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**Natural Health Products Research Program
Research Priority Setting Consultation on Homeopathic
Medicine in Canada: An Invitational Roundtable**

*Ottawa
January 10-11, 2005*

Report

Prepared by

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Natural Health Products Research Program Research Priority Setting Consultation on Homeopathic Medicine in Canada: An Invitational Roundtable

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Ottawa January 10-11, 2005*

The views expressed in this document are those of the conference participants and do not necessarily represent those of the Natural Health Products Research Program, Natural Health Product Directorate, Health Canada.

Executive Summary:

Background

In addition to its role as product regulator, the Natural Health Products Directorate is tasked with supporting natural health products (NHP) research. Created in June 2003, the Natural Health Products Research Program (NHPRP) has been developed to reflect the diverse nature of the NHP research community and can support projects both directly and in partnership with the Canadian Institutes of Health Research (CIHR). The aim of the NHPRP is to germinate interest in natural health product research by supporting research and related activities that address the following objectives:

- the need to build research capacity
- the commitment to conduct research of the highest quality
- the importance of developing community infrastructure and partnerships
- the need to enhance community infrastructure and knowledge transfer

During a consultation held on behalf of the NHPD in Montreal in February 2004¹, the need for focused attention to research as it related to specific NHPs was identified. One product group identified was homeopathic medicines, a point which has been echoed in consultations with homeopathic industry representatives and members of the homeopathic practitioner community.

Objectives

To address this need, representatives from diverse stakeholder groups within the homeopathic medicine (HM) community in Canada were invited to participate in a research priority setting consultation held in Ottawa, January 10-11, 2005. The objectives of the consultation were to:

- identify research priorities and foster partnerships within the homeopathic sector - researcher, practitioner and industry, and

¹ McCutcheon A & Fitzpatrick K. (Aug 23 2004). Natural Health Product Research in Canada: CCAB-3-0285 Final Report. Mage Consulting.

- facilitate the development of strategies in which the research priorities can be addressed.

Participants

Participants included representatives from NHP industry groups, HM practitioners and associations, governmental and non-governmental research networks, and representatives from national research funding bodies including the Canadian Institutes of Health Research (CIHR) and the Natural Sciences and Engineering Research Council of Canada (NSERC). Also in attendance were HM and integrative medicine researchers, including international invitees from the U.K. and the United States.

Process

Following presentations on a variety of research related topics, participants engaged in a series of brainstorming activities, generated a list of research priorities, ranked the priorities in order of significance, generated strategies, and refined the lists until consensus was reached.

Challenges in Homeopathic Medicine Research

Specific challenges in developing priorities in HM research were identified:

- research capacity in HM
- mechanism of action is unknown
- methodological challenges to studying highly individualized treatments
- industry interest in making claims for single ingredient products
- lack of scientific evidence to support product claims and potency restrictions for combination products
- safety concerns in regards to homeopathic doses of products which are poisonous, carcinogenic or narcotic
- funding and research bias due to perception held by many that HM is unscientific.

Participants also identified challenges in developing a research culture within HM in Canada, due in part, to the diverse educational preparation of practitioners and differing philosophical approaches to theory and practice² and the pressure to continue to achieve or maintain professional status and recognition by developing an evidence-based approach to practice.^{3,4}

² Dryden T, Findlay B, Boon H, Verhoef M, Mior S, Baskwill A. (2004). Research requirement: literacy amongst complementary and alternative health care (CAHC) practitioners. Ottawa (CAN): Natural Health Products Directorate, Health Canada.

³ Health Canada. (2001). Perspectives in complementary and alternative health care. Ottawa: Health Canada.

⁴ Kelner M, Wellman B, Boon H, Welsh S. (2004). Responses of established health care to the professionalization of complementary and alternative medicine in Ontario. *Social Science & Medicine*, 59, 915-30.

Key Themes

Several key themes emerged. Roundtable participants clearly expressed their desire to work together to build an infrastructure for research in HM in Canada. Identified gaps between key stakeholder groups need to continue to be resolved through increased opportunities for communication between and among groups through networks, meetings and publications. There is a need to identify and support champions for HM research, to develop relationships with research funding bodies, and to resolve issues of intellectual property rights. Getting past long held sources of tension and disagreement within the HM community itself and with the larger health care and research communities in Canada, was openly acknowledged as critical to building a cohesive and pragmatic research agenda.

Emergence of Guiding Principles

Guiding principles for the development of research priorities also emerged and included: respect for diversity in culture, language, philosophical beliefs, and the variety of ways in which HM is practiced and by whom (e.g. homeopaths, physicians, naturopathic doctors). Priority needs to be given to studies that are designed by interdisciplinary teams and use appropriate methods for the research question asked. Research needs to be grounded in practice and adequately address safety issues, knowledge translation and have real world application. Priority should be given to clinical studies that examine effectiveness or outcomes for conditions that are commonly treated by HM practitioners, with remedies that are commonly used, and for which there is some degree of evidence to support further study. Studies should be given priority where there may be a high burden of illness for a particular population and illnesses where there are few effective conventional medical treatments, or when HM combined with standard care may prove more beneficial than standard care alone. Priorities in basic science studies should be given to building upon existing studies and identifying and participating in multi-centre studies, whose outcomes may provide foundational data for constructing rigorous clinical trials.

Research Priorities

The research priorities were summarized by consensus of the group as follows:

1. Utilization
2. Research Capacity
3. Safety, Effectiveness, Basic Science

Three Key Recommendations to NHPRP

#1 Research Priority: Utilization

Strategy: Fund an Environmental Scan (national data gathering and analysis on location of homeopaths and other practitioners utilizing homeopathy, utilization by the public, commonly prescribed remedies, commonly treated conditions etc.)

#2. Research Priority: Research Capacity

Strategy: a) Fund Research Capacity Building Workshops (e.g. satellites at the annual NHPRSC Conferences and IN-CAM Conferences and through local professional association conferences).

b) Commission a pre-workshop paper synthesizing current research data and web-based opportunities for research, networking and research literacy and capacity education for wide distribution, also present data from the environmental scan

#3 Research Priority: Safety, Effectiveness and Basic Science

Strategy: a) Analyze existing data on AE reports and link to information gathered in environmental scan and disseminate broadly

b) Support research on limits of potency

c) Identify and make linkages with existing basic science research

Conclusions

The group thanked and commended the Natural Health Products Research Program (NHPRP) of the Natural Health Products Directorate, Health Canada for facilitating the roundtable consultation and expressed their hope that the recommendations for research be taken forward for potential funding by NHPRP. The group acknowledged the need to continue to build bridges between groups with a history of internal tension and to work towards a shared respect and understanding of the diversity of beliefs and practices in HM. The group also acknowledged the importance of continuing to work together to build a culture of research and a research infrastructure in homeopathic medicine by continuing to identify, create and participate in further opportunities for interdisciplinary dialogue.

Natural Health Products Research Program Research Priority Setting Consultation on Homeopathic Medicine in Canada: An Invitational Roundtable

Introduction:

Background

Since its creation in 1999, the Natural Health Products Directorate has been primarily focused on developing and implementing the Natural Health Products Regulations¹ which came into force in January 2004.² In addition to its role as product regulator, the Natural Health Products Directorate is tasked with supporting natural health products (NHP) research. The Natural Health Products Research Program (NHPRP), launched in June 2003, has been developed to reflect the diverse nature of the NHP research community and to germinate interest in natural health product research by supporting research and related activities that address the following objectives:

- the need to build research capacity;
- the commitment to conduct research of the highest quality;
- the importance of developing community infrastructure and partnerships, and;
- the need to enhance community infrastructure and knowledge transfer.

In several national consultations³ with key stakeholders from government, industry, research and practitioner groups, NHPRP recognized that a number of issues need to be considered as the regulations come into force. Issues of particular importance were those among complementary and alternative health care (CAHC) practitioner groups who would potentially be most affected by the new regulations. A key barrier to CAHC and natural health product (NHP) research is a lack of research literacy (“understanding research language and its application to practice”⁴) and research capacity (“the ability to design and conduct research studies”⁵) among CAHC practitioners.

In order to continue the dialogue, the NHPRP supported a consultation involving stakeholders from academia, industry, practitioner associations, government representatives and funding agencies in Montreal in February 2004.⁶ The need for

¹ Natural Health Products Regulations, *Canada Gazette Part II*, June 18, 2003, available at http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/regs_cg2.pdf.

² For more information, see http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/nhp_regs_e.html.

³ Health Canada. (May 2004). Consultation on Homeopathic Products: Summary Report. Retrieved from http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/sum_rep_homeopathic_consultation_e.pdf.

⁴ Williams, J., Mulkins, A., Verhoef, M.J., Monkman D., & Findlay, B. (2002). *Needs assessment: Research literacy and capacity amongst complementary and alternative health care providers*. Perspectives on Natural Health Products – Natural Health Products Directorate, Health Canada, 14.

⁵ Ibid., 15.

⁶ McCutcheon A & Fitzpatrick K. (Aug 23 2004). Natural Health Product Research in Canada: CCAB-3-0285 Final Report. Mage Consulting.

focused attention to research as it related to specific NHPs was identified. One product group identified was homeopathic medicines, a point which has been echoed in consultations with homeopathic industry representatives and members of the homeopathic practitioner community.

Objectives

To continue to focus attention on the development of research capacity in NHPs and homeopathic medicines (HM) in particular, and to foster partnerships among stakeholders, key representatives from industry, practice and research in HM in Canada were invited to participate in a priority setting research consultation held in Ottawa on January 10-11, 2005. The objectives of the consultation were to:

- identify research priorities and foster partnerships within the homeopathic sector - researcher, practitioner and industry, and;
- facilitate the development of strategies in which the research priorities can be addressed.

Participants

Participants included representatives from NHP industry groups, HM practitioners and associations (including HM practitioner groups from homeopathy, conventional medicine and naturopathic medicine), governmental and non-governmental NHP and CAHC networks, a number of representatives from NHPD and NHPRP and other branches of Health Canada, and representatives from national research funding bodies including the Canadian Institutes of Health Research (CIHR) and the Natural Sciences and Engineering Research Council of Canada (NSERC). Also in attendance were a number of HM and integrative medicine researchers, including international invitees from the U.K. and the U.S. (*Appendix A: Participants List*).

The invitational roundtable was intended to be a focussed consultation to identify research priorities and strategies, foster partnerships and to make recommendations to the NHPRP based upon reaching a consensus among participants on proposed research priorities and strategies for NHPRP to consider. It was not meant to be an exhaustive consultation with all possible HM stakeholders but the continuation of an ongoing dialogue.

Process

Following a welcome from the NHPRP and participant introductions, the process for the two day meeting was outlined (*Appendix B: Agenda*). Following presentations on a variety of research related topics, roundtable participants in a series of brainstorming activities to generate a list of research priorities, ranked the priorities in order of significance, generated strategies and finally refined the lists of priorities and strategies until consensus was reached.

Day I:

Overview of Presentations

1. Overview of NHP Regulations and the Role of NHPRP

A senior representative from the Natural Health Products Directorate gave an overview of the NHP Regulations and the role of the NHPRP (***Appendix C: Overview of NHP Regulations and Role of NHPRP***) and oriented the roundtable participants to its mission:

- to ensure that all Canadians have ready access to natural health products that are safe, effective, and of high quality, while respecting freedom choice and philosophical and cultural diversity.

In addition to promoting excellence in NHP research that is consistent with the four pillars of Canadian Institutes of Health Research (biomedical research, clinical research, research respecting health systems and health services and research on societal, cultural and environmental on health and on the health of populations), the NHPRP was developed to build partnerships and enhance community infrastructure and knowledge transfer. The fact that the primary objective of the NHPRP is to support Health Canada's role as a regulator was emphasized in the presentation.

As part of the ongoing dialogue with CAHC practitioner groups, NHP researchers and industry, NHPRP recognized that there were specific challenges in developing HM research including:

- unclear mechanism of action;
- methodological challenges to studying highly individualized treatments, and;
- funding and research bias due to perception held by many that HM is unscientific.

There are also challenges in enhancing a research culture among HM practitioners with diverse educational preparation, lack of national standards/competencies and provincial/territorial regulation, and differing philosophical approaches to theory and practice⁷. The research priority setting roundtable was created to move the agenda forward and to, in part, address these concerns in regards to HM in Canada.

2. Overview of Research in Homeopathy

An international HM physician and researcher gave an overview of the richness, depth and limitations of current HM research (***Appendix D: Overview of Research in Homeopathy***). Results of several meta-analyses, based on a substantial number of randomized controlled trials, are cautiously positive in showing the efficacy of homeopathic treatment in patients with a number of different diseases. However, a

⁷Dryden T, Findlay B, Boon H, Verhoef M, Mior S, Baskwill A. (2004). Research requirement: literacy amongst complementary and alternative health care (CAHC) practitioners. Ottawa (CAN): Natural Health Products Directorate, Health Canada.

significant number of studies fail to discern any inter-group differences. Overall, the strength of the evidence is low because of the lack of rigor in the methodology employed in the clinical trials. Current research evidence from these meta-analyses points to the relative safety of HM. However, it also was noted that there is likely to be significant under reporting of adverse reactions, as is the case with many other NHPs and pharmaceuticals.

There are few basic science studies in HM on mechanism of action and few studies that adequately either control for, or examine, the complexity of non-specific effects (e.g. the practitioner/patient relationship, placebo effects etc.). There is a trade-off in research between the more rigorous, expensive and time consuming efficacy studies with high internal validity but little ‘real world’ application and the more pragmatic, less expensive effectiveness or outcomes-based studies with lower internal validity and higher ‘real world’ application. It was suggested that many types of studies are needed in HM and that effectiveness or outcomes-based studies should perhaps take a higher priority than both efficacy and basic science studies. These suggestions were made given fiscal and human resource limitations and the pressing need for pragmatic, evidence-informed health care information for patients, health care providers, industry and NHP regulators. The presenter also emphasized the need to build upon existing basic science studies and the importance of supporting effectiveness studies for specific populations and conditions using HM remedies that already show promise in the literature and are clearly highly utilized in the profession and by the public.

“The available research evidence emphasizes the need for much more and better-directed research in homeopathy. A fresh agenda of inquiry should consider beyond (but include) the placebo-controlled trial. Each study should adopt research methods and outcome measurements linked to a question addressing the clinical significance of homeopathy’s effects.”⁸

Copies and/or information on access to various HM research studies demonstrating a broad range of research questions and a variety of methodologies from randomized controlled trials to N = 1 studies were made available to the roundtable participants by NHPD representatives.

3. Overview of Regulating Homeopathic Medicines in Canada

A representative from the Bureau of Product Review and Assessment at NHPD, gave a brief overview of the history and basic philosophical principles of HM and the challenges and value of developing research priorities and strategies in HM to support and guide product regulation (**Appendix E: Overview of Regulating Homeopathic Medicines in Canada**).

Conventional western principles of medical diagnosis of disease and allopathic treatment are also consistent with the fundamental principles of rationalistic scientific inquiry. In

⁸ Mathie, R. (2003). The research evidence base for homeopathy: a fresh assessment of the literature. *Homeopathy*, 92, 84-91.

contrast, the key principles of homeopathy diagnosis and treatment such as the treatment of like with like, minimum dose, holistic treatments, and individualistic diagnoses result in highly idiosyncratic diagnoses and different remedies prescribed for the same disease in different individuals. It is this individualistic and holistic paradigm, along with differing schools of thought among HM practitioners, that leads to challenges in setting research priorities that are both acceptable and useful to practitioners and their patients and consistent with the dominant paradigms in western medicine of methods of scientific inquiry.

Current regulatory concerns include HM product safety, quality, efficacy and claims. A world literature search for reported adverse reactions from 1975-1995 revealed that the incidence of adverse effects is low but under reported. Furthermore, there is little safety evidence for homeopathic doses of products which are poisonous, carcinogenic or narcotic. The main risks in HM appear to be indirect and may be more practitioner than product based, such as the lack of consistent educational preparation and practice standards and regulations in Canada. It was noted that health practice regulatory issues are an individual provincial/territorial matter and therefore do not fall under the mandate of NHPD or Health Canada.

All homeopathic medicines in Canada must meet good manufacturing practice (GMP) requirements as found in the NHP Regulations. Finished HM products must also meet quality requirements outlined in Homeopathic Pharmacopoeia of the United States (HPUS), Homöopathisches Arzneibuch (HAB), Pharmacopée Française (FP) or the European Pharmacopeia.

Key regulatory concerns are primarily in regards to the efficacy of HM, as there are very few clinical trials to support proposed product claims. “Homeopathic provings”, a traditional technique of providing evidence for a particular remedy’s or combination of remedies’ efficacy are not, on their own, an acceptable level of evidence to support product claims from a regulatory perspective. More studies are needed to support efficacy for claims made from the point of view of current scientific understanding. Currently, NHP legislation requires that single ingredient products be limited to the statement ‘to be used on the advice of a health care practitioner.’ Products claiming a specific indication for use and containing a combination of at least 2 medicinal ingredients must be specific, suitable for self-care, and supported by 2 independent homeopathic references.

The presenter pointed out that other challenges in HM regulation include:

- lack of research capacity in HM;
- mechanism of action is unknown;
- industry interest in making claims for single ingredient products;
- lack of evidence to support potency restrictions for combination products; and
- lack of credibility in scientific terms, has made funding for HM research a low priority.

First Brainstorming Activity on Research Priorities

In three pre-assigned small groups, roundtable participants brainstormed research priorities for HM in Canada. Lively discussion generated diverse and overlapping lists of research priorities including:

- research literacy and capacity building (among all stakeholder groups: practitioners, researchers, peer-reviewers, funders, etc.)
- safety (adverse reactions, drug interactions, combinations of remedies, higher potencies)
- basic science studies (mechanism of action)
- efficacy and effectiveness studies (specific conditions, specific remedies, issues of potency and dosage, cost effectiveness)
- research methods (diverse and combined strategies to study HM),
- integration (between homeopathy and conventional medicine)
- utilization studies (populations, physician and consumer attitudes, referral patterns)
- studies on the practice of homeopathy itself (*Appendix F: Brainstorming List of Research Priorities*).

Several ideas arose across the three groups, that were not specifically research priorities but related to barriers or facilitators in research such as: the difficulty of obtaining ethics review (for HM schools and practitioner/researchers that are not affiliated with traditional academic ethics review boards), trade-offs between rigor and practicality in research methods and the use of innovative and combined methods, creation of, or linkages to existing HM research studies and databases, education and knowledge translation among all stakeholder groups, multiculturalism and respect for diversity, and an ongoing question of intellectual property rights for non-patentable products.

Ranking Research Priorities

The conference facilitator and representatives from NHPD grouped the lists of research priorities from the first brainstorming session into 7 main research priorities and asked participants to rank the priorities. Each participant was given 5 dots to use in anyway they saw fit, to rank the priorities in order of importance. The outcome was as follows:

1. Efficacy/Effectiveness (12.5 dots)
2. Research Methods (10 dots)
2. Utilization (10 dots)
4. Knowledge Translation (6 dots)
5. Research Capacity (5 dots)
6. Safety (4.5 dots)
7. Basic Science/Mechanism (3 dots)

Participants expressed some concern and surprise that safety and mechanism studies were lowest on the list of priorities. After some discussion it was decided that no further work on priority setting could be meaningfully accomplished until strategies were generated.

To facilitate small group selection and adequate numbers in each self-selected group, three brainstorming groups on strategies were developed:

- Effectiveness/Efficacy and Safety
- Research Methods and Basic Science
- Utilization and Knowledge Translation

Overview of Two National Research Networking Initiatives

To provide roundtable participants with information on two existing national research networks, in advance of brainstorming strategies for the research priorities, brief overviews of the Natural Health Products Research Society of Canada (NHPRS) and the Canadian Interdisciplinary Network for Complementary and Alternative Medicine Research (IN-CAM) were given.

Natural Health Product Research Society of Canada (NHPRS)

The NHP Research Society is a non-profit organization founded in 2003 by a collaboration of academic, industry and government researchers from across Canada. NHPRS membership is open to all NHP stakeholders and within a few months, it has already grown to encompass some 200 individual, association, affiliate and corporate members. The mission of the NHPRS is to support and promote scientifically rigorous research and education on natural health products, to enable the safe, informed and appropriate use of NHPs that are effective, non-toxic and of the highest quality and to help protect and promote the health of Canadians.

The society's specific objectives are to facilitate and support Canadian natural health product education and research priorities to:

- ensure the safe and appropriate use of natural health products (NHPs);
- ensure the efficacy, safety, and high quality of NHPs;
- facilitate effective NHP knowledge transfer and translation;
- inform decision-making and evidence-based policy development;
- foster interdisciplinary NHP research collaborations and networking;
- build NHP research and education capacity;
- develop national product quality standards, reference materials and validated methods;
- advocate and uphold fair and ethical standards in NHP education and research;
- provide representation and a communication forum for the NHP research community, and;
- promote the use of high quality, well-characterized and standardized NHPs in research.

To accomplish these objectives, the NHPRS is developing an array of programs and projects. The first major initiative undertaken by the society was the organization of the

First Natural Health Product Bridge Building Conference to showcase Canadian NHP research, and to foster networking and new collaborations amongst researchers, industry and government stakeholders. Held February 20-22, 2004 in Montreal, the sold-out conference was a resounding success with over 300 participants in attendance. The Second Natural Health Product Research Society Conference will be held in Vancouver February 11-13, 2005.

The Canadian Interdisciplinary Network for Complementary and Alternative Medicine Research: IN-CAM

The mission of IN-CAM is to create a sustainable, well-connected, highly trained Complementary and Alternative Medicine (CAM) research community in Canada that is internationally recognized and known for both its excellence in research and its contributions to understanding CAM and its use.

IN-CAM will increase the capacity for high quality, inter-disciplinary, collaborative CAM research by:

- building a sustainable network that facilitates and supports researchers studying CAM from a health services and policy perspective;
- developing CAM research priorities and a research agenda;
- building CAM research capacity;
- promoting knowledge transfer among researchers, health care practitioners, policy makers, research funders, and the public about CAM; and
- linking with other relevant networks, organizations, and educational institutions to develop partnerships that further our objectives.

The network's major activities consist of building research capacity, developing research priorities and a research agenda, promoting knowledge transfer and linking with relevant networks, organizations, and educational institutions to develop partnerships that further the network's objectives.

The network hosts annual funding competitions for project seed funding and graduate studentships. The ultimate goal is to develop a program that becomes a recognized career path for graduate students interested in social-policy and health care. An annual CAM Research Symposium will provide an opportunity for members in the CAM research community to network, to share results of recent research and to participate in educational workshops. Membership in IN-CAM is free of charge and may be established by completing a brief questionnaire on the Member's portion of the IN-CAM web site.

Roundtable participants were encouraged to access the online information and explore these networks for potential linkages and as potential research capacity building partners for their organizations. It was also acknowledged that there are a number of well-organized and useful NHP and CAHC research networks in Canada and that the two presented were the only two national research networks to date.

Developing Strategies

Participants self-selected, by interest, into one of three small research priority groups to brainstorm potential obstacles, facilitators and pragmatic strategies.

1. Effectiveness/Efficacy and Safety

Strategies:

- create or link with practice-based networks
- develop sites or centres for research, accessible to practitioner/researchers as well as to academic researchers
- study commonly prescribed remedies
- prioritize clinical research (while not precluding other kinds of research) that is diagnosis oriented vs. patient-oriented: high burden of disease, limited effectiveness of conventional treatments, limited # HM remedies, commonly used remedy
- clinical trials: priority to controlled equivalence trials, adjunctive trials, N = 1 trials
- all research should explicitly address safety issues with additional care taken in pediatrics, with potential drug interactions, concentration of remedies
- adverse effects reporting needs to be adapted and standardized (based on the national standards) to be useful for HM practitioners and practitioners need continued education in the use of this proposed new tool
- work to remove publication biases so that HM research of all kinds can be more widely published

2. Research Methods and Basic Science

Facilitators of HM Research:

- rich cultural diversity in Canada
- high level of public demand
- increased atmosphere of openness (among many stakeholders)
- existing infrastructure for excellence in health research in Canada
- public and government concerns about ecological/environmental safety (e.g. side effects, toxicity of some pharmaceuticals) and public health issues are fueling an interest in HM as another source of medicines with potentially fewer side effects

Strategies:

- bridge gap between practitioners/researchers – identify interested research teams, interested practitioner groups (professional associations, educational institutions)
- create opportunity for multidisciplinary face to face meetings (capacity building for all involved)
- build clinical trials consensus on focus of research by surveying HM practitioners and consumers about what is most frequently prescribed and for what purpose

- recruit practitioners to consistently document treatments to share this information stripped of patient identifiers to study how HM is actually practiced
- encourage and build capacity (workshops and mentoring) in publication of HM research
- liaise with existing networks: IN-CAM, NHPRS
- develop multi-centre basic science studies that build on existing studies

3. Utilization and Knowledge Translation

Barriers:

- lack of knowledge of, or inability to access and coordinate existing data sets and databases in HM
- diverse populations
- publication biases
- the need to create a useful survey tool for HM
- proprietary industry data is rarely accessible because of intellectual property concerns
- lack of overall funding going to health service research
- not enough access to statisticians and conventional researchers to build teams with practitioner/researchers
- few mechanisms for information access – what works best to facilitate informed decision making for consumers
- relative cost of care

Strategies:

- do survey research: inclusive of who, what (conditions/drugs), attitudes of practitioners, conventional health care providers, survey self-care use, identify the educational institutions
- examine the role of homeopathy in self-care, health promotion, prevention
- include cost comparisons and analysis in studies (pharmacoeconomics)

Day II:

Consensus Building

Key Themes

Several key themes emerged from the first day of the conference. Roundtable participants clearly expressed their desire to work together to build an infrastructure for research in HM in Canada. Identified gaps between key stakeholder groups need to be resolved through increased opportunities for communication between and among groups through networks, meetings and publications. The need to identify and support champions for HM research and to develop relationships with research funding bodies was also identified. Getting past long held sources of tension and disagreement within the HM community itself and with the larger health care and research communities in Canada, and resolution of issues of intellectual property rights, was openly acknowledged

as critical to building a cohesive and pragmatic research agenda.

Emergence of Guiding Principles

In addition, the previous day's discussions resulted in the formation of guiding principles for the development of a research priorities agenda for HM; principles such as respect for diversity in culture, language, philosophical beliefs, and the variety of ways in which HM is practiced and by whom (homeopaths, MDs, naturopathic doctors). Guiding principles for research in HM should be consistent with the fundamental principles of HM practice and yet be broad and flexible enough to safely hold a diverse range of philosophical beliefs from classical HM to new and emerging theories and practices.

Priority needs to be given to studies that are designed by interdisciplinary teams and use the appropriate methodology for the question being asked (model validity fit). Research needs to be grounded in practice and adequately address safety issues, knowledge translation and have real world application. Priority should be given to clinical studies that examine outcomes for conditions that are commonly treated by HM practitioners, with remedies that are commonly used and for which there is some degree of evidence to support further study. Studies should be given priority where there may be a high burden of illness for a particular population and illnesses where there are fewer effective conventional medical treatments, or when HM combined with standard care may prove more beneficial than standard care alone. Priorities in basic science studies should be given to building upon existing studies and identifying and participating in multi-centre studies, whose outcomes may provide foundational data for constructing rigorous clinical trials.

Key Research Priorities

The research priorities generated in the first day of the conference were summarized by consensus as follows:

Utilization
Research Capacity
Safety, Effectiveness, Basic Science

The group was reminded that recommendations made to the Natural Health Products Research Program are more likely to be considered for implementation if they are consistent with NHPRP's objectives in that they focus on NHPs and:

- the need to build research capacity,
- the commitment to conduct research of the highest quality,
- the importance of developing community infrastructure and partnerships, and
- the need to enhance community infrastructure and knowledge transfer;

Research is more likely to be recommended for funding through the NHPRP if it also addresses the product regulatory issues of safety, quality, efficacy and claims.

Identifying Recommendations

Key Research Strategies

Having reached consensus on research priorities, and guided by the wealth and depth of potential strategies generated the previous day, participants re-focused on generating a list of specific and pragmatic strategies to address research priorities:

- map homeopathy in Canada (an environmental survey/scan)
- monitor and analyze basic science studies in HM for potential replication and/or as opportunities to become an additional site partner
- commission a summary paper on HM to synthesize what is known and disseminate broadly
- poll practitioners on what is an adverse effect versus what is an aggravation
- foster clinical audit among practitioners
- determine safe and effective levels of potency (e.g. potency restrictions for combination products)
- create links between HM associations and existing HM research databases
- organize an HM research symposium to bridge the gap between stakeholder group
- coordinate HM research capacity building satellite workshops with existing conferences in both the conventional and complementary and alternative health care research communities
- support linkages with existing networks such as IN-CAM and NHPRS
- build and facilitate partnerships between grassroots practitioners and researchers
- create and/or disseminate information on research literacy and capacity building workshops to HM practitioners
- create a national database of HM practitioners
- strengthen adverse reactions reporting by working with government and practitioner groups to create an appropriate reporting tool
- promote and strengthen membership in professional associations to increase standards in research literacy and capacity
- build relationships between HM and funding bodies
- identify research champions and mentors within all HM stakeholder groups

Three Key Recommendations to NHPRP for Research Funding in HM:

Participants were asked to identify and rank in order of priority, three key recommendations to NHPRP, by answering the following questions:

“If you were the product regulator research program funding research in HM to support product regulation and could fund only one study what would it be? If you could fund two studies? If you could fund three studies?”

The group reached consensus on the following three priorities:

#1 Research Priority: Utilization

Strategy: Fund an Environmental Scan (national data gathering and analysis on location of homeopaths, utilization by the public, commonly prescribed remedies, commonly treated conditions etc.)

#2. Research Priority: Research Capacity

Strategy: a) Fund Research Capacity Building Workshops (satellites at the annual NHPRSC Conferences and IN-CAM Conferences and through local professional association conferences).

b) Commission a pre-workshop paper synthesizing current research data and web-based opportunities for research, networking and research literacy and capacity education for wide distribution, also present data from the environmental scan

#3 Research Priority: Safety, Effectiveness and Basic Science

Strategy: a) Analyze existing data on adverse reactions reports and link to information gathered in environmental scan and disseminate broadly

b) Support research on safe and effective levels of potency (e.g. potency restrictions for combination products)

c) Identify and make linkages with existing basic science research

Conclusions

The group thanked and commended the Natural Health Products Research Program (NHPRP) of the Natural Health Products Directorate, Health Canada for facilitating the roundtable consultation and expressed their hope that the recommendations for research be taken forward for potential funding by NHPRP. The group acknowledged the need to continue to build bridges between groups with a history of internal tension and to work towards a shared respect and understanding of the diversity of beliefs and practices in HM. The group also acknowledged the importance of continuing to work together to build a culture of research and a research infrastructure in HM by continuing to identify, create and participate in further opportunities for interdisciplinary dialogue.

Appendix A: List of Participants

**PRIORITY SETTING RESEARCH CONSULTATION ON HOMEOPATHIC
MEDICINES IN CANADA**

Ottawa
January 10th and 11th, 2005

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Appendix B: Agenda

**INVITATIONAL ROUNDTABLE OF NATURAL HEALTH PRODUCTS
RESEARCH PROGRAM'S (NHPRP)
PRIORITY SETTING RESEARCH CONSULTATION
ON HOMEOPATHIC MEDICINE IN CANADA**

**Ottawa
January 10th and 11th, 2005
The International Development Research Centre
250 Albert St., 14th floor, Nayudamma Lounge**

AGENDA

Monday, January 10th, 2005

8:10am	Coffee and Tea in the meeting room	
8:30am	Welcome from NHPRP, Health Canada	Michael J. Smith
8:50am	Introductions (all participants)	Facilitator assisted
9:20am	Orientation to Consultation Process	
9:30am	Presentations	
	Overview of NHPs Regulations and NHPRP	Michael J. Smith
	Overview of Homeopathy Research Presentation	Peter Fisher
	Regulation of HMs in Canada	Melissa Johnson
10:30am	Health Break	
10:50am	Brainstorm Research Priorities (assigned small groups)	Facilitator assisted
11:45am	Report Back to Larger Group	Facilitator assisted
12:30pm	Lunch	
1:30pm	Identify top 3-5 Research Priorities	Facilitator assisted
2:00pm	Brainstorm Effective Strategies for each of the top Research Priorities (one break-out group per strategy)	Facilitator assisted

3:00pm	Health Break	
3:20pm	Report of individual break-out groups	Facilitator assisted
4:00pm	Reflections on Findings	Facilitator assisted
4:30pm	Wrap up of Day 1	Facilitator

**INVITATIONAL ROUNDTABLE OF NATURAL HEALTH PRODUCTS
RESEARCH PROGRAM'S (NHPRP)
PRIORITY SETTING RESEARCH CONSULTATION
ON HOMEOPATHIC MEDICINE IN CANADA**

**Ottawa
January 10th and 11th, 2005
The International Development Research Centre
250 Albert St., 14th floor, Nayudamma Lounge**

AGENDA

Tuesday, January 11th, 2005

8:10am	Coffee and Tea in the meeting room	
8:30am	Orientation to Day 2	Facilitator
8:40am	Recap of Day 1	
9:00am	Overview of Current Initiatives	
9:30am	Next Steps: Create Pragmatic Action Plans for Research Strategies	Facilitator assisted
10:30am	Health Break	
10:45am	Consensus Building: Identify Recommendations	Facilitator assisted
11:45am	Concluding remarks	Michael J. Smith
12:00pm	Close of Conference Lunch will be served	

Appendix C: Brainstorming List of Research Priorities

First Research Priorities Brainstorming

Group A

Education (capacity building)

- practitioners: adverse effects, funding, methodology, research literacy
- funders and peer-reviewers

Research Methods

- polarity between rigor (efficacy) and practicality (effectiveness)

Safety

- adverse effects reporting, drug interactions, combinations of remedies, high potency

Research Studies

- mechanism, specific conditions, effectiveness, integration & collaboration, population (utilization), motivation, consulting practices

Group B

Proving, clinical relevance, role, new substances

Integration with conventional medicine

New research methods needed

Equivalence trials

Research homeopathic consultations/diagnoses

Research database

Ethics

Knowledge translation – cultural diversity

Education – public, practitioners

Intellectual property rights for non-patentable products

Practice-based research

- effectiveness, cost, epidemiology, adverse effects

Basic research

- mechanism of action, inflammation research

Who is doing homeopathy research and who should be doing it?

Link to public health priorities

Group C

Clinical Research

- specific medical conditions: acute burns, emergencies, trauma, provings as evidence, principles of homeopathy, substitutions vs. adjunct, case studies, integration, dose, posology, duration, clinical trials

Incidence/Prevalence

- physician attitude, referral patterns, level of evidence
- consumers utilization

Research Capacity & Training, Methods

- research literacy: terminology, ethics: REB, access to research facilities (hospitals) and researchers, publication (bias), multidisciplinary networking, central research portal, knowledge translation

Safety

- interactions, adverse effects

Cost/Economics

- comparison studies, self-treatment (economic impact)

First Strategies Brainstorming

1. Effectiveness/Efficacy and Safety

Strategies:

- create or link with practice-based networks
- develop sites or centres for research, accessible to practitioner/researchers as well as to academic researchers
- study commonly prescribed remedies
- clinical research should be diagnosis oriented vs. patient-oriented: high burden of disease, limited effectiveness of conventional treatments, limited # HM remedies, commonly used remedy
- clinical trials: priority to controlled equivalence trials, adjunctive trials, N=1 trials
- all research should explicitly address safety issues with additional care taken in pediatrics, with potential drug interactions, concentration of remedies
- work to remove publication biases so that HM research of all kinds can be more widely published

2. Research Methods and Basic Science

Facilitators:

- rich cultural diversity in Canada
- high level of public demand

- increased atmosphere of openness (among many stakeholders)
- existing infrastructure for excellence in health research in Canada
- public and government concerns about ecological/environmental safety (e.g. side effects, toxicity of some pharmaceuticals) and public health issues are fueling an interest in HM as another source of medicines with potentially less side effects

Strategies:

- bridge gap between practitioners/researcher – identify interested research teams, interested practitioner groups (professional associations, educational institutions)
- create opportunity for multidisciplinary face to face meetings (capacity building for all involved)
- build clinical trials consensus on focus of research by surveying HM practitioners and consumers about what is most frequently prescribed and for what purpose
- recruit practitioners to consistently document treatments to share this information stripped of patient identifiers to study how HM is actually practiced
- encourage and build capacity (workshops and mentoring) in publication of HM research
- liaise with existing networks: IN-CAM, NHPRS
- develop multicentre basic science studies that build on existing studies

3. Utilization

Barriers:

- lack of knowledge or an inability to access and coordinate existing data sets and databases
- populations
- publication biases
- the need to create a useful survey tool
- proprietary industry data is rarely accessible because of intellectual property concerns
- lack of overall funding going to health service research
- not enough access to statisticians and conventional researchers to build teams with practitioners/researchers
- few mechanisms for information access – what works best to facilitate informed decision making for consumers
- relative cost of care

Strategies:

- do survey research: inclusive of who, what (conditions/drugs), attitudes of practitioners, conventional health care providers, survey self-care use, identify the educational institutions
- examine the role of homeopathy in self-care, health promotion, prevention
- include cost comparisons and analysis in studies (pharmacoeconomics)

References:

- Dryden T, Findlay B, Boon H, Verhoef M, Mior S, Baskwill A. (2004) Research requirement: literacy amongst complementary and alternative health care (CAHC) practitioners. Ottawa (CAN): Natural Health Products Directorate, Health Canada.
- Health Canada. (May 2004). Consultation on Homeopathic Products: Summary Report. Retrieved from http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/sum_rep_homeopathic_consultation_e.pdf.
- Health Canada. Natural health products regulations. Retrieved from Natural Health Products Directorate Web site: http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/nhp_regs_e.html.
- Kelner M, Wellman B, Boon H, Welsh S. (2004). Responses of established health care to the professionalization of complementary and alternative medicine in Ontario. *Social Science & Medicine*, 59, 915-30.
- Mathie, R. (2003). The research evidence base for homeopathy: a fresh assessment of the literature. *Homeopathy*, 92, 84-91.
- McCutcheon A & Fitzpatrick K. (Aug 23 2004). Natural Health Product Research in Canada: CCAB-3-0285 Final Report. Mage Consulting.
- Natural Health Products Regulations, *Canada Gazette Part II*, June 18, 2003. Retrieved from http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/regs_cg2.pdf.
- Williams, J., Mulkins, A., Verhoef, M.J., Monkman D., & Findlay, B. (2002). *Needs assessment: Research literacy and capacity amongst complementary and alternative health care providers*. Perspectives on Natural Health Products – Natural Health Products Directorate, Health Canada, 14.