHPD, has enhanced the networking among Canadian TCM products researchers. This was reflected in the number of TCM-related presentations at the Annual NHP Research Conferences as previously discussed. Moreover, the idea of the formation of a national organization dealing with Chinese medicinal research was conceived by several researchers at the First Annual NHPR Conference in 2004; and this has subsequently led to the formation of the **Canadian Institute of Chinese Medicinal Research (CICMR)** in September of 2004.



The mission of the Institute is to promote the safe and responsible use of Chinese medicines. Important to this mission is the generation of credible (or reliable) evidence from fundamental and clinical research that are supported by a strong national and international collaborative network, translation of this evidence to the consumer community, and training of highly qualified personnel to add capacity of those engaged in research, product development and regulation, education advocacy on the use of Chinese medicinal products through out Canada.

**Table 3. Organization of CICMR**

<p><b>President:</b> Edmund Lui (University of Western Ontario)</p> <p><b>Vice-Presidents:</b> Jean-Paul Collect (McGill University) Yuewen Gong (University of Manitoba) Francis Law (Simon Fraser University)</p> <p><b>Hon Secretary:</b> Joseph Tai (University of British Columbia) Patrick Choy (University of Manitoba) (past Hon Secretary)</p> <p><b>Hon Treasurer:</b> Stephen Lam (BC Cancer Agency)</p> <p><b>Regional Directors:</b> Thor Arnason (University of Ottawa) Chris Siow (University of Manitoba) Carmen Tamayo (University of Western Ontario)</p>	<p><b><u>Advisory Board:</u></b></p> <p>Kelvin Chan (HK Baptist University) Peter Chan (Health Canada) Keji Chen (Beijing) Zhouhan Hu (China) Brad Lau (Macao) Pin-Chung Leung (Chinese University of HK) Timao Li (Health Canada) Ricky Man (University of HK) Pingniang Shen (China) Michael Smith (Health Canada) Sunita Vohora (University of Calgary)</p>
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Several initiatives have already been launched: i) the First Annual Conference on the Medicinal Use of Chinese Herbs was held in September of 2004; ii) filing of application for a non-profit organization status in Feb 2005; iii) the 2<sup>nd</sup> Annual Conference on the Medicinal Use of Chinese Herbs has been set for September, 2005 in Vancouver; iv) the creation of a web-site for communication and promotion of TCM research. The web site will be administered by Bepress Electronic Publishing Co and will be linked to the Journal of Complementary and Integrative Medicine. This will serve as information resources for researchers, health care practitioners, and consumers concerning regulations, product safety, and latest development in TCM research/practice both nationally and internationally as well as funding opportunities in North America and abroad.

This institute is believed to be in a position to provide strong leadership role in dissemination of information as well as forming the nucleus of a virtual research center linking scientists and health professionals to further research in TCM.

**Canadian Interdisciplinary Network for CAM Research (In-CAM)** was established in September 2003 to develop CAM research priorities, build CAM research capacity, promote CAM knowledge transfer and develop strategic partnerships. Unfortunately, biomedical and clinical researchers involved in TCM products research do not normally associate themselves with other CAM research/researchers and as such have limited interaction with this organization. Efforts are being made to enhance interaction between the two organizations, e.g. a plan for CICMR to participate in the In-CAM conference scheduled for December 2005 is being discussed.

#### **Potential resources in TCM products research**

According to the survey, the majority of researchers have expressed very favorable responses regarding the potential resources for TCM products research in their institutions. Both research expertise and facilities could be directed to TCM products research if funding is made available. These areas of research may include: quantitative chemical analysis, biomedical sciences, chemical and biochemical engineering, social sciences and clinical trial. This is particular true in the area of “information resources and health services research” in which current research activity is relatively limited. Role of In-CAM in fostering collaboration among researchers in this area of researcher would be invaluable.

#### **V. Challenges faced by researchers involved in TCM products studies**

The ranking of the “challenges” identified in the survey in decreasing order of importance are presented below:

1. Funding and appropriate/competent personnel for peer-review.
2. Leadership, research priority.

3. Human resources (recruitments), support for trainees, lack of critical mass in specific research areas.
4. Product quality: Lack of standardized products, multiple name brands of the same formula, counterfeit products, purity, stability and consistency.
5. Lack of recognition of significance of TCM research by peers.
6. Lack of availability of competent TCM practitioners interested in collaboration.
7. Lack of opportunity and mode/forum of communication among researchers/practitioners/industry/government agencies at national and international level.
8. Information resources. Lack of relevant peer-reviewed publication/data in English/French: latest research findings, report of adverse events associated with use, historical/ethnobotanical/traditional use information; product monographs, access to Chinese data bases; usage patterns and trends in sale.

It should be acknowledged that because of the relatively small sample size and differences in the backgrounds and expertise of the researchers that participated in the survey; the order of the ranking may not truly reflect the opinion of researchers in a specific field of study. However, lack of “funding” and “leadership and research priority” were the obvious top two concerns.

The survey showed that lack of funding is unanimously the most significant challenge. Since majority of the researchers involved in TCM products research are considered part of a multi-disciplinary team, engaging in broader NHPs- or CAM-based research programs, it is difficult to identify the exact source of their funding at this time. Although a few current TCM projects have received funding from CIHR and NSERC, significant numbers of researchers are dependent on foundations, charitable organizations, and internal sources from home institutions for support. It has been pointed out by researchers that funding from CIHR for clinical trials is much more limited as compared to the US agencies. It is hoped that the new partnership in NHP research funding between NHPD and CIHR will improve the profile of NHP research and opportunity for funding. The Collaborative Health Research Projects (CHRP) program which is administered jointly by NSERC and CIHR should be a source of funding for TCM products research, since the objective of this program is to: i) advance interdisciplinary research leading to knowledge and technologies useful for improving the health of Canadians; ii) promote the translation of research results to users/stakeholders; and, iii) train highly qualified people in collaborative and interdisciplinary research of relevance to health.

The Holistic Health Research Foundation of Canada was launched in November 2004. Its mandate is to support and fund i) multi-disciplinary, outcomes-based research in

complementary therapies; ii) public awareness and information activities regarding the safe and effective use of complementary therapies; iii) dialogue between complementary and conventional health professionals towards a common vision. It is anticipated that TCM products research should fall within the mandate of this foundation.

It appears that significant progress in TCM products research at Canadian universities has been made in a relatively short period of time; however, organizational activity at the national level could be improved upon. With appropriate leadership, well defined research priorities, and availability of funding, our research productivity and impact in TCM products research will be greatly improved. It is hope that collaborative effort among the research networks/organizations, government funding agencies and NHPRP will bring new and sustainable TCM products research of relevance to health.

## **VI. Relevance of current research to the regulatory function of NHPD**

To critically assess the impact of TCM products research currently conducted in Canadian universities in the context of the regulatory function of Health Canada, one has to examine the research activity in view of the mandate of NHPD in the regulation of NHPs. One aspect is registration of TCM products in the Canadian market applicable to the manufacturing and importing industry; the other is concerned with the responsibility to the consumers and indirectly to the health care practitioners. It is our understanding that product licensing requirement may vary depending on whether the products are for traditional or non-traditional use. It is critical to have good understanding of the traditional formulae with respect to their health claims and to determine whether these could be translated into meaningful or appropriate biomedical terminology.

**Table 4. Basis for the regulation of TCM products: role of research**

<b>Regulatory Function</b>	<b>Information base required</b>	<b>Research support</b>
<u>Product registration</u>		
<u>Guideline for industry:</u> Health claims for products - Traditional and non-traditional use - Self care	Classical literature for validation Understanding of TCM based-claims in biomedical terms	Research and interpretation of literature on traditional formulae and indication in both TCM and biomedical terminology. Clinical trials to provide scientific evidence of safety and efficacy. Application of quality of life measurement
Product quality	Markers for multi-component products	Standardization
Safety	Adulteration, contamination	Chemical analysis: phytochemicals, heavy metals, drug, solvent and

		pesticide residues.
<u>Consumers/practitioners</u> Proper use and misuse	Prevalence, usage pattern, attitude	Health services research
To prevent or minimize adverse events associated with self-care	Identify population at risk: pediatrics and geriatrics; pregnancy, HIV-positive	Epidemiology, social sciences, toxicology/pharmacology
Knowledge transfer- Education of: - consumer (indication) - practitioner (monitoring of adverse event)	Translation of TCM-based health claim to biomedical correlates for outreach activity. Herb-drug interactions	Literature review and hypothesis testing by research Design of case reporting mechanism and health services research

One of the new research initiatives as discussed in the above section is designed to examine the efficacy of TCM treatments using a combination of conventional and TCM principle-based strategies in both diagnosis and outcome measurements. This type of research will have a strong impact on the appropriate use of TCM products, but more research should be encouraged to translate and validate terminologies that are used in TCM diagnosis. It should also be noted that there are recent publications (e.g. C. Kwong-Robbins. 2004. Traditional Chinese Medicine: Treatment of Cardiovascular Disease, U.S. Pharmacist.vol 29 (02) [www.uspharmacist.com](http://www.uspharmacist.com)) about the use of TCM treatments in the context of allopathic medicine, e.g. a patient with a TCM holistic diagnosis of damp and phlegm accumulation in blood/Qi deficiency with blood stasis/kidney yang deficiency could be equated to an allopathic diagnosis of hypercholesterolemia and mild atherosclerosis. Similarly, a case of heart and kidney disharmony/liver yang rising/upward disturbance of liver wind could be related to a condition of essential hypertension. This information and approach are relevant to TCM products research and regulation, but further research is required for scientific validation. In addition, the biomedical basis of TCM treatment has been examined: e.g. the neuroprotective role of the external Qi of Yan Xin Life Sciences and Technologies in cultured retinal neurons was published by Yan et al in Brain Res 2004, 1006: 198-206. It is envisioned that similar types of research could be accomplished with a multi-disciplinary team of Canadian researchers/practitioners with clinical, biomedical and TCM expertise. Quality of life measurement has been examined in several clinical studies and should find application in the evaluation of TCM products, particularly if the quantitative aspects of this endpoint could be established.

One of the mandates of NHPD is to focus on NHPs for self care; and this is an important factor to consider in developing research priorities. Research activities that are directed at treatment of diseases classified under *Schedule A* may have little direct relevance; however, research findings on TCM products activity on organ structure and function, particularly those that act like adaptogen, would be applicable to issues

concerning traditional and non-traditional uses of TCM products. Phase II and III clinical trials are very expensive. To rapidly screen TCM products for specific applications, it is important that research be directed towards development and validation of pre-clinical models that are integrated with modified Phase I clinical trials in the human so that only promising products will undergo Phase II and III clinical trials. These areas of research could also enhance our understanding of TCM based-health claims in biomedical terms.

The research effort in the area of product quality and safety is less intense; however, these are important areas of research that would support NHPD's role in the regulation of TCM products. This is highly relevant in light of the published reports of adulteration, contamination and wrongful substitutions of TCM products as well as the findings of low GMP compliance among manufacturers of TCM products in China. Establishment of a quality control centre in Canada may ensure that TCM products imported from China do meet GMP standards.

The outreach for consumers in the safe and responsible use of TCM products must involve effective knowledge transfer. The importance of translating TCM-based health claims and possible side effects into terminologies that would make sense to the average Canadian consumers (and to some extent physicians) are being recognized and some of the strategies for promoting this have already been covered in the above discussion. Health services research should be an important contributor. Although there is limited current research in this area, we do have excellent potential resources (particularly via In-CAM) that could be called upon if funding is made available. In addition, there is a paucity of information regarding the extent of use and usage pattern of TCM products in Canada as well as their labeling information and nature of their health claims. These should be considered as new initiatives in TCM products research.

## **VII. Recommendations and Relationship to findings of previous consultation conducted by NHPD on NHPs**

### **Recommendations:**

1. Examine the characteristics of TCM products in the Canadian market (health claims and labeling practices) and consumer usage patterns.
2. Develop research models to examine health/disease paradigms with particular focus to the relationship between TCM and biomedical/social sciences.
3. Support infrastructure for multi-disciplinary research. Promote translational research collaboration among basic scientists, clinicians and TCM practitioners.
4. Support basic and clinical research that addresses the use of self-care TCM products.
5. Knowledge transfer to consumers and practitioners to promote safe and responsible use of TCM products.

6. Build infrastructure and support research to standardize TCM products in Canada.

Our recommendations are designed to address the unique characteristics of TCM products and specific challenges that are related to the regulation of these products; however, we do agree in general terms with the findings of previous consultations sponsored by NHPD. This includes the support of study on usage patterns, development of research models, and knowledge transfer.

**Appendix 1.**  
**Survey of Research Capacity and Challenge in Traditional Chinese Medicine**  
**Finished Products in Canada**

*Part I*

**A. Research activity and capacity**

**1. Overall objective(s) of your research:**

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**2. Types of current research**

**2.1 Quality:**

- Descriptive: monitor product quality, contamination, adulterations, purity
- Standardization: Chemical markers, chemical fingerprinting;  
Pharmacological/biological markers
- Identification, authentication, DNA fingerprinting
- Dosage forms, extraction
- GMP, GAP
- Others

**2.2 Efficacy:**

**2.21 Basic**

- Descriptive: biological/pharmacological effects; screening test
- Methodology development
- Mechanism/biological plausibility



- Others

### **2.2.2 Clinical**

Standard of evidence

- Methodology
- Study design: conventional, integration with TCM principles/practices, N = 1 study, case study reporting
- Endpoint measurements - quality of life; placebo effect; ethics.
- Product trials – as sole agent; adjunctive treatment
- Others

### **2.3 Safety:**

- Herb-drug interactions (pharmacodynamics, pharmacokinetics); predictive modeling
- Toxicity testing *in vitro* and *in vivo*
- Monitoring, reporting and evaluation
- Others

### **2.4 Information resources and education of health care professional and the public:**

- Health services research: Utilization, attitude, practitioner and consumer education
- Psycho-social, population and cultural determinants studies (use and misuse)
- Health economic analysis
- Other

### **2.5 Product development (if not already covered in the above)**

## 2.6 Others

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## 3. Resources

- TCM-specific
- Part of a NHP research program
- Potential resources that could be directed towards TCM if funding is made available:
  - \*Quantitative chemical analysis
  
  - \*Basic medical Sciences: Pharmacology/Toxicology/Clinical pharmacology/immunology/ microbiology/medicine/oncology
  - \*Engineering (Chemical/biochemical)
  - \*Social Science, anthropology.
  - \*Epidemiology
  - \*Informatics
  - \*Others
  
- Availability of training/educational program

## 4. Research Funding

### 4.1 Level of Support

- Current funding
- Pending
- Application not funded
- Tentative planning

### 4.2 Source of Funding

- Government agency (NSERC, CIHR, Agri Food etc)
- Foundation and charitable organizations
- Internal funding from university, research institute, hospital
- Through international collaboration
- Others

**5. Scope of Research:**

- Primary focus on TCM
- Part of a large program

**6. Organizational aspects**

- Individual
- Multi-disciplinary and nature of collaboration: medical science, medicines, science, social science, engineering science
- Collaboration with TCM school/TCM practitioners
- Collaboration with industry (service contract)/government agency
- National and international collaboration
- Others

**B. Challenges facing researchers: Please rank the following in order of their importance.**

- Product quality: Lack of standardized products, multiple brands of the same formula, counterfeit products, purity and consistency
- Funding and appropriate/competent personnel for peer-review
- Leadership, research priority
- Human resources (recruitments), support for trainees, lack of critical mass in specific research areas
- Availability of competent TCM practitioners interested in collaboration
- Lack of recognition of significance of TCM research by peers
- Information resources: Lack of relevant and peer-reviewed publication/data in English/French: latest research findings, report of adverse events associated with use, historical/ethnobotanical information, usage pattern, trends in sale.
- Lack of opportunity and mode/forum of communication among researchers/practitioners/industry/government agency at national and international level.

- Others

***Part II***

a) Name, position and contact information

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b) Affiliation

- University  
 Research Institute  
 School of Traditional Chinese Medicine  
 Governmental agency with adjunct appointment at an university  
 Industry with adjunct appointment at an university  
 Other \_\_\_\_\_

**THANK YOU!!**

Please return the completed survey to [elui@uwo.ca](mailto:elui@uwo.ca) or by fax: 519-661-3827