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NATURAL HEALTH PRODUCTS RESEARCH PROGRAM - FORMATIVE EVALUATION

Final Report

Approved by

Health Canada
Departmental Audit and Evaluation Committee

April 27, 2007

Canada

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**Natural Health Products Directorate
November 2006**

MANAGEMENT ACTION PLAN
TO THE FORMATIVE EVALUATION OF THE NATURAL HEALTH PRODUCTS
RESEARCH PROGRAM

This is the management response to the Formative Evaluation of the Natural Health Products Research Program. The management response consists of the management action plan in response to the key findings and recommendations of the evaluation.

Contextual factors and impact on management action plan

In August 2006, the Natural Health Products Directorate (NHPD) was required to take drastic measures to remain within its allocated budget and one such measure was to suspend the research program temporarily and use this funding to bolster the NHPD primary mandate, which is to regulate natural health products. The management response was written in this context and the implementation of some of the recommendations is conditional upon resumption of funding.

For fiscal year 2007-2008, funding remains uncertain and hinges on the outcome of a business case submitted to the Treasury Board Secretariat by NHPD.

Follow up actions and moving forward

The evaluation has 8 recommendations and 17 specific actions were identified to improve the research program. A number of these activities are dependent upon funding resuming, especially areas addressing improvements in implementation and effectiveness. The NHPD has identified that it can move forward on the following **5 actions** with minimal costs as part of its overall objective to support the NHP regulatory community and facilitate informed choice by consumers.

- 1- Coordination and risk management: NHPD to initiate more frequent and regular communication with the CIHR for improved coordination of current multi-year collaborative agreements.
- 2- Funding environment: NHPD to encourage and facilitate funding opportunities, collaborative activities and interest in NHP research funding and support by national and international research agencies.
- 3- Community Outreach: NHPD to facilitate and strengthen partnership-building and collaboration at the national level and foster opportunities to further the development of a strong NHP research community.
- 4- NHP regulatory process: NHPD to encourage the continued contribution of research to the NHP regulatory environment by facilitating and participating in discussions relating to national and international regulatory issues and in the identification of knowledge gaps.
- 5- Information dissemination: NHPD to work with both internal and external stakeholders to identify measures to enhance the transfer of scientific knowledge and promote information dissemination on NHPs.

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Scope of formative evaluation

The formative evaluation is part of the accountability requirements identified in the Results-Based Management and Accountability Framework for the research program. Its purpose is to provide a preliminary assessment of progress made by the research program and to provide objective information to assist management with decisions on the direction, priorities and delivery of the program.

The evaluation covers the first 3 years of the program (June 2003-March 2006). The evaluation identified four areas of enquiry:

- Role and Relevancy
- Implementation Progress
- Program Results
- Effectiveness and Alternatives

Methodology

Qualitative and quantitative data were collected through an external evaluation process and relied on from five key sources:

- A review of 83 program and background documents
- Telephone interviews with 25 recipients of project funding
- An internal panel discussion
- An external panel discussion with representatives from research funding organizations, the research community, non-governmental organizations practitioner groups, industry groups and consumer groups
- A review of selected literature on capacity building, partnerships and knowledge transfer.

Consultative Process

An Evaluation Working Group was created to provide advice during the course of conducting the formative evaluation and to provide comments on key deliverables.

The terms of reference and the formative evaluation report were reviewed by the members of the Evaluation Working Group, Health Canada's Departmental Performance Measurement and Evaluation Directorate (DPMED) and the Branch Policy Planning and International Affairs Directorate (PPIAD).

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List of recommendations

Recommendation 1:

Develop a strong relationship between regulators and the broad NHP community to ensure an integrated approach in addressing the knowledge gaps and challenges of the NHP regulatory environment.

Recommendation 2:

Sustain and improve efforts in the generation of knowledge in the areas of quality, safety and efficacy and its dissemination to stakeholders, partners and the Canadian public.

Recommendation 3:

Improve the coordination of grant funding between NHPD and CIHR.

Recommendation 4:

Improve the contribution funding process with respect to the launching and broadcasting of Call for Proposals, the timely availability of funds and reporting requirements.

Recommendation 5:

Involve broader representation of various internal and external stakeholders in various priority-setting and knowledge-based activities.

Recommendation 6:

Explore new funding opportunities and support efforts to further build the sustainability of the NHP research community.

Recommendation 7:

Enhance knowledge transfer and dissemination of information on NHPs.

Recommendation 8:

Deliver program in more cost-effective manner, maintaining balance between flexibility and effectiveness and further strengthening the research community infrastructure.

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1. Are of enquiry: Role and relevance issues			
Key findings	Recommendations	Action required	Action taken
<p>The evaluation identified that three years into the implementation of the research program there is still a need to bridge the following gaps:</p> <ul style="list-style-type: none"> • Need for timely response to needs of the NHP regulatory environment. • Need for additional research on NHP safety, quality and efficacy – areas critical to the regulatory role and the question of informed choice. • Need to disseminate evidence-based information and findings to a broader audience and to sustain dialogue with stakeholders. 	<p><u>Recommendation 1:</u> Develop a strong relationship between regulators and the broad NHP community to ensure an integrated approach in addressing the knowledge gaps and challenges of the NHP regulatory environment.</p> <p><u>Recommendation 2:</u> Sustain and improve efforts in the generation of knowledge in the areas of quality, safety and efficacy and its dissemination to stakeholders, partners and the Canadian public.</p>	<ul style="list-style-type: none"> • NHPD to build on activities initiated through the research program to enhance linkages with various regulatory entities and build new linkages with the broad NHP community, addressing the need for enhanced research-based regulatory decisions. Action to be initiated upon resumption of funding. • NHPD to ensure increased attention on the national and international stage in research necessary to support the NHP regulatory environment by facilitating and/or participating in discussions relating to regulatory issues and in the identification of knowledge gaps. Actions to continue Fall 2006 onwards. • Explore mechanisms to enhance the number and quality of research in the areas of quality, safety and efficacy. Any further initiatives are dependent upon funding resuming. • NHPD to develop communication and dissemination plan to transfer knowledge acquired and communicate findings of related research. A dissemination plan is in process of development. <p>Contribute to national and international research coordination efforts in order to advance knowledge and raise awareness of specific issues. Actions taken and to continue Fall 2006 onwards.</p>	<ul style="list-style-type: none"> • Working relationships have been developed while working on specific regulatory challenges however further efforts are required. Lead: NHPRP Program manager, Science Officer. Lead: NHPRP Program manager, Science Officer. • Efforts were made to encourage research in these areas – such as launching a targeted call for proposals. Lead: NHPRP Program Manager, Science Officer. Lead: NHPRP Program Manager, Science Officer. • Contributed to the discussion paper for the International Regulatory Cooperation on Herbal Medicines (IRCH) Oct 2006 meeting in China. Lead: NHPRP Program Manager, Science Officer.

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2. Area of enquiry: Program implementation			
Key findings	Recommendations	Action required	Action taken
<p><u>Implementation and delivery mechanisms</u></p> <p>Three years into its mandate, the research grants and contributions program has implemented numerous program activities and funded a total of 60 projects. However, the evaluation demonstrated a less than optimal use of available grant funding. Some improvements are required to ensure full allocation of funds under the grants mechanism.</p>	<p><u>Recommendation 3:</u> Improve the coordination of grant funding between NHPD and CIHR.</p>	<ul style="list-style-type: none"> NHPD management to build on past initiatives and initiate more frequent and regular communication with the CIHR for improved coordination of current collaborative agreements. Actions taken for current agreements and to continue Fall 2006 onwards. For future funding opportunities, NHPD to initiate the development of coordination processes when funding resumes. The NHPD to strengthen financial and reporting mechanisms to improve the early identification and timely transfer of funds between CIHR and NHPD. Some steps taken and further actions will be pursued when funding resumes. 	<ul style="list-style-type: none"> NHPD has presented twice to the CIHR Scientific Priorities and Planning Committee and initiated opportunities for communication and dialogue with the CIHR to address financial and management issues that arise in the implementation of collaborative agreements. Lead: Director of Bureau of Research, Outreach and Programs and NHPRP manager. NHPD has developed a plan to implement the RBAF and RMAF approved by TBS for its research program. This plan includes activities to strengthen financial and reporting mechanisms. Lead: Director of Bureau of Research, Outreach and Programs, Director of Planning and Operations and NHPRP manager.

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2. Area of enquiry: Program implementation			
Key findings	Recommendations	Action required	Action taken
<p><u>Funding process</u> In general, the contribution funding process has been deemed satisfactory however there is a need to streamline the process. Improvements to the call for proposals, funding timing and availability, and reporting requirements are required for increased effectiveness and transparency.</p>	<p><u>Recommendation 4:</u> Improve the contribution funding process with respect to the launching and broadcasting of Call for Proposals, the timely availability of funds and reporting requirements.</p>	<ul style="list-style-type: none"> For future funding calls, NHPD will look into best practices and existing benchmarks with regards to the timing of the announcement, funding and the period of time for preparation of proposals. Action to be initiated upon resumption of funding. NHPD to work with the Office of Consumer Affairs and Public Involvement (OCAPI) to augment the distribution of the announcements for call for proposals. Further involvement of OCAPI for future funding calls to be initiated upon resumption of funding. In consultation with the HC Grants and Contributions Centre of Expertise, the NHPD will review and streamline reporting formats and related tools so as to obtain program outcome information in a cost-effective and standardized manner. Action to be initiated upon resumption of funding. 	<p>The contribution funding process was developed when HC was reviewing the management of grants and contributions. NHPD reflects departmental policies and guidelines however improvements are continuously in progress. <u>Lead:</u> NHPRP manager NHPD involved consumer groups in the development and launch of the most recent funding call and in the peer review process.</p> <p><u>Lead:</u> NHPRP manager, Program officer and Outreach Officer.</p> <p><u>Lead:</u> NHPRP manager and Program officer.</p>

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2. Area of enquiry: Program implementation			
Key findings	Recommendations	Action required	Action taken
<p><u>Program reach</u> The report noted the need to be inclusive and to better reflect the diversity of stakeholders in program activities, in particular activities which involve consultation, priority-setting or the identification of solutions in relation to knowledge gaps.</p>	<p><u>Recommendation 5:</u> Involve broader representation of various internal and external stakeholders in priority-setting and knowledge-based activities.</p>	<ul style="list-style-type: none"> NHPD to investigate new ways and mechanisms to continue to engage representation and involvement from all stakeholders groups, including representatives from consumers groups, practitioner groups, NGOs as well as HC and other government departments and agencies in its efforts to address various knowledge-based issues and challenges faced as a regulator. <p>Some initiatives taken early in 2006-07. Further action is dependent upon funding resuming.</p>	<ul style="list-style-type: none"> NHPD has recognized the value of diversity of representation for an informed and comprehensive dialogue. In year four, the NHPD initiated an internal consultation process with staff to identify specific issues and knowledge gaps faced in the implementation of the <i>NHP Regulations</i>. <p><u>Lead:</u> Program officer and NHPD Outreach Officer.</p>

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3. Area of enquiry: Program results			
Key findings	Recommendations	Action Required	Action taken
<p><u>Research capacity</u> The evaluation report noted that funded activities, participation at conference and workshops as well as networking with representatives from a broad spectrum of disciplines led to increased awareness of NHP issues and enhanced research capacity.</p> <p><u>Supporting the conduct of research,</u> Access to grants and training awards led to opportunities for research funding and development. This was achieved through the funding from NHPRP, the CIHR and collaboration with research networks.</p> <p><u>Collaboration and partnerships</u> Continued partnership with the CIHR and new ways to foster collaborative efforts with other funding agencies, industry and other partners is important to sustain NHP research and help build a critical mass of researchers and research infrastructure.</p>	<p><u>Recommendation 6:</u> Explore new funding opportunities and support efforts to further build the sustainability of the NHP research community.</p>	<ul style="list-style-type: none"> NHPD to promote and facilitate funding opportunities with other government funding agencies (such as NSERC, CFI, NRC-IRAP, National Centres of Excellence, provincial/territorial funding agencies and industry associations), collaborative activities and interest in NHP research funding and support. Initiatives taken and to continue Fall 2006 onwards. NHPD to strengthen the development of partnerships and collaboration at the national level and foster opportunities to further the development of a strong NHP research community. Initiatives taken and to continue Nov 2006 onwards. 	<ul style="list-style-type: none"> NHPD is working with its Expert Advisory Committee, its Management Advisory Committee which has 25% consumer participation, and with other funding programs within HC and other federal departments to support the research community. <u>Lead:</u> Director of Bureau of Research, Outreach and Programs NHPRP manager, Outreach Project Officer. The NHPD has submitted a Business Case to TBS which includes a component seeking sustainable funding for the NHP research program. <u>Lead:</u> Program manager, Outreach Project Officer.
<p><u>Knowledge transfer</u> The evaluation reported some evidence of knowledge transfer appearing between researchers and those associated with the implementation of the regulations, but less so to consumers and the Canadian public. In order to improve accessibility of evidence-based information to stakeholders and consumers and facilitate informed decisions about the use of NHPs, knowledge transfer and dissemination requires additional attention.</p>	<p><u>Recommendation 7:</u> Enhance knowledge transfer and dissemination of information on NHPs.</p>	<ul style="list-style-type: none"> NHPD will work with both internal and external stakeholders to identify measures to enhance the transfer of scientific knowledge and promote information dissemination for access to accurate and consistent information on NHPs by stakeholders and consumers. Initiatives taken and to continue Nov 2006 onwards. Participation at conference and workshops and networking with representatives from a broad spectrum of disciplines to remain a continuing activity. Action to be initiated upon resumption of funding. 	<ul style="list-style-type: none"> NHPD has initiated steps for the promotion of the dissemination of research findings internally and with the NHP community. <u>Lead:</u> Director and various staff in NHPD Bureau of Research, Outreach and Operations. <u>Lead:</u> NHPRP Manager

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4. Area of enquiry: Effectiveness and alternatives			
Key findings	Recommendations	Actions required	Action taken
<p><u>Effectiveness</u></p> <p>The evaluation findings demonstrated progress achieved in all four program areas and their respective importance in meeting the program's objectives.</p> <p>The grants delivery mechanism was identified as an effective way to bring NHP research into mainstream research and to raise the profile of this area of research on a national level.</p> <p>Operating funds provided flexibility, ability to target needed research in a timely manner and bring together groups of stakeholders to explore common issues resulting in qualitative benefits to the program.</p> <p>The contribution delivery mechanism was identified as less cost-effective: it was able to generate broad interest in NHP research in various institutions however the process is labor-intensive, needs a more focused approach and funding is not always sufficient to make a real change in the body of knowledge.</p> <p><u>Alternatives</u></p> <p>Adjustments are required to deliver the program in a more cost-effective way, keeping in consideration the research priorities, the amount of funding and the need to fund a combination of both large focused initiatives and smaller projects.</p>	<p><u>Recommendation 8:</u> Deliver program in more cost-effective manner, maintaining balance between flexibility and effectiveness and further strengthening the research community infrastructure.</p>	<p>If program specific funding becomes available NHPD to:</p> <ul style="list-style-type: none"> • Award larger amounts per call per proposal; • Use a portion of the envelope to fund more focused initiatives around specific NHP topics identified as priority by NHPD, its advisory committee and the broad NHP community and important to support regulatory decisions; and • Maintain a portion of the funds for smaller projects or projects at the stage of inception where scientific research is still largely underdeveloped and capacity to obtain funding limited. <p>Actions dependent upon funding resuming.</p> <p>With other NHP partners and to achieve greater effectiveness:</p> <ul style="list-style-type: none"> • NHPD in consultation with HC partners and associated programs, other national and international funding agencies and the Treasury Board Secretariat, will examine ways to improve the delivery of the research program, for improved cost-effectiveness and optimal flexibility and responsiveness to the regulatory environment. <p>Action dependent upon funding resuming.</p>	<p>Actions were taken based on advice received from stakeholders and in the most recent 2006 funding call:</p> <ul style="list-style-type: none"> • NHPD reviewed options for funding levels and maximum contribution allocation for proposals. • NHPD solicited both internal and external input through the evaluation process to further define research priorities and scope of the call for proposals. <p><u>Lead:</u> Program manager</p> <p>In the last funding call, steps were taken to deliver on this point:</p> <ul style="list-style-type: none"> • NHPD included representation of consumers groups in the 2006 call for proposals and in the evaluation process. • NHPD used available resources and existing infrastructure for the peer review and selection process. <p><u>Lead:</u> Program manager and Program Officer</p>



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Formative Evaluation of the Natural Health Products Research Program

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Prepared for

Natural Health Products Research Program
Natural Health Products Directorate
Health Products and Food Branch
Health Canada

Submitted by

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The views expressed herein are solely those of the authors and do not necessarily represent the official views of Health Canada.

Executive Summary

INTRODUCTION

The present report discusses the formative evaluation of the Natural Health Products Directorate research program at Health Canada. The Natural Health Products Research Program (NHPRP) was launched in June 2003 in response to a need for Health Canada to support research on natural health products, as identified by the Standing Committee on Health's Advisory Panel on Natural Health Products in 1998.

THE NATURAL HEALTH PRODUCTS REGULATIONS

The federal government has responded to the increased popularity and use of natural health products (NHPs) by Canadians by taking steps to better understand and define the area and ensure the appropriate framework and supporting structures are in place. In March 1999, following the work of the Standing Committee on Health's Advisory Panel on Natural Health Products, the Minister of Health accepted all 53 of the Standing Committee's recommendations and announced the creation of the Office of Natural Health Products (now the Natural Health Products Directorate).

The Natural Health Products Directorate (NHPD) is the regulating authority for the sale of natural health products in Canada. Its mandate is to ensure that all Canadians have ready access to natural health products that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. An investment in research was identified as necessary to bridge the gap in research-based knowledge about NHPs and help the directorate achieve its mandate.

THE NATURAL HEALTH PRODUCTS RESEARCH PROGRAM

The NHPRP is a \$5M (\$1M per year for 5 years) grants and contributions program which directs funding to natural health products research and related activities that are relevant to the regulatory function of the NHPD. The objective of the research program is to contribute to improved knowledge of NHPs and to enable Canadian consumers to make informed choices about NHPs as part of their health care options.

The NHPRP works towards meeting these objectives by focusing on four key areas of activity:

- Building research capacity;
- Supporting the conduct of research;
- Fostering collaboration, community infrastructure and partnership building; and
- Enhancing information retrieval and knowledge transfer.

PURPOSE AND SCOPE OF THE FORMATIVE EVALUATION

At the time the formative evaluation was undertaken, the research program was in its third year of five-year funding. The current evaluation was undertaken for three purposes:

1. To provide the NHPD with a preliminary assessment of the progress made by the research program towards its stated outcomes;
2. To gather information which will assist the NHPD in making decisions and adjustments required to best deliver the research program; and
3. To provide objective information to assist management with decisions on the direction, priorities and delivery of the research program.

In keeping with the Treasury Board of Canada Secretariat requirements regarding the evaluation of government-funded programs and policies, the formative evaluation addressed the following evaluation issues:

1. **Role and relevance:** Is the research program responsive to the NHP research environment and the needs of Canadians?
2. **Implementation:** What progress has been made and where are the gaps in implementation?
3. **Program outcomes:** What has been achieved to date as a result of the research program?
4. **Effectiveness and alternatives:** Are the most appropriate and cost-effective methods used to deliver the research program?

METHODOLOGY

The design of the formative evaluation was based on the NHPRP Logic Model, which articulates how the program activities are expected to lead to the hoped for outcomes. Both qualitative and quantitative data were collected from five key sources:

- A review of 83 program and background documents;
- Telephone interviews with 25 recipients of project funding;
- An internal panel discussion with 10 Health Canada staff from various bureaus within the NHPD and representatives from the Office of the Chief Scientist (OCS), the Health Products and Food Inspectorate (HPFI), and the Marketed Health Products Directorate (MHPD);

- An expert panel's examination of the program's strengths, weaknesses, opportunities and threats with respect to each of its four key program areas. Panel members included representatives (at the local and national levels) from research funding organizations, the research community, non-governmental organizations (NGOs), practitioner groups, industry groups and consumer groups; and
- A review of selected literature on the topics of research capacity development, the development of partnerships and community infrastructure, and knowledge transfer as well as consultations with contacts at academic and research institutions.

FINDINGS

Role and relevance issues

The use of NHPs by Canadians has continued to increase since the examination and consideration of a regulatory framework for NHPs by the Standing Committee on Health's Advisory Panel on Natural Health Products in 1998. Yet a recent poll suggests that in general, more Canadians are unfamiliar than familiar with NHPs.

A solid base of credible NHP research would complement and support the regulatory regime for NHPs. Now that the *NHP Regulations* are in place, it is even clearer that there are gaps in the knowledge of NHP safety, efficacy and quality – areas critical to this regulatory function. The NHPD is unique as few jurisdictions – if any – have a research program with resources for research funding specific to this regulatory role. Within Health Canada and on the national scene, the NHPD research program is distinctive in that it supports research to bolster its regulatory decisions and facilitate the implementation of the *NHP Regulations*.

Program implementation

Using three delivery mechanisms (i.e., grants, contributions and operating funds) and committing 84% of its allocated \$3M, the NHPRP has funded a total of 60 projects in its first three years, many of which cross program activity areas, disciplines, research themes, NHP products, and geographic locations. During the first three years of implementation, the NHPRP staff have encountered successes and also responded to a number of challenges in program delivery.

The NHPRP collaboration with the Canadian Institutes of Health Research (CIHR) resulted in a total of five collaborative agreements to support research and training awards. With the exception of the first program year, not all of the funds available for grants were used (68% of allocated funds spent in Year 2 and 57% in Year 3). Ongoing issues related to coordinating the flow of funds with the timing of the CIHR funding calls, improving the timely identification of unused funds, and coordinating the timing of

accounting within the CIHR and Health Canada are being addressed in a collaborative fashion with the CIHR.

The NHPRP launched four requests for proposals and a total of 30 contributions agreements were signed during the first three years with funding amounts ranging from \$20K to \$75K. In general, funding recipients report that they are satisfied with the contributions funding process; however, the evaluation identified improvements for increased effectiveness and transparency.

Operating funds have been used to support numerous consultations, priority setting meetings, conferences and workshops. There is a need to increase the involvement of groups other than the established research community for optimal representation of stakeholders. The flexibility of the operating funds mechanism has allowed the NHPRP to adapt as gaps in NHP research knowledge emerge. A number of gaps in knowledge remain and there is still a need to fund priority-setting consultations in areas such as the NHPs used in the field of homeopathy, naturopathy and essential oils/aromatherapy.

Program outcomes

Of the six beneficiary groups named in the submission to the Treasury Board of Canada Secretariat, the NHPRP has made significant strides in reaching three, namely the research community, industry, and the individuals and entities involved in the development of the NHP regulatory framework. In support of this statement, the formative evaluation uncovered evidence that the NHPRP has, for example: increased access to research funding; involved industry in consultations, communication activities and funded projects; and funded credible research in NHP safety, efficacy and quality.

The program also aims to achieve results in four key areas and has done very well in a short period of time, particularly in terms of supporting the conduct of research and building research capacity. To maintain this momentum, continued efforts are now required in the areas of collaboration, partnership building and the development of community infrastructure as well as knowledge transfer and dissemination.

The work done to achieve consensus on NHP research priorities among a wide variety of stakeholder groups who have competing interests is significant. The current partnerships with the CIHR, industry and practitioners will be important to nurture in order to ensure sustained credibility and affordability of NHP research and the successful implementation of the *NHP Regulations*. These – along with other – partnerships must be developed with a focus on building NHP research infrastructure (i.e., physical, monetary and human). Given its successful work thus far in increasing the credibility and legitimacy of NHP research, the NHPRP is well positioned to identify and build partnerships at the local, regional, national and international levels that will further its objectives.

The development of multidisciplinary NHP research teams and the creation of NHP research networks already resulting from the NHPRP have the potential to contribute to the establishment of a critical mass of research expertise and/or centres. Furthermore, multidisciplinary research teams such as those developed thus far by the NHPRP have been linked in studies of similar research programs to enhancing knowledge transfer and information dissemination. A key part of the program's mandate is to enable Canadian consumers to make informed choices about the safe use of NHPs. Some uncertainty has arisen over how to proceed with communicating research findings, particularly to the public, but suggestions were made by those consulted for the formative evaluation.

Effectiveness and alternatives

The NHPRP has used both partnerships and third-party delivery mechanisms to maximize efficiency and impact. Key informants have noted the success of this approach.

Through its grants mechanism, the NHPRP was able to leverage research funds from the CIHR. Other returns on the NHPRP's investment are more intangible and/or indirectly related to the program and include the funding of NHP researchers by the CIHR. Furthermore, all costs related to peer review and overall management are covered by the CIHR, making grants an efficient way for the NHPRP to support NHP research. Moreover, the partnership with the CIHR has served to increase the credibility and legitimacy of NHP research on a national level.

The contributions mechanism has proven effective at fostering the interest in NHP research within various institutions across Canada. The support provided has helped some organizations to obtain further funding from other agencies. In comparison to grants, contributions are much more labour intensive for both the NHPRP and the funding recipients.

Through its operating funds, the NHPRP has funded background papers on key regulatory issues, some of which have already formed the basis for further exploration and resulted in concrete applications in relation to the *NHP Regulations*. Key to the success of these projects was the ability to use the funds in a flexible manner to target research that is identified on an ongoing basis and needed in a timely fashion. Other successful projects were the priority-setting exercises and technical workshops which brought different stakeholder groups together. These projects are particularly significant because many have resulted in achieving some consensus on NHP research priorities among a wide variety of stakeholder groups who have competing interests.

RECOMMENDATIONS

In an effort to ensure the continued relevance of the program, it is recommended that the NHPD:

1. Develop a strong relationship between regulators and the broad NHP community to ensure an integrated approach in addressing the knowledge gaps and challenges of the NHP regulatory environment.
2. Sustain and improve efforts in the generation of knowledge in the areas of quality, safety and efficacy and its dissemination to stakeholders, partners and the Canadian public.

For improvements to program implementation, it is recommended that the NHPD:

3. Improve the coordination of grant funding with the CIHR.
4. Improve the contribution funding process with respect to the launching and broadcasting of Call for Proposals, the timely availability of funds and reporting requirements.
5. Involve broader representation of various internal and external stakeholders in various priority-setting and knowledge-based activities.

To work towards achieving stated outcomes across all four key program areas, it is recommended that the NHPD:

6. Explore new funding opportunities and support efforts to further build the sustainability of the NHP research community.
7. Enhance knowledge transfer and dissemination of information on NHPs.

For improvement in the effectiveness of the delivery mechanisms, it is recommended that the NHPD:

8. Deliver the program in a more cost-effective manner, maintaining the balance between flexibility and effectiveness and further strengthening the research community infrastructure.

Acknowledgements

A number of key stakeholders contributed their support and expertise to this formative evaluation.

I would first like to extend sincere appreciation to those (almost 50 individuals in total) who volunteered thoughtful and invaluable comments in the telephone interviews, internal panel and expert panel discussions on the Natural Health Products Research Program (NHPRP) and the Natural Health Products research community.

Special thanks are extended to the NHPRP evaluation project team – Brigitte Bélanger, Christine Cryan, Michael J. Smith and Marie Nyiramana – for their guidance, insights, and collaboration, and to members of the Evaluation Advisory Committee for their role in reviewing products related to the formative evaluation.

And, finally, I would also like to thank Evelyn Valge and Laurie McCaffrey – members of the evaluation consulting team – for their superb support in research, facilitation and reviewing draft products.

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Principal and Owner
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List of Acronyms Used in this Report

AAFC	Agriculture and Agri-Food Canada
AFMNet	Advanced Food and Materials Network
AHFMR	Alberta Heritage Foundation for Medical Research
BCFN	BC Functional Food and Nutraceutical Network
BCIT	British Columbia Institute of Technology
CAHC	complementary and alternative health care
CAM	complementary and alternative medicine
CATIE	Canadian AIDS Treatment and Information Exchange
CCAM	Cancer and Complementary/Alternative Medicine (CCAM) Research Team
CHN	Canadian Health Network
CHSRF	Canadian Health Services Research Foundation
CICMR	Canadian Institute of Chinese Medicinal Research
CIHR	Canadian Institutes of Health Research
EAC	NHPRP External Expert Advisory Committee
EFA	essential fatty acid
EPO	evening primrose oil
FA	fatty acid
FRSQ	Fonds de recherche en santé du Québec
FTE	full-time equivalent
Gs & Cs	grants and contributions
GMP	good manufacturing practice
HC	Health Canada
HIV	human immunodeficiency virus
HPFB	Health Products and Food Branch
HPFI	Health Products and Food Inspectorate
IAHP	Institute of Aboriginal People's Health (CIHR)
ICE	Interdisciplinary Capacity Enhancement Team

IHSPR	Institute of Health Services and Policy Research (CIHR)
III	Institute of Infection and Immunity (CIHR)
IMHA	Institute of Musculoskeletal Health and Arthritis (CIHR)
INCAM	Canadian Interdisciplinary Network for Complementary and Alternative Medicine (INCAM) Research
MAC	NHPRP Management Advisory Committee
MHPD	Marketed Health Products Directorate
MOUs	memoranda of understanding
NCCAM	National Centre for Complementary and Alternative Medicine
NCIC	National Cancer Institute of Canada
NET	New Emerging Team
NGO	non-governmental organization
NHP	natural health product
NHPD	Natural Health Products Directorate
NHPRP	Natural Health Products Research Program
NHPRSC	Natural Health Products Research Society of Canada
NIH	National Institutes of Health (United States)
NRC	National Research Council of Canada
NSERC	Natural Sciences and Engineering Research Council of Canada
OCS	Office of the Chief Scientist
OHTN	Ontario HIV Treatment Network
ROI	return on investment
SAP	Systems, Applications and Products (SAP) Database
SSHRC	Social Sciences and Humanities Research Council of Canada
SWOT	strengths, weaknesses, opportunities and threats
TBS	Treasury Board of Canada Secretariat
TCM	Traditional Chinese Medicine
WHO	World Health Organization

Definitions of Terms Used in this Report

The following is a list of working definitions of key terms that are used throughout the evaluation report:

- **Impact:** Typically, evaluation questions relating to a program's impact are asked after a program has been in place for an extended period of time. At that point, the emphasis of an impact evaluation is on how effective the program's intervention was on influencing specified factors. In other words, an impact evaluation measures a program's effects and the extent to which program goals were attained as identified in a program logic model. Often, the data collected to assess a program's impact comes from person-referenced outcomes, such as self-reported impacts (e.g., satisfaction with a program, behavioural changes), in addition to other statistical data (e.g., crime rates, health outcomes). (See Hess & Klekotka, n.d. & Posavac & Carey, 1992.)

The focus of the present formative evaluation is on the program's implementation to date and the extent to which the program is still considered to be relevant. However, the Terms of Reference for the formative evaluation also asked for preliminary evidence regarding the program's outcomes, which include several questions about the program's intended impact on six beneficiary groups. Thus, in the present report, the term *impact* refers to the self-reported benefits or drawbacks of the program, as experienced by the stakeholders consulted and as identified in the NHPRP Logic Model.

- **Leverage:** Leverage is commonly used in a metaphorical sense such as to describe any strategic or tactical advantage. (Retrieved September 2006 from http://whatis.techtarget.com/definition/0,,sid9_gci347744,00.html.) In the present report, the term leverage is used in this manner and not in a technical sense, such as may be used in the field of finance.

The term leverage was introduced into this evaluation report to describe how the NHPD intends to achieve several of its outcomes, as identified in the NHPRP Logic Model. For example, the NHPRP Logic Model indicates several outcomes that are to be achieved through the development of partnerships and the acquisition of additional NHP research funds. As described throughout the evaluation report, funds invested by the NHPD have resulted in the acquisition of additional funds for NHP research projects through a variety of direct and indirect means. An example of direct leveraging by NHP research funds would be through the memoranda of understanding (MOUs) with the CIHR. An example of indirect leveraging as reported by key stakeholders consulted for this evaluation would be the investment by the NHPD in NHP research, which has led to increased

credibility of NHP research which, in turn, has led to investments in NHP research by other funding organizations.

- **Return on investment:** In the present report, the term return on investment (ROI) is used to describe what the NHPD gets back for the money it spends. It includes the “financial” as well as “non-financial” or “social” benefits resulting from the NHPD’s investment in NHP research as reported by the key stakeholders consulted for this evaluation. (Retrieved September 2006 from http://www.rms.net/lc_faq_other_roi.htm.) It is not the intent of the authors to suggest that ROI calculations have been undertaken as would be the case in the field of finance.
- **SWOT analysis:** When engaging in strategic planning – a process involving questions similar to those asked in this formative evaluation – it is often useful to systematically examine a program’s or organization’s strengths, weaknesses, opportunities and threats. This process is commonly referred to as a SWOT analysis.

For the formative evaluation of the NHPRP, NHP stakeholders who may or may not have direct experience with the NHPRP but who are recognized as having a broader perspective of NHPs in Canada were asked to examine the extent to which NHPRP activities are having the desired impact in the broader community as identified in the NHPRP Logic Model (e.g., enhancing NHP research capacity and partnership building). They were also asked to brainstorm ideas on ways to engage new partners in the NHP dialogue, ways to better understand knowledge gaps and areas requiring priority research funding, and to comment on the fit of the NHPRP within other government or stakeholder NHP initiatives.

When designing the process to gather this broad scope of information in a one-day group session, it was determined that the best approach would be one similar to a SWOT analysis. Thus, participants in the external panel discussion were asked various questions about the program’s strengths, weaknesses, opportunities and threats in each of the four program areas.

In particular, the assessment of the program’s results was based on an examination of the NHPRP in terms of its:

- Strengths: areas where the NHPRP has been most effective or has made the most significant progress to date;
- Weaknesses: areas where the NHPRP could improve its ability to achieve progress;
- Opportunities: ways the NHPRP can best move forward in each program area; and
- Threats: things that might challenge the program’s ability to move forward in each program area.

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1.0 Introduction

The present report discusses the formative evaluation conducted for Health Canada's Natural Health Products Research Program (NHPRP). The formative evaluation reviews the NHPRP's implementation and progress from its official launch in June 2003 to the end of March 2006.

The first sections of this report briefly describe Health Canada's *Natural Health Products Regulations*, the research program and purpose and scope of the evaluation. After setting the context, details on the evaluation methodology are presented, followed by the key findings and a discussion of lessons learned and recommended action for program improvement. The evaluation was conducted by an independent evaluation consulting firm and findings were based on input from consultations with a wide variety of stakeholders and Health Canada staff, as well as a review of program documents and relevant literature.

1.1 THE NATURAL HEALTH PRODUCTS RESEARCH PROGRAM

1.11 Context

The NHP Regulations

As part of its mandate to protect the health of Canadians, the federal government has responded to the increased popularity and use of natural health products (NHPs) by Canadians by taking steps to better understand the topic and resource itself accordingly. These actions have, in part, the intent to better define the subject area and have included the development of an appropriate regulatory framework.

In October 1997, the Standing Committee on Health undertook to study NHPs and to make recommendations regarding the legislative and regulatory regime. At the time, the estimates suggested that the gross income of the NHPs industry in Canada ranged between 1.5 billion and 2 billion dollars in 1997, with annual growth of 10 to 15 percent. Current figures indicate that Canadian consumers have steadily increased their usage of NHP for general nutrition, for enhancement of health, or for preventative measures (Canadian Health Foods Association, 2002). Canadian sales figures for sport, meal, homeopathic and specialty supplements, vitamins, minerals, herbs and botanicals were estimated to be \$1.3 billion US in 2003 (Ferrier, 2005), a 10% increase over 2002 figures.

It was also documented in various 1997 surveys that 56% of Canadians reported taking one or more NHPs and that 67% of Canadians felt that the federal government should regulate NHPs in order to ensure product safety and quality. Consumers are indeed looking for good sources of valid information with regard to their health care choices. In 2005, the Natural Health Products Directorate (NHPD) commissioned a benchmark

survey which measured awareness levels, attitudes towards, knowledge about and behaviours of Canadians as they pertain to NHPs. Seven in ten Canadians (69%) agree they need more information on NHPs and an even larger majority (84%) believes that more needs to be done to inform Canadians about the safe use of NHPs (Health Canada, March 2005).

In March 1999, following the work of the Standing Committee on Health's Advisory Panel on Natural Health Products, the Minister of Health accepted all 53 of the Standing Committee's recommendations and announced the creation of the Office of Natural Health Products (now the Natural Health Products Directorate).

Widespread, comprehensive and inclusive consultations were conducted with Canadian consumers, academics, health care practitioners and industry stakeholders in order to develop the *NHP Regulations*. The *Regulations* came into force on January 1, 2004 and apply to all natural health products. These *Regulations* include provisions on:

- Product licensing;
- Site licensing;
- Good manufacturing practices;
- Adverse reaction reporting;
- Clinical trials;
- Labelling; and
- A full range of health claims that will be supported by evidence.

The NHPD is the regulating authority for the sale of natural health products in Canada. Its mandate is to ensure that all Canadians have ready access to natural health products that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity.

Rationale for the program

To support its regulatory function – while respecting philosophical and cultural diversity and free choice for consumers' health decisions and ensuring that Canadians have ready access to NHPs that are safe, effective and of high quality – the Standing Committee on Health recommended that the NHPD regularly consult with relevant consumer, industry and practitioner groups about the nature of information required about NHPs (Recommendation 44); encourage research on NHPs (Recommendation 45); and disseminate the resulting information to health care professionals and consumers (Recommendation 46). In fulfillment of these requirements and following a series of national consultations to identify NHP research priorities, the Natural Health Products Directorate launched the research program in June 2003.

1.12 Program description

The Natural Health Products Research Program is contained within the Natural Health Products Directorate of Health Canada's Health Products and Food Branch (HPFB). The research program is a five million dollar, five-year program that supports research and knowledge-based development in the area of NHPs with an ultimate outcome of *substantive, accurate and timely research information that supports the regulatory process and facilitates informed choice by consumers* (see the NHPRP logic model on p. 5). The NHPRP is the only such program in Health Canada that either works with other academic or research institutions in promoting NHP research or leverages partnerships with other funding agencies to provide funds for research into natural health products which is specific to the regulation of NHPs.

The NHPRP reach is intended to be broad, with benefits accruing to the following constituencies:

- Those involved in the development of an effective regulatory framework (through the generation of research based evidence);
- Industry (through opportunities for collaboration and exchange of information);
- The research community (by directing funding to such research and related activities);
- Health care communities and professionals that produce and utilize NHPs (through the generation of research based evidence on the NHPs used and the integration of conventional and complementary health care approaches);
- Voluntary and not-for-profit organizations (by directing funding to these organizations for NHP research); and
- Canadian consumers (through the generation and diffusion of information to help them make informed choices about NHPs as part of their health care options).

Over five years, one million dollars per annum is to be distributed through three delivery mechanisms, namely, grants delivered in collaboration with the Canadian Institutes of Health Research (CIHR), contributions and operating dollars.

The NHPRP has identified a range of activities to be undertaken in four key areas:

- Building research capacity;
- Supporting the conduct of research;
- Fostering collaboration, community infrastructure and partnership building; and
- Enhancing information retrieval and knowledge transfer.

1.13 Governance

The research program is administered centrally by the NHPD. The funds required to administer the research program are separate from the overall \$5M budget dedicated to grants, contributions and other complementary activities.

1.2 PURPOSE AND SCOPE OF THE FORMATIVE EVALUATION

At the time the formative evaluation was undertaken, the Natural Health Products Research Program was in its third year of five-year funding. The formative evaluation was undertaken for three purposes:

1. To provide the NHPD with a preliminary assessment of the progress made by the research program towards its stated outcomes;
2. To gather information which will assist the NHPD in making decisions and adjustments required to best deliver the research program; and
3. To provide objective information to assist management with decisions on the direction, priorities and delivery of the NHPRP.

1.21 NHPRP logic model

The following exhibit is the logic model for the NHPRP (see Table 1). A logic model for a program illustrates the program's main activities, outputs and intended outcomes and how these are logically linked. In other words, the program logic model represents the means by which the program is expected to achieve its stated outcomes.

The design of the formative evaluation for the NHPRP was based on the Logic Model. Using the Logic Model, specific evaluation questions, indicators and data sources were developed by the NHPRP and are presented in the Evaluation Information Summary Table (see Appendix A). Data collection tools for the formative evaluation were developed using the Logic Model, the Evaluation Information Summary Table and the Terms of Reference for the formative evaluation. All data collection tools are presented in the section beginning on page 87.

Table 1. NHPRP Logic Model					
	Activities	Building research capacity	Supporting the conduct of research	Developing partnerships and community infrastructure	Enhancing knowledge transfer
	Sub-activities	<ul style="list-style-type: none">▪ Personnel training awards▪ Training centre awards▪ Curriculum development▪ Research network development	<ul style="list-style-type: none">▪ Research funding and development▪ Encouraging research funding by other stakeholders	<ul style="list-style-type: none">▪ Partnership development▪ Community infrastructure development▪ Stakeholder consultation	<ul style="list-style-type: none">▪ Support to NHP related workshops, seminars, conferences, etc▪ Literature reviews▪ Electronic information support
	Outputs	<ul style="list-style-type: none">▪ Selected personnel undertake sponsored training▪ Multi-disciplinary research training programs developed▪ Curriculum development in NHP research training▪ Networks created (e.g., conventional & complementary health care providers, different groups of stakeholders)	<ul style="list-style-type: none">▪ Research grants awarded and findings achieved▪ Research grants awarded with funds from other sources/research findings provided	<ul style="list-style-type: none">▪ Development of collaborations, networks or partnerships▪ Increased involvement of voluntary and not-for-profit organizations and other collaborators in activities related to NHP research▪ Increased stakeholder input into NHPRP research priorities and activities	<ul style="list-style-type: none">▪ Stakeholders in different sectors who have received and benefited from current information or participated in dialogue on NHP related issues▪ Literature reviews▪ Web pages of not-for-profit organizations include component on NHP research
		Research capacity results	Supporting research results	Partnerships and community infrastructure results	Knowledge transfer and dissemination results
	Immediate outcomes	<ul style="list-style-type: none">▪ Increased number of Canadian researchers trained in NHP research that will generate an increase in grant applications▪ Increased training opportunities on NHP research for Canadian researchers▪ Increased awareness of NHP issues and challenges among students and practitioners▪ Increased cooperation and interoperability between network members, best of evidence-based medicine from conventional health care combined with clinical evidence from complementary health care	<ul style="list-style-type: none">▪ Increased knowledge of NHPs based on research conducted in key areas including safety, efficacy, utilization and cost effectiveness of NHPs▪ Better understanding of knowledge gaps and areas requiring priority research funding▪ Knowledge of NHPs based on research conducted in specified areas and obtained through partnerships or co-sponsorship.	<ul style="list-style-type: none">▪ Enhanced understanding of NHP research issues and increased synergistic joint activities based on complementary strengths▪ Expanded role and involvement of voluntary and not-for-profit organizations in NHP research▪ Sharpened focus on key areas of interest and concern across different sectors	<ul style="list-style-type: none">▪ Increased sharing of relevant information across different sectors that could impact on NHP research, contribute to informed choice of consumers, and contribute to development of the NHPRP research agenda▪ Increased knowledge from literature reviews translates into research priorities and products, and contributes to the development of the regulatory framework▪ Increased accessibility of information on NHP research to stakeholders, including consumers
	Ultimate outcome	Substantive, accurate and timely research information that supports the regulatory process and facilitates informed choice by consumers			

1.22 Areas of inquiry for the formative evaluation

In keeping with the Treasury Board of Canada Secretariat requirements regarding the evaluation of government-funded programs and policies, the formative evaluation addressed the questions of program relevance, program implementation, progress towards achieving desired outcomes (as identified in the NHPRP logic model), and the effectiveness of the methods used to deliver the program. These four evaluation areas of inquiry are detailed below in Table 2.

Table 2. Areas of inquiry for the formative evaluation	
Area of evaluation inquiry	Description
Role and relevance issues: Is the NHPRP responsive to the NHP research environment and the needs of Canadians?	This area looked at the extent to which the program, and the projects it supports, continues to be relevant to government priorities and public interest needs. It also explored the particular role of the NHPRP and whether there is still a need for a Health Canada NHP research intervention.
Program implementation: What progress has been made and where are the gaps in implementation?	The intent of this area was to focus on implementation progress to date, to determine whether the NHPRP has been implemented as identified in its program rationale and logic model. In particular, the ability of the program to deliver planned activities to intended beneficiaries, according to agreed terms and conditions, while being responsive to changing needs and identified priorities was addressed.
Program outcomes: What has been achieved to date as a result of the NHPRP?	The intent of this area of focus was to determine whether the NHPRP has made progress toward the achievement of anticipated outcomes. In particular, the issues of NHP research knowledge, research capacity, partnerships and research community infrastructure and knowledge transfer were examined.
Effectiveness and alternatives: Are the most appropriate and cost-effective methods used to deliver the NHPRP?	The intent of this area of focus was to identify useful lessons learned which could be used by the NHPRP stakeholders and by program managers to improve program delivery and ensure optimal program reach and impact.

Given the timing of the evaluation, the present study emphasizes the extent of the progress made to date at the output level with some immediate outcomes identified (see NHPRP Logic Model on p. 5). The evaluation questions, indicators, and their respective data sources are highlighted in the Evaluation Information Summary Table (see Appendix A). The findings of this formative evaluation will be used to guide program direction and planning.

1.3 METHODOLOGY

1.31 Overview of the approach

In an effort to increase the utility of the evaluation findings, the evaluation consulting team worked in a collaborative manner with the Natural Health Products Directorate.

Interview and discussion questions for each stakeholder group, as well as templates used in the document review, were designed in consultation with the NHPD (including the Evaluation Advisory Committee), the NHPRP's program theory (as articulated in the Logic Model), specific evaluation questions and indicators (as articulated in the NHPRP's Evaluation Information Summary Table and the Terms of Reference), instruments previously designed by the lead consultant to collect similar types of information, and readily available literature in the areas of capacity development, networking/partnership, and knowledge transfer.

Overview of the Data Collection

Both qualitative and quantitative data were collected from five key sources:

- A review of 83 program and background documents;
- Telephone interviews with 25 recipients of project funding;
- An internal panel discussion with 10 Health Canada staff from various bureaus within the NHPD and representatives from the Office of the Chief Scientist (OCS), the Health Products and Food Inspectorate (HPFI), and the Marketed Health Products Directorate (MHPD);
- An expert panel's examination of the program's strengths, weaknesses, opportunities and threats (SWOT analysis) with respect to each of its four key program areas. Panel members included representatives (at the local and national levels) from research funding organizations, the research community, non-governmental organizations (NGOs), practitioner groups, industry groups and consumer groups; and
- A review of selected literature on the topics of research capacity development, the development of partnerships and community infrastructure, and knowledge transfer as well as consultations with contacts at academic and research institutions.

Ethics approval was obtained prior to conducting the recipient interviews and panel sessions. All data were gathered by the proposed evaluation team members and

conducted according to accepted standards of systemic inquiry balanced with the rights of the participants. Prior to their participation, all participants were informed of the purpose of the project, limitations to confidentiality, their rights as participants, and use of the data. An invitation for participants to ask questions of the evaluation team was also extended. A summary of the evaluation methodology is presented in Appendix B.

Data analysis

Qualitative and quantitative data from all sources were analyzed and summarized separately. The NHPRP Logic Model and Evaluation Information Summary Table were used to guide all analyses. Summary notes from the internal and expert panel sessions were sent to participants for review and comment prior to finalization.

1.32 Strengths and limitations of the formative evaluation

Strengths

Program theory and systematic data collection

All instruments and processes developed and implemented for the formative evaluation were based on the NHPRP Logic Model (which articulates the program's theory or how the program activities are expected to lead to the hoped for outcomes), the Evaluation Information Summary Table and the Terms of Reference for the formative evaluation. This provided a focused and systematic framework for the evaluation. Furthermore, the Evaluation Information Summary Table provided a documented common understanding of the scope of the evaluation prior to undertaking any data collection activities.

External benchmark used

As part of the methodology adopted for the evaluation, the program was assessed against knowledge derived from the literature regarding research capacity development (see Mulholland Consulting, 2004; Overseas Development Institute, 2002), the development of partnerships and community infrastructure (see Scott & Thurston, 1997; Scott, 2000), and knowledge transfer (see Barwick et al., 2005; Buxton et al., 1999; Gastel, 2001; Gerhardus et al., n.d.; L'Heureux, Zimmer & Pearson, 2003). This process served to ground the evaluation questions in the literature and provide an external benchmark against which to assess the program's performance.

Balanced input from a variety of key data sources

A random probability sampling strategy was used to select participants for the telephone interviews with funding recipients. A stratified sampling framework based on a number of criteria established jointly by the NHPRP evaluation project team and the evaluation consultants was used to select participants for the internal and expert panel discussions.

Most individuals who were initially selected agreed to participate or sent another individual on their behalf. Reasons for not participating were generally related to the short timeframe between the invitation and the selected consultation date and a conflict with another departmental event. Feedback from a wide range of stakeholders was balanced with the information contained in program documents.

Limitations

Inability to assess policy-related questions due to federal election

A key evaluation question related to knowledge transfer involved an assessment of the extent to which the findings from the research program funded projects may have been used to influence policy. However, just prior to undertaking the consultations, a federal election was announced, and it is a departmental guideline not to ask policy-related questions during an electoral period.

Methodological weaknesses in the assessment of program relevance

In comparison to methods commonly used by evaluators to assess the key evaluation questions of success and cost-effectiveness of Canadian federal government programs (e.g., return on investment, cost/benefit analysis), methods generally used to assess the question of program relevance are relatively weak from a methodological standpoint. Specifically, evaluation frameworks typically include few key questions to assess program relevance and rationale, and the methods generally employed are essentially an assessment of the face validity of the fit between the program mandate and the government's priorities. In the current evaluation, an attempt was made to improve on these identified weaknesses by assessing the research program against several criteria outlined by the Expenditure Review Committee (e.g., *Role of Government Test*, *Public Interest Test*, *Value for Money Test*).

Attribution of program outcomes, assessment of program impacts and statement of evaluation conclusions

Given that this is a formative evaluation, the preliminary assessment of program outcomes is required. As part of this preliminary assessment of outcomes, the Terms of Reference for the formative evaluation required the consultants to assess to what extent the program is impacting the six beneficiary groups as outlined in the submission to the Treasury Board of Canada Secretariat. However, with the employed non-experimental design, the evaluation can only provide information on the extent to which program outputs and outcomes are achieved without being able to directly attribute outcome achievement to the program. Given the limited influence of any program over *impacts* on stakeholders, conclusions regarding the NHPRP's impacts are necessarily even more tentative than those regarding its outcomes, particularly at this early stage in the program's implementation and without comparative baseline data or conclusive external benchmarks.

It is the responsibility of the consultants to be mindful of the above methodological limitations when stating conclusions about program outcomes and impacts. Conclusions should be stated only with a level of assuredness that can be supported by the evidence collected and the employed methodology. For the summative evaluation, it will be necessary to employ an experimental or quasi-experimental design in order to more definitively identify program impacts.

The decision-oriented focus of the evaluation

Evaluations are conducted for a variety of reasons. The focus of the formative evaluation of the research program was to help managers make programmatic decisions. The necessary collaboration between the consultants and the decision-makers in such decision-oriented evaluations also introduces an opportunity to bias results. (Retrieved October 2006 from <http://en.wikipedia.org/wiki/Evaluation>.) To reduce this potential for bias, data were collected from multiple sources to address each evaluation question and the NHPRP Logic Model, the Evaluation Information Summary Table and the Terms of Reference for the formative evaluation were used to guide all data collection and analyses.

Duplication of indicators in the NHPRP Evaluation Information Summary Table

As mentioned above, three documents were used to guide the formative evaluation of the NHPRP: the Logic Model, the Evaluation Information Summary Table and the Terms of Reference for the Formative Evaluation of the NHPRP. At the request of the NHPD, information collected that could inform the questions posed by the Expenditure Review Committee (TBS, 2003) was weaved into the final report. Because of extensive duplication in the indicators outlined in the Evaluation Information Summary Table, some components (including evaluation questions outlined in the Terms of Reference) were eventually eliminated or combined to reduce the duplication of the information presented in the final report. For future evaluations, it is suggested that data be collected on only the most informative indicators and evaluation questions.

2.0 Key Findings

Key findings for the first three areas of evaluation inquiry, namely, role and relevance issues, program implementation, and program outcomes are presented next. The findings and discussion related to effectiveness and alternatives – the fourth area of inquiry – are presented in the context of lessons learned and recommendations.

2.1 ROLE AND RELEVANCE ISSUES

This area looked at the extent to which the program and the projects it supports continue to be relevant to government priorities and public interest needs, and explored the particular role of the NHPD. The following questions are addressed in this section:

1. Is there a legitimate and necessary role for the NHPD in this program area?
2. Does the NHPRP complement, overlap, duplicate or conflict with other government or stakeholder NHP initiatives?
3. Is there consistency between the program and the needs and priorities of the primary beneficiaries?

Relevance is confirmed if a program or initiative demonstrates that it addresses a verified need. The following sections summarize the findings from the formative evaluation that provide evidence for two tests outlined by the Expenditure Review Committee (TBS, 2003) to assess issues related to relevance, namely, the *Role of Government Test* and the *Public Interest Test*. These two tests address the role and relevance issues identified in the Evaluation Information Summary Table.

2.11 Role of the NHPD in NHP research: The role of government test

The *Role of Government Test* asks whether there is a legitimate and necessary role for government in this program area or activity. It further inquires as to who else is involved in this program area, and whether there is any overlap or duplication in the efforts.

In the formative evaluation, the rationale articulated in two key documents regarding the initial need for the program (i.e., Standing Committee on Health, 1998; submission to the Treasury Board of Canada Secretariat) was compared to the data collected from the document review and stakeholder consultations which made reference to a continued government role in NHP research.

The initial need for the program

The need for Health Canada to be involved in NHP research was first identified in the work of the Standing Committee on Health's Advisory Panel on Natural Health Products (Standing Committee on Health, 1998), which was itself established in response to increased pressure for regulatory changes affecting NHPs. According to the work of the Standing Committee on Health and the submission to the Treasury Board of Canada Secretariat, the NHPRP was established due to the identified needs to:

- Provide consumers with information that would better enable them to make informed choices about NHPs; and
- Base regulatory decisions on objective and credible information of the type that is familiar to the scientific and conventional health care communities.

Furthermore, it was identified that there was limited research being conducted on NHPs and that there were few organizations and resources available in the natural health products industry and academia for research into NHPs. Due to the infancy of the NHP industry in Canada, it was rationalized that it was unlikely that market forces alone would generate sufficient research investment to bridge these gaps in a timely manner.

Evidence supporting a continued role for the NHPRP

Need for research based information

Two key issues were identified in the formative evaluation that support the continued need for research based information on NHPs: 1) NHPD staff need a strong base of credible research, in part, to help them make regulatory decisions quickly and accurately; and 2) there is still some ambiguity surrounding NHP product classification, a prominent concern for NHPD staff and industry. These two issues are further outlined in the sections below.

i) Need for research based information to support regulatory decisions

The *NHP Regulations* were introduced in January 2004, approximately six months after the official start of the NHPRP. Consequently, the full nature of the regulatory issues was not apparent in the first program year and participants in the internal panel discussion noted that the achievement of the regulatory function is still hampered by the lack of objective and credible NHP research based information. This suggests that continued NHP research is necessary in order to identify and fill these gaps.

Currently, there are approximately 40,000 products on the market which must comply with the *NHP Regulations* by 2010. Furthermore, figures presented in the Natural Health Products Research Society of Canada's Business Plan (2006) indicate that the NHP category is the third fastest growing product category at the retail level in Canada and that

NHP production is expected to remain primarily in Canada, with a current NHP import proportion of only 20%.

The need to continue to iron out these wrinkles regarding the NHPD's regulatory function suggests a corresponding and legitimate need for a government-led research program to support this regulatory role.

ii) Need for research based information to assist in NHP product classification and the differentiation of products

Closely associated with the regulatory function of the NHPD are the ongoing issues around product classification and the differentiation of products. The need for clarity around these issues often arises with respect to drugs, foods and functional foods.

In the area of drugs, Health Canada staff can consult with the Therapeutic Products Directorate, and in the area of foods, with the Food Directorate. However, according to internal panel participants and some funded researchers, some products – namely, functional foods – are not clearly differentiated and fall into grey areas which cross over into both NHPs and food products. This lack of clarity is a prominent concern for all stakeholders involved in the regulation of NHPs and therefore, requires research resources to assist in building the necessary evidence base that will clarify these issues and support product claims made by manufacturers.

NHPRP providing important role in bringing stakeholders together and building a stronger NHP community

Prior to the implementation of the research program, the NHP research community in Canada was essentially nonexistent, in that few, if any, accredited institutions were researching NHPs and/or making their work known on a national level.

The NHPRP has contributed to the important progress made in building the capacity of the NHP research community over the past three years, exemplified, in part by:

- Developing at least three NHP research networks of national scope, and research expertise along condition-specific or product specific issues (see Program Results for additional detail);
- Increasing the legitimacy of NHP research as an important and needed area of investigation – both inside and outside the research community – due to the funding of NHP research through credible institutions such as the Canadian Institutes of Health Research and Health Canada;
- Making funding more accessible to research teams that include participants who are working outside of university settings (an important achievement that is not

currently the norm and has been linked in studies of similar programs to increasing knowledge transfer and information dissemination); and

- Developing a variety of partnerships that have helped to leverage NHP research funding and increase the credibility of NHP research both nationally and internationally [e.g., NHPD support for the two consultations held with the World Health Organization's (WHO's) Traditional Medicines Initiative leveraged funds from WHO and the Government of the Netherlands].

However, there is still more work to be done in order to more confidently ensure the sustainability of the NHP research community, particularly in further building the critical mass of researchers and research infrastructure. Furthermore, the NHPRP is viewed as necessary to continue in its role, by helping to further the creation of expertise and more sustainable research niches/centres.

“NHPRP is helping to build capacity, and to legitimize an important and needed area of investigation. They are also expressing the importance of good peer reviewed research in this area. Providing very valuable contributions.” NHPRP funded researcher

Not duplication

Most funded researchers who were interviewed ($n = 19$; 76%) reported that the research program was not duplicating the efforts of other funding agencies, a statement echoed by expert panel participants. Although the majority of NHPRP funded research projects listed other partners (including other funding sources), fifty-two percent ($n = 13$) of interview participants reported that their project would not have been conducted, or would have been unlikely to proceed without support from the NHPRP.

Twenty-eight percent ($n = 7$) of these interview participants reported that their project may have proceeded without NHPRP funding, although several of these individuals noted that the project would likely have taken longer to get started and the scope of the project would have been much smaller (e.g., local versus national or international). The apparent discrepancy between the findings of “not duplication” yet having a number of partners listed on the funding applications may be explained, in part, by the credibility that Health Canada and the Canadian Institutes of Health Research (CIHR) bring to the table. All stakeholder groups consulted for this evaluation noted that the credibility of these institutions has the value added benefit of encouraging more groups to come to the table.

“The NHPRP fills a good niche. Because this area of research involves both health and plants it does not easily fit into a particular niche. The NHPD funding addresses this gap in research funding.” NHPRP funded researcher

“The NHPRP funding is very significant because this is a pilot study and [I’m] not sure that other funders would support such a study... This seed funding is very important. There is a need to put more dollars into research based studies.” NHPRP funded researcher

“The fact that Health Canada – the funds were coming from Health Canada – has largely contributed to bring a certain credibility to the project which has facilitated recruitment and participation of people to the project.” NHPRP funded researcher

“Not aware of any programs that NHPRP would be duplicating in Canada.” NHPRP funded researcher

2.12 Alignment with needs and priorities of primary beneficiaries: The public interest test

The *Public Interest Test* asks: “Does the program area or activity continue to serve the public interest? How does it align with current government priorities and the core mandate of the organization?”

For the formative evaluation, trends in public consumption of NHPs – both before and after the implementation of the NHPRP – were examined in addition to data sources that addressed the need for the NHPRP to play a role in providing consumers with NHP information.

Use of NHPs

The use of NHPs by Canadians has continued to increase since the work of the Standing Committee on Health (1998) and a recent poll conducted on behalf of the NHPD in March 2005 by Ipsos-Reid now suggests that approximately 71% of Canadians have ever used an NHP, and 38% from this group continue to do so on a daily basis (Health Canada, 2005). Furthermore, 81% of Canadians think that the use of NHPs will increase over the next ten years. This data is similar to that collected by the Berger Population Health Monitor (2001) survey which demonstrated that the use of NHPs continues to grow, that Canadians are increasingly substituting the use of NHPs for prescription and non-prescription drugs, and that the number of people taking an NHP instead of seeing a physician has increased.

Moreover, the Ipsos-Reid poll shows that a majority of Canadians (91%) agree that all NHP manufacturers must ensure that the products they sell to consumers are safe, 84%

agree that the Government of Canada should regulate the claims made by manufacturers of NHPs, and 84% believe that more needs to be done to inform Canadians about the safe use of NHPs.

Need to inform Canadians

Enabling Canadian consumers to make informed choices about NHPs as part of their health care options is a key component of the program's mandate.

The Ipsos-Reid poll demonstrated that currently, one-half of Canadians (52%) do not believe that Health Canada does a good job of informing Canadians about NHPs, while one-quarter (26%) feels that they do. The NHPD needs to explore mechanisms for how to best reach the public as 69% of Canadians agree that they need more information on NHPs, particularly regarding the safe use of NHPs (84%).

Need for research on NHP safety

By means of providing a concrete example of the consumer demand for information on NHP safety and the importance of continued research in this area, the Motherisk Project – funded through the NHPRP – reported that Motherisk is contacted by up to 200 cases per day for counseling on safety of exposures to NHPs during pregnancy and lactation and over 6000 callers every year seek advice on the safe use of NHPs.

Our review of the documents indicates that, in line with the public's priority for information on the safe use of NHPs (which includes assurance that the product is of good quality, that the health claims made by manufacturers have been verified, and that the product is free of contaminants and suitable for use), the research program has funded a total of 16 of 60 (27%) projects in the areas of product quality, safety and efficacy. A total of 2 projects were funded in 2003-04, 1 in 2004-05 and 13 in 2005-06.

Some of these projects were funded through operating dollars and involved consultations that relate specifically to NHP safety, for example, the Natural Health Products Directorate (NHPD) Consultation on Fatty Acids and Essential Fatty Acids (EFAs) and the World Health Organization's Final Consultation on Safety Monitoring of Herbal Medicines.

Some of the other projects relating to NHP product quality, safety and efficacy were funded through contributions. In particular, the NHPRP launched a request for proposals in April 2005 titled *Bridging the Regulatory Gap: Funding Priorities in NHP Safety, Quality and Efficacy*. A total of eight projects were funded through this request.

While there has been a dramatic increase in the third program year in the number of projects funded in the areas of product quality, safety and efficacy, it remains important to build these research areas as it is critical to the question of informed consumer choice.

Furthermore, it is crucial that the knowledge gleaned from the funded research reach the public. As shown in Figure 2 on page 22, approximately 25% (15 of 60) of the funded projects aimed to transfer knowledge and/or disseminate information. Only 10% (6 of 60) were specifically targeted to consumers and helping them to make informed choices about NHPs, namely:

- Workshop Modules and Practical Guides for the Canadian AIDS Treatment and Information Exchange (CATIE);
- 3rd Annual Conference and Tradeshow – From Concept to Consumer;
- Integrated Program for Supporting Decision-making About NHPs for Middle-aged Women Going Through or Having Gone Through Menopause: Requirement Study;
- Establishing a Canadian Network for NHP in Pregnancy and Lactation;
- Reporting Suspected Adverse Effects Associated with NHPs: Research Proposal Development; and
- Natural Health Products in Primary Psychotic Disorders: Use and Attitudes.

Stakeholders consulted in the formative evaluation were not sure of the extent to which the findings and knowledge from the NHPRP funded projects have reached the public. As an example, forty-four percent ($n = 11$) of funded researchers who were interviewed reported that their intended user groups had been reached – primarily through attendance at conferences, workshops, and meetings. However, it was not always known if information obtained from such events was being used or further disseminated. The biggest reported impact (as a result of reaching various user groups through conferences, etc.) was increased dialogue and networking between diverse stakeholders. The remaining interview participants ($n = 14$) reported one or more of the following: (a) they did not know the extent to which intended user groups had been reached; (b) groups had been reached but not yet as well as envisioned; and/or, (c) it was too soon to tell.

NHPRP funded researchers were also asked if anything has hindered publication or the dissemination of findings from their project. Most participants reported that nothing has hindered publication with the exception of a lack of human resources, funding, and time (i.e., time required to prepare an article for publication), possibly suggesting areas where the research program can fill a funding gap given its mandate to enable Canadians to make informed choices. Furthermore, a number of suggestions were provided for reaching an audience beyond the research community (see Appendix C).

2.2 PROGRAM IMPLEMENTATION

The intent of this area was to focus on implementation progress to date, to determine whether the NHPRP has been implemented as identified in its program rationale and logic model. Key questions addressed in this section include:

1. Is funding being used fully and in keeping with plans and authorities?
2. What activities have been funded to date?
3. What groups are benefiting from the program interventions?
4. Is the NHPRP delivering planned activities while being responsive to identified priorities and research areas?
5. Is the NHPRP implemented according to anticipated delivery mechanisms?

Our review of the program documents demonstrates that the NHPRP is not quite fully expending its resources but is funding a wide range of projects in each of the four priority areas of the program. The funded priority areas are in line with those developed via the consultations and priority-setting exercises conducted with a wide and comprehensive range of stakeholder groups.

2.21 Allocation of program funds

The NHPRP is obligated to spend its funds in keeping with the plans outlined in its submission to the Treasury Board of Canada Secretariat while being responsive to any changes in the broader environment that may suggest that funding priorities have changed. This section examines the extent to which the NHPRP met this requirement.

Funding mechanisms

Each fiscal year (beginning in 2003/04 and ending in 2007/08), the NHPRP is to distribute a total of \$1M per annum as outlined below:

- \$400K in grants: This is to be achieved by partnering with the Canadian Institutes of Health Research (CIHR) in order to take full advantage of their expertise and infrastructure in the management of large or complex research studies in which the CIHR manages the distribution of the funds. In some instances, the CIHR has matched the grant funding offered by the NHPD;
- \$400K in contributions: This is to be achieved by providing funding to eligible external organizations who will further the objectives of the research program; and
- \$200K in operating funds for complementary activities and initiatives.

It is important to note that the allocations were planned prior to the consultations with the NHP community and prior to the confirmation of the *NHP Regulations*. A separate operational budget for the management of the research program activities was not identified at the time of the development of the research program itself and required resources are taken from the central NHPD budget. Currently, two full time staff equivalents (FTEs) are assigned to this program.

Challenges encountered and correction of funding allocations

Since the 2003/04 fiscal year, the capacity of the program staff to manage grants and contributions (G&Cs) has grown, and after three years of implementation, a total of \$2.5M has been expended (see Table 3). In 2003/04, \$400K was allocated to Grants, \$0 to Contributions, and \$400K to Operating Funds. Thus, the percentages presented are based on the actual expenditures for the reallocated distribution. In 2005/06, \$400K was allocated to Grants, \$540K to Contributions, and \$60K to Operating Funds. Thus, the percentages presented are based on the actual expenditures for the reallocated distribution.

Table 3. Comparison of planned allocations vs. actual expenditures for the NHPRP 2003/04 – 2005/06						
Planned allocation per delivery mechanism per fiscal year	Actual expenditures per fiscal year (\$) & percentage of planned allocation					
	2003/04 (reallocated)	2003/04 (Actuals)	2004/05 (Actuals)	2005/06 (reallocated)	2005/06 (Actuals)	TOTAL
Grants (\$400,000) for partnership with CIHR	400,000	400,000 (100%)	273,250 (68%)	400,000	228,175 (57%)	901,425 (75%)
Contributions (\$400,000) for community support	0	0	399,929 (99%)	540,000	521,175 (97%)	921,104 (98%)
Operating Funds (\$200,000) for contractual work, conference support and continued consultation	400,000	377,185 (94%)	272,777 (136%)	60,000	60,958 (102%)	710,920 (108%)
TOTAL (\$1,000,000 per annum) & percentage of planned allocation	0.8 Million	777,185 (97%)	945,956 (95%)	1.0 Million	810,308 (81%)	2,533,449 (84%)

Initial variances in planned allocations were due to several factors including: a late fiscal year start (the program was launched in June 2003); the limited capacity within the

NHPD for the management of contributions (the required personnel with expertise in grants and contributions had to be recruited; therefore, contribution funding was not initiated until the second year of the program); and the challenge faced by the NHPD as it tried to identify research opportunities within an environment where the *Regulations* were still in the process of being defined. The research program requested and received approval to make adjustments to allocations across each delivery mechanism to better respond to the context and maximize the use of available funds.

2.22 Key activities funded to date

In an effort to further understand the scope of the program's implementation to date, the formative evaluation also examined the key activities that have been funded. The NHPRP engages in a number of activities in an effort to build NHP-related research capacity, support the conduct of NHP-related research, develop partnerships and community infrastructure, and enhance knowledge transfer (see the highlighted box below for a description of each key area of program activity).

According to the submission to the Treasury Board of Canada Secretariat, the areas of key program activity are:

Building research capacity: Under this area, the NHPRP provides funds to educate or train researchers and to develop education or training programs that will generate NHP researchers or awareness about NHP research.

Supporting the conduct of research: Alone and in partnership, the NHPRP provides funding for NHP research, the results of which will contribute to the evidence base required to support the regulatory framework and to facilitate informed choice by consumers.

Developing partnerships and community infrastructure: The NHPRP encourages others to become more involved in NHP research by: developing or facilitating the development of partnerships with and among other stakeholders; expanding the role and involvement of voluntary and not-for-profit organizations in NHP research; and consulting with stakeholders for their input to the development of NHPRP research priorities and activities.

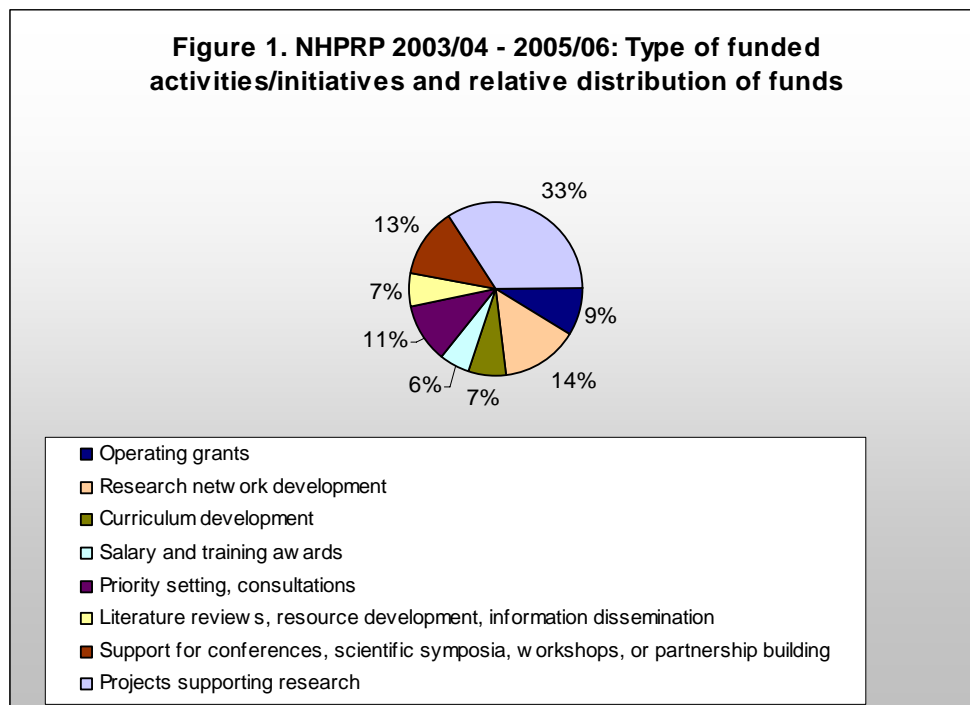
Enhancing knowledge transfer: Directly and indirectly, the NHPRP seeks to contribute to an improvement in the scientific and public understanding of NHPs by: promoting dialogue and knowledge transfer among stakeholders; sponsoring and disseminating literature reviews that capture and synthesize published information on a given area in NHP research; and providing financial support to workshops, seminars, conferences, and for the inclusion of information in the web page of stakeholder organizations and related disciplines.

A total of 60 projects were funded between June 2003 and March 2006. Our review of the funding applications and project reports, interviews with funding recipients and consultation with the expert panel demonstrate that many of these funded projects cross program activity areas, disciplines, research themes, type of natural health products, and geographic locations. The scope of the projects funded is illustrated in the sections below. A complete list of the projects funded NHPRP's funding commitments for 2003/04 – 2007/08 can be found in Appendix D.

NHPRP funded activities and initiatives

The NHPRP has funded a number of different types of projects. Figure 1 illustrates the type of activities/initiatives funded over the first three years of the program, along with the relative distribution of funds for each type of activity/initiative.

The largest amount of funding has been allocated to projects supporting research (33%; average award = approximately \$60K); research network development (14%; average award = approximately \$123K); support for conferences, scientific symposia, workshops, or partnership building (13%; average award = approximately \$26K; and priority setting consultations (11%; average award = \$28K).

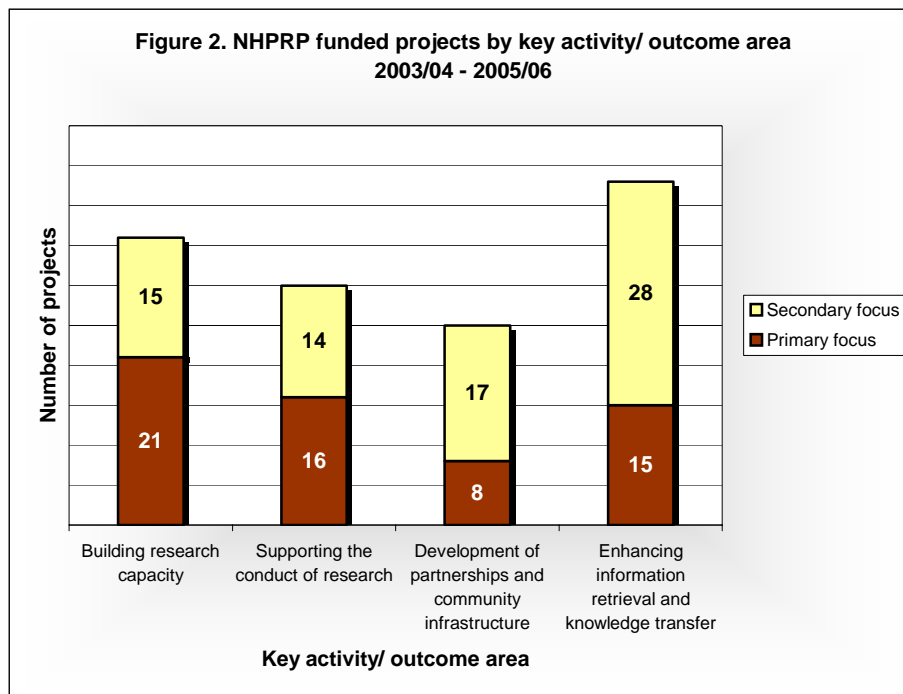


NHPRP funded projects by key activity/outcome area

We also examined the funded projects in terms of the four key areas of program activity/outcomes identified in the NHPRP logic model.

In Figure 2, the red portion of the bar indicates the number of projects funded with a primary focus in that area of program activity, for a total of 60 across the four areas. However, most funded projects actually address more than one program area and thus, the yellow portion of the column has been added to demonstrate the number of projects that have an additional focus in each of the key areas of program activity. The numbers presented are conservative categorizations of primary and secondary foci. They are presented to provide a sense of the overall distribution of funding across key areas of program activity.

It is important to note that although the number of projects funded under the category of “developing partnerships and community infrastructure” is comparatively low, this category does not include efforts to develop NHP research networks, such as the Interdisciplinary Capacity Enhancement Team (ICE) Grant Supporting Research in Complementary and Alternative Health Care (CAHC). While these research networks also involve the development of partnerships and received a relatively large amount of funding compared to other projects, they were categorized under “building research capacity”.



2.23 Program beneficiaries

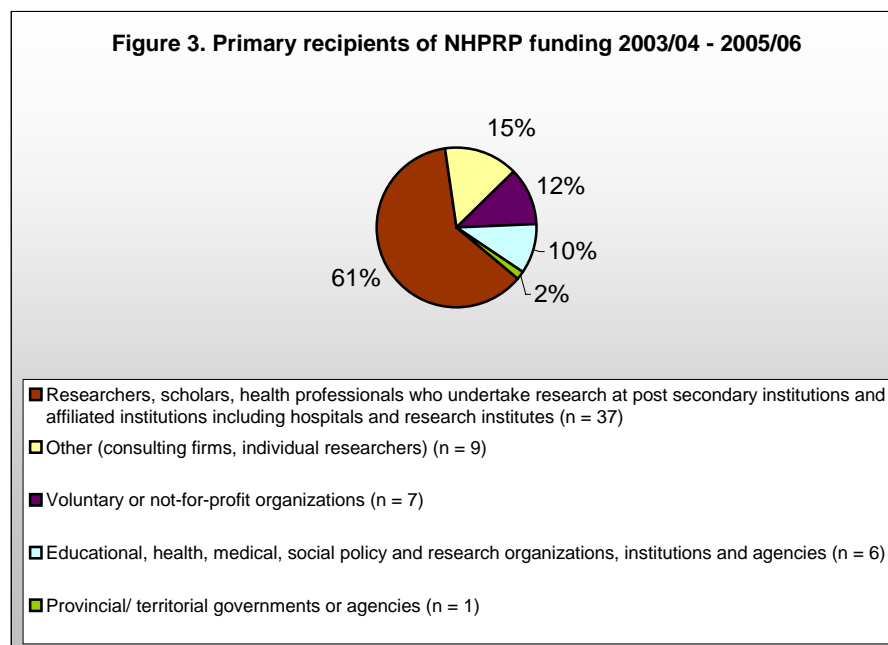
According to the submission to the Treasury Board of Canada Secretariat, NHPRP activities should benefit constituents in at least six key stakeholder groups, including the research community, industry, regulators, voluntary and not-for-profit organizations, health care professionals, and the Canadian public. From a program implementation perspective, we examined the extent to which the NHPRP is attempting to reach each of these groups, namely, by consultation and/or the provision of funding.

Stakeholder consultations with beneficiary groups

Since the official launch of the NHPRP in June of 2003, all identified stakeholder groups – with the exception of the Canadian public – have had involvement on some level. For example, stakeholder consultations have been conducted with a number of groups such as NHP researchers, industry, health care practitioners, the federal government, crown corporations, not-for-profit organizations, and representatives from international governments to develop and refine NHP research priorities (see Appendix D for a complete list of consultation projects).

Funding recipients

Since the implementation of the NHPRP, over 60% of the funding has been awarded to researchers and health professionals who are affiliated with research institutions. Figure 3 presents only those who directly received the NHPRP funding, and not the entire multidisciplinary team who may have worked on the project.



The NHPRP has implemented mechanisms to allow individuals/groups other than researchers to be eligible for NHPRP funding. However, as noted above, these groups are not yet represented in large numbers as the funding recipients.

When interpreting this finding, it is important to note that it is reasonable to expect that few individuals from outside the research community will have the research skills, resources and infrastructure necessary to take on a lead research role. It is also important to note that sixty percent ($n = 15$) of NHPRP funded researchers who were interviewed reported that at least one member of their project team was a member of a stakeholder group other than the research community, including representatives from industry, voluntary and not-for-profit organizations, and health care professionals. Furthermore, members of stakeholder groups other than the research community filled a variety of roles on project teams including advisor, consultant, team leader, reviewer, and overall collaborator.

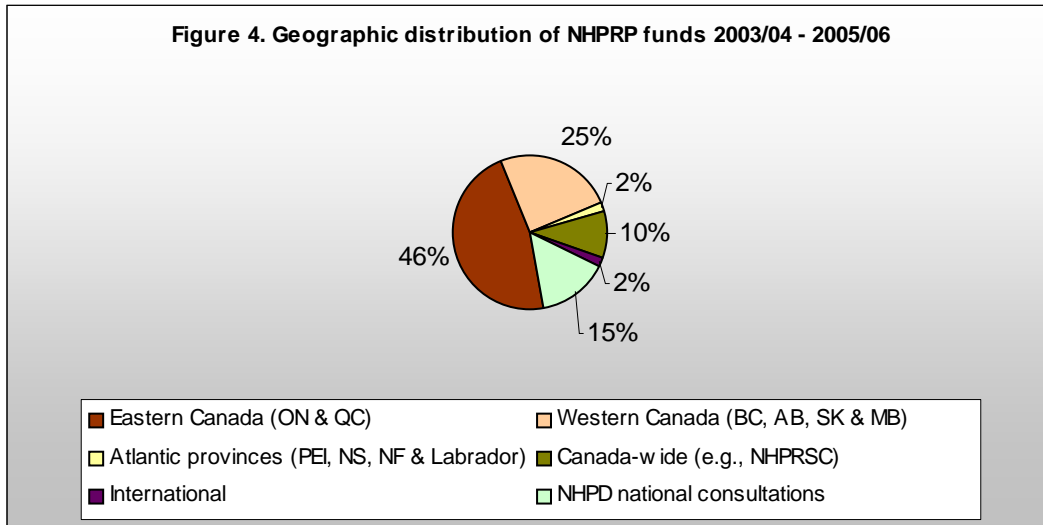
This type of funding model (i.e., researcher-led multidisciplinary team which includes members from outside the research community) has been employed by the Alberta Heritage Foundation for Medical Research (AHFMR) since 1996. An assessment of the outputs and outcomes of the AHFMR research projects funded between 1996 and 2000 indicated that this type of funding model could be attributed to outcomes such as further research in the area, the development of increased research capacity in the area (e.g., additional training, qualifications), projects contributing to knowledge generation and knowledge transfer (e.g., through presentations to diverse audiences, including those outside the research community), and impacting evidence-based decision making (e.g., policy). There was also some preliminary data to suggest that those teams which included decision makers and/or users of health information were more successful than other teams at contributing to outcomes related to knowledge transfer, additional professional qualifications, and influencing health policy and practice (Magnan, L'Heureux, Taylor & Thornley, 2004).

Participants in the expert panel discussion noted that the NHPRP could further facilitate the development of research capacity within practitioner groups (e.g., how to design a study, how to access funding, how to assess safety/efficacy of their NHP-related practices) by: providing salary support for fellowships and graduate training, providing bridge support to the CIHR, and mandating the involvement of practitioners in NHPRP funded projects.

Geographical distribution

As another perspective on the scope of beneficiaries of a national program, the extent to which project funding has been distributed across all Canadian provinces and territories was examined. As indicated in Figure 4, the program funds have been distributed across the country, though the distribution of NHPRP funding to the primary researcher is most heavily weighted in Ontario, Quebec and British Columbia. This is perhaps, in part, due

to the current location of NHP research expertise and may evolve with the continued allocation of funding across the country. Program managers may want to reflect on the relative importance of working to establish NHP research expertise and/or centres across the country compared to further developing the current NHP research expertise with the time-limited program funding.



2.24 Demonstrated responsiveness to identified priorities and research areas

This section of the evaluation compares the extent to which the identified priorities and research program areas have been addressed to date by the NHPRP.

Research themes

When attempting to ascertain the extent to which the NHPRP funding allocations are in line with the identified priorities and research areas, the following perspective is offered for consideration.

The research themes that were outlined in the submission to the Treasury Board of Canada Secretariat and also identified through the initial consultations (e.g., Natural Health Products Research Priority Setting Conference in Halifax, 1999) were: 1) quality, efficacy and safety; 2) development of new research methodologies and health systems research; 3) population groups and issue areas; and 4) information, informed choice and utilization. These four areas were adopted when the NHPRP was subsequently developed and further refined by the program into the six areas presented in Figure 5.

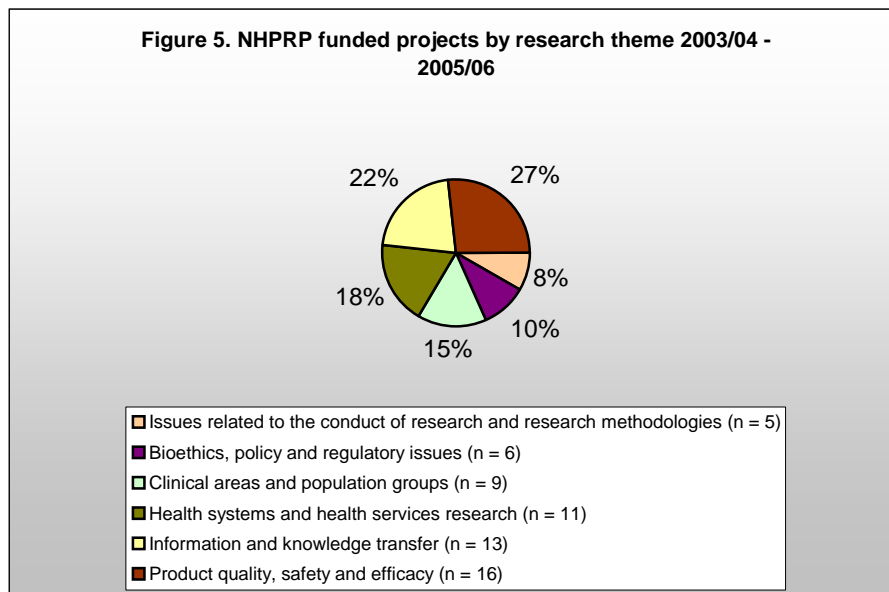


Figure 5 indicates that all priority themes have been covered by NHPRP funded projects; however, within the area labeled “clinical areas and population groups”, expert panel participants suggested that more work is needed to set research priorities in order to inform the use of natural health products in the areas of homeopathy, naturopathy and essential oils/aromatherapy.

Figure 5 also indicates that almost one-third of the funded projects addressed the areas of NHP product quality, safety and efficacy, and another 10% addressed bioethics, policy and regulatory issues. Participants in the internal panel discussion commented that the areas of quality and safety have been covered by some excellent NHPRP funded consultations but also noted these areas as those most in need of immediate research funding in order to support the NHPD in its regulatory role.

2.25 Use of anticipated delivery mechanisms

The NHPRP has built a complex program of grants, contributions and operating funds in order to reach out to the potential NHP research community and to encourage multi-disciplinary research teams. Participants in the research program include not only established researchers who are affiliated with academic or research institutions, but also practitioners (e.g., in the areas of homeopathy and Traditional Chinese Medicine), students, Canadian voluntary and not-for-profit organizations, and provincial/territorial governments and agencies.

Each delivery mechanism is outlined below, including its intended purpose and a brief assessment of the extent to which it has succeeded in this endeavour. Following this,

feedback obtained from those consulted for the formative evaluation relating to the funding processes is presented.

Grants

The grants program is intended primarily to support the first and second key areas of program activity, namely, building research capacity and supporting the conduct of research. Grants funded in partnership with the Canadian Institutes of Health Research (CIHR) are directed solely toward the research community, that is, researchers, scholars and health professionals affiliated with Canadian post-secondary institutions and their allied institutions such as hospitals and research institutes.

In the first year (2003/04), the NHPRP was able to partner with the CIHR on large, multi-year projects aimed primarily at capacity building and/or partnerships and on projects of short duration. However, other funding opportunities needed to be created or negotiated for full allocation in the following years.

In the second year (2004/05), the NHPRP worked with the CIHR to identify proposals already submitted as part of the standard research cycle and to establish mechanisms to best leverage their partnership for future funding cycles. As a result, the NHPRP supported two transfers to the CIHR: one for \$250K and one for \$23.25K, totaling \$273,250. As a result, approximately 68% of the available funding was allocated and disbursed, a good result, but not optimal.

In the third year (2005/06), the NHPRP was able collaborate with the CIHR on two priority announcements to provide funding for operating grants and salary and training awards.

To date, the NHPD has entered into five collaborative agreements with the CIHR, as indicated in Table 4. In the Memoranda of Understanding (MOUs), the CIHR manages the requests for proposals process, the peer review, and the granting and management of the funds. The NHPRP assists in the development of the priority areas for each request for proposals and the peer review process to ensure relevancy to the NHPD. In addition to the administrative support, the CIHR and/or its Institutes provided additional dollars in four of the five grant initiatives to add to the contribution provided by the NHPD. Reports are not required from recipients of grants.

Table 4. NHPRP/CIHR grants envelope 2003/04 – 2005/06		
Arrangement	Outcome	Funding (\$ and %)
ICE grant	<ul style="list-style-type: none"> Large initiative from CIHR which is multi-year/multi-discipline with a specific objective to build capacity [i.e., the Interdisciplinary Capacity Enhancement Team (ICE) Grant Supporting Research in Complementary and Alternative Health Care (CAHC) (CIHR - IMHA/III/IHSPR)] 	HC-NHPD: \$250K CIHR-IMHA/III/IHSPR: \$386K %HC:%CIHR:36%:64%
NET grant	<ul style="list-style-type: none"> Rigorous Scientific Evaluation of Selected Anti-diabetic Plants: Towards an Alternative Therapy for Diabetes in the Cree of Northern Quebec [i.e., CIHR – New Emerging Team (NET) grant - Institute of Aboriginal People's Health]] 	HC-NHPD: \$390K CIHR-IAPH:\$660K %HC:%CIHR: 43%:57%
Partnership Grant	<p><u>Fall 2004 Priority Announcement</u></p> <ul style="list-style-type: none"> CIHR received 10 applications 9 were deemed responsive to objectives of NHPRP 9 were rated above the competition cut-off and recommended for funding 3 awards (2 fellowships/1 doctoral research award) funded by NHPD Funding amount available: \$120,000; amount awarded: \$116,083* <p><u>Spring 2005 Priority Announcement</u></p> <ul style="list-style-type: none"> CIHR received 39 applications 28 passed relevancy to NHPRP objectives 16 were rated above the competition cut-off and recommended for funding 3 were funded 100% by CIHR 3 were funded by NHPD Funding available: \$230,000; amount awarded: \$113,550** 	HC-NHPD: \$251,425 CIHR: \$230,572 %HC:%CIHR: 49%:51% *Original allocated amount was \$122,000. CIHR advised NHPD that researchers started later than anticipated. Amounts awarded were decreased for 2005-06 **Original allocated amount was \$227,099. CIHR advised NHPD that researchers started later than anticipated. Amounts awarded were decreased for 2005-06.
Grant for Echinacea in Children study	1 single grant (total NHPRP funding is \$75K) [Study of Echinacea in Children with Upper Respiratory Tract Infections (funded with CIHR)]	HC-NHPD: \$75K/65% CIHR: \$40K/35%
1 joint funding call dating back to 2001	<ul style="list-style-type: none"> 3 awards funded by NHPD for year 2003-2004 1 award extended for one year 2004-2005 	HC-NHPD: \$35K

Contributions

Contributions are managed solely by the NHPRP allowing a focus on issues directly related to the NHPD's role as product regulator and an opportunity to support the involvement of groups and sectors new to research. In particular, the contributions program is intended to be provided to stakeholders other than the CIHR to support the development of research capacity and the conduct of research; to support curriculum development, research networks and conferences/workshops in which the CIHR is not already engaged; and to provide access to information on NHP research.

The NHPRP was able to initiate annual funding calls under its contribution funding allocation starting in its second year of funding. Four calls have been initiated: January 2004, September 2004, April 2005 and May 2005. In the second year (2004/05), 99% (\$399,929) of the \$400K allocation for contributions was used. In the third year (2005/06), approval was received to increase contribution funding from 400K to 540K to fund more projects. In total, 97% (\$521,175 of the \$540K available) was spent.

To date, the program has launched four solicitations/requests for proposals under the contribution envelope as indicated below in Table 5.

Table 5. NHPRP contributions envelope 2003/04 – 2005/06				
Solicitations/ Requests for Proposals	Purpose of the Solicitation/ Request for Proposal	# of application s received	# of projects meeting funding criteria and recommended for funding by peer review panel	# of projects funded/ # recommended for funding
January 2004 - Seed Funding Request for Proposal (max. award of \$75K)	To provide seed funding to support research initiatives in the following subject areas: clinical areas and population groups; research capacity and network building; health promotion and wellness research; product quality and standards; bioethics, policy and regulatory issues; the conduct of research; and knowledge translation/transfer.	51	15	11/15 (73%)

Table 5. NHPRP contributions envelope 2003/04 – 2005/06				
Solicitations/ Requests for Proposals	Purpose of the Solicitation/ Request for Proposal	# of application s received	# of projects meeting funding criteria and recommended for funding by peer review panel	# of projects funded/ # recommended for funding
September 2004 - Workshop & Conference Support (max. award of \$25K)	To provide support to workshops, meetings and conferences dealing with issues related to NHP research under 2 themes: 1) support for scheduled conferences/symposia; and 2) support of workshops/small meetings for the development of research proposals, multidisciplinary networks and or partnerships.	13	7	5/7 (71%)
April 2005 - Bridging the Regulatory Gap (max. award of \$20K)	To support the NHPD role as a regulator by supporting activities for the preparation of research proposals, business cases or literature reviews that addressed specific priorities in the area of NHP safety, quality and efficacy	22	13	8/13 (62%)
May 2005 - Conference Support (max. award of \$20K)	To provide support for scheduled conferences/symposia and for the planning and development of multidisciplinary networks.	12	7	6/7 (86%)
2 unsolicited proposals received; 1 has been funded	--	--	--	--
		Total # of projects funded/ # recommended for funding		30/42 (71%)

As demonstrated in Table 5, the NHPRP has provided relatively small amounts of funding (\$20K, \$25K and \$75K) for a total of 30 projects including workshops, conferences, the preparation of research proposals, literature reviews and seed funding. Table 5 also indicates that the NHPRP has not had sufficient funds available to provide awards to all the proposals that were screened positively and recommended for funding by the peer review panel despite converting an additional \$140K of the operating dollars into contributions funds in the 2005/06 fiscal year.

Operating dollars

Operating dollars are available for continued consultation and priority setting, and can support contracted research such as literature reviews, infrastructure support, conference sponsorship, and the development of training programs and research curricula. The operating dollars target priorities identified in the consultations and are intended to further support the role of the NHPD as a product regulator. The NHPRP manages these funds by contracting organizations or individuals to conduct the desired project. Projects may be funded solely by the NHPRP or co-sponsored with partners within Health Canada and potentially with other government departments such as Agriculture and Agri-Food Canada.

To date, over \$710K of the \$660K (or approximately 108%) allocated to operating funds has been used to support a total of 18 projects, including literature reviews, resource development and information dissemination; projects supporting research; priority setting meetings/ consultations; support for conferences, scientific symposia, workshops, or partnership building; and curriculum development. The overspending in this area highlights the importance of this funding mechanism.

Funding Process

As part of the formative evaluation, researchers funded through the NHPRP and/or through its partnership with the CIHR were asked to comment on several aspects of the funding process, including: the scope and objectives of the requests for proposals, the timing of the application due dates and receipt of funding, the funding amount, and the perceived fairness of the review process.

Scope and objectives of the solicitations/requests for proposals

Interview participants generally reported high levels of satisfaction with the scope and objectives outlined in the requests for proposals launched by the NHPD and those launched by the CIHR (average score = 4 or “satisfied” on a 5-point scale with “1” representing “very dissatisfied” and “5” representing “very satisfied”). Some respondents noted that due to the variety of projects that are eligible under contributions, it was at times difficult to complete sections in the proposals that seemed to be geared towards research projects. However, respondents did indicate that NHPRP staff were particularly helpful in providing assistance and answering questions.

Timing of the application due dates and receipt of funding

Using the same satisfaction rating scale, funding recipients who were interviewed provided somewhat lower ratings on average (when compared to those who received funds through the CIHR) with respect to the timing of the application due dates (average

= 3.8 for NHPRP funding recipients) primarily expressing that the NHPRP timeframe is too short between the request for proposals and the proposal deadline.

Respondents who had received funds from the NHPRP contributions and operating dollars envelopes were also less favourable with their ratings regarding the timing of the receipt of funding (average = 2.8). Recipients who had received funds through the CIHR were generally more satisfied with the timing of the process (ratings ranged between 4.5 and 5).

With respect to the timing of the receipt of NHPRP funds, respondents noted that several lags occurred throughout the process – delays in learning of their award and in receiving funds – which, in turn, resulted in a delay in getting the funds released by their university and a postponement of several months in getting the project underway. After these delays, the projects were still expected to conclude on time. An illustrative comment is provided in the box below.

“Firstly, we got a letter stating that the project proposal had reached last stages of review and then it was months before we were told that we were funded. This letter of successful funding was well past the date that the project was supposed to start. Then we needed to get a contract signed, which, in a university setting can take months. It can be 2-4 months into a project’s anticipated start date before one actually receives the money; however, the fiscal year end can’t change and, as a result, the project had to be condensed [in order] to be completed on time...” **NHPRP funded researcher**

Funding amounts

Respondents who had received funds from the NHPRP contributions and operating dollars envelopes were also less favourable (when compared to those who received funds through the CIHR) with their ratings regarding the funding amount provided (average = 3.8 for NHPRP funding recipients). Those who had received funds through the CIHR were generally more satisfied with the amount of funding (ratings ranged between 4.5 and 5, with one respondent providing a rating of 3 regarding the amount of funding).

Researchers were not alone in their concern over the amount of funding provided through the NHPRP; internal panel participants were also unsure if researchers are being given enough funding.

While most funding recipients expressed gratitude for the funding that they did receive, a concern was expressed that the small awards (\$20K or less) are “almost not worth it” when the reporting requirements are so “cumbersome”. This was especially true for those who were working in university and small not-for-profit settings and the need to streamline and reduce the paperwork related to project reporting was reinforced by participants in the expert panel discussion.

Other respondents expressed that, since pilot studies are exploratory, a number of unexpected delays and complications undoubtedly arise, consequently raising costs. One respondent suggested that a minimum of an additional 20% would have been helpful.

Transparency

Forty-eight percent of respondents ($n = 12$) reported that they believed that the funding review process was fair, but were unsure as it is not transparent. Differences were not noted between respondents funded through the NHPRP and those funded through the partnership with the CIHR. An additional 44% ($n = 11$) of respondents did not know or could not comment.

2.3 PROGRAM OUTCOMES

The intent of this area of focus was to determine whether the NHPRP has made progress toward the achievement of anticipated outcomes, as defined in the NHPRP Logic Model. Though difficult to assess definitively at this early juncture in the program's development and with the employed methodology, the intent was to look at preliminary results and whether the actions taken by the program give indications of ability to arrive at expected outcomes. The following questions are addressed in this section:

To what extent are NHPRP activities...

1. ...building NHP research capacity?
2. ...supporting the conduct of NHP research?
3. ...developing partnerships and community infrastructure?
4. ...enhancing information retrieval and knowledge transfer?

In addition, secondary issues were examined that cross more than one key program area:

5. To what extent is the program impacting the intended beneficiaries?
6. To what extent are NHPRP activities resulting in other organizations providing funds for NHP research?

The following sections summarize the findings from the formative evaluation that provide evidence of the program's progress toward achieving the outcomes identified in the NHPRP Logic Model. In addition, two tests outlined by the Expenditure Review Committee (TBS, 2003) to assess issues related to program results, namely, the *Value for Money Test* and the *Partnership Test* are addressed.

2.31 Extent to which the NHPRP is achieving results in the four key program areas identified in the NHPRP Logic Model

The intent of this section is to examine what has been accomplished in each of the four key program areas identified in the NHPRP Logic Model, as well as to compare this with the suggested direction provided in the literature, in order to get a sense of whether the program is moving on the right path.

A comparison of the intended and actual outcomes in each program area was performed based on:

- The analyses conducted by the internal and expert panels of the program and the larger NHP context; and
- Our analysis of the literature.

The internal panel analysis was based on an assessment of program benefits and challenges while the assessment of the external panel was based on an examination of the Strengths, Weaknesses, Opportunities and Threats (SWOT analysis) of the NHPRP. The SWOT process is described in the Definitions section of this report. See Appendix E and F for a detailed summary of the recommendations from the internal and expert panel discussions. It is important to note that there is a lot of overlap in the literature in terms of strategies believed to build capacity, develop partnerships and community infrastructure, and enhance knowledge transfer. It is also important to note that our search of the literature did not reveal any definitive answers regarding the best approaches to meet such objectives for a research program. A summary of the analysis is provided below and the full analysis in Appendix G.

The assessment that follows serves to highlight areas of program success as well as those areas that are now emerging as most in need of attention.

Though difficult to assess definitively at this early juncture in the program's development and with the employed methodology, the evidence collected for the formative evaluation indicates that the NHPRP has developed a suitable multi-pronged approach to meet its objectives that is:

- In line with the best available literature;
- Based on widespread stakeholder consultations; and
- Conducive to achieving progress and anticipated results in each of the program areas.

Building research capacity

According to the NHPRP logic model, the research program will build research capacity by achieving outcomes such as:

- An increased number of Canadian researchers trained in NHP research;
- Increased training opportunities on NHP research;
- Increased awareness of NHP issues and challenges among students and practitioners; and
- Increased cooperation and sharing of best practices among, for example, the fields of conventional and complementary and alternative health care.

Our analysis indicates that the program has made strides towards achieving these outcomes, but that other factors should be considered if the program is to build long-term and sustainable capacity in NHP research in Canada.

Changes in training and related opportunities for Canadian researchers

Several changes were noted in training and related opportunities for Canadian NHP researchers as a result of the research program such as:

- Training opportunities created through fellowships and training grants awarded in partnership with CIHR;

Through the CIHR/NHPD partnership, multi-year funding up to \$230K per year commencing 2004-2005 for operating grants and up to \$120K per year for fellowships and doctoral research awards is awarded. Six researchers received multi-year funding.

A large amount of the total NHPRP funds (\$390K) is awarded in partnership with the CIHR in the form of a research grant to study the use of NHPs in the treatment of Type 2 diabetes among the Cree of Northern Quebec.

- Mentoring opportunities through networks that were supported in their development;

The NHPRP contributed to the development of three research networks, including the Canadian Interdisciplinary Network for Complementary and Alternative Medicine (INCAM) research, which encourages research uptake and helps build research capacity, a Canadian research network for the identification and study of fetal and neonatal safety and risk related to NHP exposure during pregnancy and lactation, and the Development of a Network for Research of Natural Health Products in HIV. As an example, this last network alone has provided researchers in Canada with the opportunity to work in collaboration with researchers from other countries to publish close to 10 articles in peer-reviewed journals.

- The development of a comprehensive curriculum on NHPs for integration into Canadian undergraduate medical education programs; and

As an initial step, the program supported the exploration of research literacy amongst complementary and alternative health care practitioners (CAHC) through the completion of an environmental scan of educational CAHC institutions, continuing education opportunities and research initiatives within training institutions for CAHC practitioners. This was followed by an invitational workshop with representatives from 14 of the 16 Canadian medical schools to develop a national vision regarding complementary and alternative medicine (CAM) in undergraduate medical education.

With the support of the research program, competency-based student learning objectives and curriculum content specific to NHPs have been developed and strategies identified for the integration of NHP content into undergraduate medical education.

- Support for the development of a national interdisciplinary network to build capacity within the NHP/CAHC sector.

The Interdisciplinary Capacity Enhancement Team (ICE) Grant Supporting Research in Complementary and Alternative Health Care (CAHC) is a multi-year grant to support research activity in this area. INCAM has a grant funding program, is a focal point for research in this sector and has created communication links and fostered dialogue with groups such as CAHC practitioners and NHP researchers.

Sustainability in research capacity

In the context of a program as broad as the NHPRP, cross-sector partnerships are crucial in order to avoid duplication of efforts and increase chances of sustainability. According to the principles of capacity development, the partnership with the CIHR has the potential for sustainable impact if it continues to be well nurtured. In addition, the fact that the research program has increased the credibility and legitimacy of NHP research because of its partnership with the CIHR and the quality research produced thus far will move the program further ahead towards realizing its objectives.

Based on the experiences shared in the literature and the developmental stage of the NHPRP, the NHPRP would do best to continue to fund a mixture of projects including those which would lead to the establishment of research expertise and/or centres and those which support individual researchers through competitive grants. There is no clear indication based on the evidence collected for the formative evaluation that one approach should be favoured over another. In fact, this mixed-bag approach is a strategy employed in the network development literature to encourage ongoing innovation (Hill, 2002) and

innovation would seem to be an important feature for long-term capacity building in any research program. However, program managers should be cautioned that the issue of long-term capacity building is very complex (Mulholland Consulting, 2005) and not yet well understood.

Supporting the conduct of research

With respect to supporting the conduct of research, the research program Logic Model indicates that there will be:

- Better understanding of the knowledge gaps and areas requiring priority research funding;
- Increased knowledge of NHPs based on research conducted in key areas (i.e., safety, efficacy, utilization and cost effectiveness of NHPs); and
- Knowledge of NHPs based on research conducted through partnerships or co-sponsorship.

The priority setting consultations have helped to create a better understanding of knowledge gaps and research priorities in a number of NHP areas, including the areas specific to the implementation of the regulatory framework. In addition, progress has been made in creating a knowledge base in areas such as CAHC/CAM and EFAs.

Better understanding of the knowledge gaps

The priority setting consultations have helped to create a better understanding of knowledge gaps and research priorities in a number of NHP areas.

A total of eight priority setting projects and consultations in the areas of essential fatty acids (EFAs), probiotics, TCM, homeopathic medicine, the safety monitoring of herbal medicines, the coordination of NHP research, and NHP research funding have received funding and led to discussions among experts and stakeholders of the gaps requiring most attention and measures to address these gaps. In addition, through the NHPRP, there has been support for 13 conferences, scientific symposia and other national venues to facilitate a better understanding of regulatory issues, share the current state of knowledge on various NHPs and facilitate the development of research directions to benefit regulators, Canadian industry and consumers.

Contributions from NHPRP funded projects towards informing the implementation of the regulatory framework

In their project reports, most NHPRP funded researchers mention a link with the regulatory framework. Some of these linkages are mentioned in the form of identifying gaps or what still needs to be done. In addition, presentations made at conferences have been about regulatory issues. Some NHPD staff have been in attendance at these consultations. Other linkages to the regulatory framework have been in the form of

publications. A few projects have been able to directly address issues important to the implementation of the *NHP Regulations*, as detailed in the sections below.

Safety

To date, the NHPRP has addressed the area of NHP safety through, for example, the Invitational Consultation on Essential Fatty Acids (EFAs) and Fatty Acids (FAs), where experts in EFAs, FAs and fish oils were in attendance. Internal panel participants who attended this consultation had their questions answered regarding the safety of using fish oil during pregnancy and found the information to be useful in developing product monographs. Internal panel participants recommended that this type of “expert” consultation be done two to three times per year.

Efficacy

Efficacy was also seen as a high priority area for continued research funding. An example of how the area of efficacy has been addressed is the research on selected anti-diabetic plants. This project carried out an ethnobotanical survey to identify key plants traditionally and safely used by the Cree for diabetes, and performed laboratory tests *in vivo* animal models and performed *in vitro* bio-assays to ascertain bio-activity and modes of action. A randomized double-blind placebo-controlled pilot clinical trial was carried out in the Cree community to validate the plant’s efficacy and appropriate ways to incorporate the effective plants into the Cree diet and lifestyle were explored.

Quality

This area was perceived to be of high importance for continued research funding. The British Columbia Institute of Technology (BCIT) through the funded Pilot Project of NHPs Analytical Laboratory Proficiency Program was noted as an example of how the NHPRP has addressed the area of quality as this project has initiated important and needed work on the conduct of accurate, reliable and reproducible analyses of NHPs through analytical laboratory techniques. The project is also helping to build the evidence base on the quality of selected NHPs.

Other key examples of the NHPRP’s contribution to the implementation of the regulatory framework are presented in the box below.

Key examples of how the NHPRP has been able to contribute to the implementation of the regulatory framework:

- Development of **World Health Organization (WHO) technical documents** and guidelines on safety and efficacy in the use of traditional medicine has been improved and promoted;
- Development of **monograph** on fish oil as a result of NHPRP sponsored Consultation on Fatty Acids (2005); revisions to monographs on flaxseed and evening primrose oil (EPO); and identification of need for a separate monograph on seal oil.
- Three projects supporting progress on the **development of botanical authentication and standardization and certification protocols** (i.e., NHP Analytical Laboratory Proficiency Program; feasibility study on applying metabolomics to the authentication and quality control of NHPs; and the Development of Good Wildcrafting Practice Guidelines and Wildcrafter Certification for the Harvesting of Wild Medicinal Botanicals), a need repeatedly emphasized by researchers, industry and regulators in Canada and world-wide;
- Publication of **at least 12 articles in peer reviewed journals** such as the Canadian Journal of Physiology and Pharmacology; the Canadian Journal of Clinical Pharmacology; the Journal of Ethnopharmacology; the Annals of Internal Medicine; New Scientist; the Journal of Cell Biology; the Journal of Biological Chemistry; the Journal of Cell Science; and the Proceedings of the International Symposium, Biodiversity and Health, Focusing Research to Policy; and
- Development of **standardized learning objectives and curriculum content on natural health products** and topics for integration into Canadian undergraduate medical education.

Need to build the scientific capacity of the NHPD

Expert panel members also expressed a concern that there is a need to invest further in the development of an internal NHPD research capacity in science (because the focus to date has been on building external research capacity at the expense of building the internal scientific and laboratory research capacity of the NHPD).

Suggested research directions from the internal panel participants

While internal panel participants indicated that the NHPRP has done excellent work to date in funding research in each of the above regulatory areas, some questioned whether the NHPRP can continue to make much progress if the focus of the program remains the same and suggested that perhaps the funding should instead be directed at one regulatory area per year.

By way of providing some direction, internal panel participants noted the need for research on specific regulatory related issues, namely to:

- Find a way to increase the capacity for testing for active ingredients/markers (to facilitate, for example, the quality match of product labels and their contents); and
- Support good manufacturing practices (GMPs).

Developing partnerships and community infrastructure

As identified in the Logic Model, the research program hopes to develop partnerships and community infrastructure, by achieving:

- Enhanced understanding of NHP research issues through complementary strengths across sectors;
- An expanded role and involvement of voluntary and not-for-profit organizations in NHP research; and
- A sharpened focus on key areas of interest and concern across different sectors.

The program has started on the right track with regards to developing partnerships within the NHP community but many of the accomplishments to date are in the areas of the NHPRP Logic Model's outputs (e.g., the development of the partnership with the CIHR, the establishment of at least three NHP research networks, and the direct provision of funding to voluntary and not-for-profit organizations for a total of seven projects).

Next steps that are favoured by key informants and that fit with the literature regarding the development of partnerships and community infrastructure involve providing a database that will facilitate ongoing connections among key stakeholders, and funding research that will be conducted through a partnership effort.

In order to best ensure the sustainability of NHP research, the NHPD needs to use the next two years to most effectively leverage partnerships with credible organizations in research, industry, consumer groups, voluntary and not-for-profit organizations, and government. In particular, the partnerships with industry and practitioners are critical to ensuring the successful implementation of the *NHP Regulations*, for example, in terms of gaining an accurate picture of what can feasibly be done through the *Regulations*. But there must also be attention paid to developing the infrastructure necessary to sustain the research expertise established to date, thus raising the importance of the partnership with the CIHR.

Given its successful work thus far in increasing the credibility and legitimacy of NHP research, the NHPRP is well positioned to identify and build partnerships at the local, regional, national and international levels. The work done to achieve consensus on NHP research priorities among a wide variety of stakeholder groups who have competing interests is particularly significant.

Enhancing knowledge transfer

To enhance knowledge transfer, the research program Logic Model specifies that the program hopes to:

- Increase the sharing of relevant information across different sectors that could impact NHP research, contribute to the informed choice of consumers, and contribute to the development of the NHPRP research agenda;
- Increase the extent to which knowledge from literature reviews translates into research priorities and products and contributes to the development of the regulatory framework; and
- Increase the accessibility of information on NHP research to stakeholders, including consumers.

Sharing information across sectors: Working in multidisciplinary teams and employing various information dissemination strategies

As indicated in the section on Program Implementation, the NHPRP has funded projects to enhance collaborative efforts among several NHP stakeholder groups, including researchers, industry, conventional medicine, and CAHC/CAM. In addition, evidence indicates that NHPRP funded researchers are disseminating their research findings (e.g., through conferences, workshops, networking, and at least 12 articles published in peer reviewed journals). There have been numerous presentations at North American and international venues such as the Complementary and Alternative Medicine Annual Conference in Exeter, UK; the American Association of Naturopathic Physicians; the Canadian Association for HIV Research; American Society for Bone and Marrow Research; the conferences held by the Natural Health Products Research Society of Canada; the BC Functional Food and Nutraceutical Network (BCFN); scientific symposia (e.g., the Chan Centre Auditorium in the Child and Family Research Institute in Vancouver); grand rounds (e.g., at the Centre for Addiction and Mental Health); public forums; and various universities and colleges as a result of NHPRP funded projects.

According to the literature reviewed for the formative evaluation, these strategies are best suited to enhancing knowledge transfer in a way that will have a chance to impact knowledge uptake and application, and will have promise in achieving the intended outcomes if these efforts are expanded to other groups and through additional means.

Perceived changes in awareness of NHP research among funders, industry, practitioners and researchers

As reported by NHPRP funded researchers, perceived changes in awareness in stakeholder awareness, attitudes, or practice were generally limited to perceived changes in awareness. Examples included increased awareness:

- Among funders and included mention that there is some increased acceptance within this group of traditional medicine as a valid funding option;
- Among industry regarding clinical research (i.e., awareness regarding the clinical research that is occurring);
- Regarding the complexity of the NHP sector, including issues facing various stakeholders;
- Among NHP practitioners regarding NHP research (*“what it entails and how they need to train themselves and future practitioners”*);
- Regarding types of research in progress (e.g., “n of 1” methodologies); and
- Regarding “who’s doing what” as a result of networking, meetings, and conferences.

The NHPRP needs to continue to build on this progress. Stakeholders consulted for the formative evaluation agree that there is still a need for the NHPRP to focus on projects related to NHP safety and efficacy, and on communicating tangible information/knowledge to the public.

Suggested ways to reach consumers

The program would like to increase the public’s understanding of NHPs but it is difficult to ascertain the extent to which this has happened. The evaluation has demonstrated that:

- The public was involved in initial consultations to set NHP research priorities;
- Almost one-third (27%) of the projects funded to date were in the area of NHP product quality, safety and efficacy, areas particularly important to enable consumers to make informed decisions about the use of NHPs;
- The research program facilitated the dissemination of research information through sponsored conferences; and
- A total of 6 projects were directly aimed at improving informed choices by consumers. Examples include practical guides for use of NHPs in HIV/AIDS and a study of the requirements for supporting decision-making about the use of NHPs for women of menopausal age.

The focus in the first three years of the program was the generation of a strong research foundation, including research in areas that are directly related to enabling consumers to make informed decisions about the use of NHPs. The dissemination of the research

findings would normally follow as the research is completed. Progress towards reaching the Canadian public should be more apparent as the program matures.

The recent (March 2005) Ipsos-Reid poll of Canadians indicated that in general, more Canadians are unfamiliar (45%) than familiar (36%) with NHPs. Additional polls will be needed to determine if the public understanding of NHPs is indeed increasing. Currently, the poll indicates that pharmacies, Health Canada's website, and Health Canada's publications are the most preferred means of receiving information on NHPs so this presents an opportunity to reach the public and then to later gauge the impact of the program.

To increase the accessibility of information on NHP research to consumers, it will be important for the NHPRP to continue outreach to practitioners and consumer organizations because they are the closest to consumers. It was suggested, for example, that the program could create opportunities for consumer organizations to conduct conferences for public education about NHPs. Other suggested ways to reach audiences beyond the research community are provided in Appendix C.

2.32 Extent to which the NHPRP is impacting intended beneficiaries: The value for money test

The extent to which the NHPRP has impacted the six beneficiary groups as articulated in the submission to the Treasury Board of Canada Secretariat is a key consideration of the *Value for Money Test*, which asks: Are Canadians getting value for their tax dollars? What is the evidence that the initiative is achieving the stated objectives? The discussion of this evaluation question aligns with a discussion of the outcomes identified in all four program areas.

According to the submission to the Treasury Board of Canada Secretariat, NHPRP activities should have benefits for constituents in at least six key stakeholder groups, including the research community, industry, regulators, voluntary and not-for-profit organizations, health care professionals, and the Canadian public. It is evident, based on the types of projects undertaken, that the NHPRP has actively tried to meet the obligation to reach and impact this vast scope of beneficiaries.

Several examples exist of how the primary beneficiaries listed in the submission to the Treasury Board of Canada Secretariat have been impacted through the NHPRP. Comparisons of the intended impact (as described in the submission to the Treasury Board of Canada Secretariat) and evidence of the actual impacts achieved to date on each constituent group are presented below and in greater detail in Appendix H.

Research community

The evaluation identified that progress has been made in terms of impacting the research community. This finding is not surprising given that they are the primary recipients of NHPRP funding. Specifically, there is good evidence from a variety of sources that, as intended, the NHPRP has contributed to increasing the number and quality of NHP research projects undertaken, as well as provided opportunities for education and training of new NHP researchers.

As noted in the submission to the Treasury Board of Canada Secretariat, as well as in the literature (e.g., DANIDA, 2000 in ODI, 2002), the development of infrastructure (e.g., physical infrastructure such as research buildings and equipment, operational budgets, and human resources) within academic and research institutions related to NHP research is critical to sustaining and building on this momentum. Thus, to achieve its outcome to build NHP research capacity, it will now be necessary for the program to identify ways to encourage these institutions to identify and develop the necessary infrastructure.

Industry

Industry has had many opportunities to build relationships in the NHP research community, including with the NHPD, due to the large number of consultations undertaken, communication activities, and participation in research projects. Again, if this momentum is to be sustained, more needs to be done to encourage industry to fund or to co-sponsor NHP research.

Individuals and entities involved with the NHP regulatory framework

Some NHPRP funded consultations have helped NHPD staff to put the *NHP Regulations* into practice. However, prior to the internal panel session, most participants reported that they had a general understanding of the NHPRP but were not aware of the specific objectives and details of the program, or of the projects that have been funded and the findings from completed projects. This finding indicates a need for increased communication of the NHPRP's activities and products within the NHPD and among other Health Canada departments (e.g., OCS, HPFI, and MHPD). Internal panel participants made a number of recommendations for how the research program can better enable the Directorate to develop an effective and appropriate framework for NHPs. These recommendations are detailed in Appendix E.

Voluntary and not-for profit organizations

The NHPRP has funded a total of seven projects of which voluntary and not-for profit organizations were the primary recipients of funding. In addition, such organizations were a part of other NHPRP funded research teams, suggesting that the program is on the right track with this target group. The submission to the Treasury Board of Canada

Secretariat does not indicate what is to be considered “meaningful activities related to NHP research” and so no further assessment can be provided at this time.

Health care professionals

The evaluation data suggests that several important preliminary steps have been made by the NHPRP in terms of making progress towards impacting health care professionals. This target group was not consulted for the formative evaluation so further assessments of the extent to which the NHPRP funded projects have impacted health care professionals cannot be proffered. However, a survey of health professionals conducted by Environics Research Group for Agriculture and Agri-Food Canada (2005, cited in the Natural Health Products Research Society of Canada’s Business Plan, 2006) indicates that physicians and nurses want more information regarding NHPs and functional foods, particularly on the benefits and effectiveness of such, and that this and other information be based on unbiased research.

In order for impacts to occur among health care professionals, a significant amount of knowledge transfer (related to the NHP research) will have to occur, as well as uptake of the knowledge.

Canadian public

The focus in the first three years of the program was the generation of a strong research foundation, including research in areas that are directly related to enabling consumers to make informed decisions about the use of NHPs. The dissemination of the research findings would normally follow as the research is completed. Progress towards reaching the Canadian public should be more apparent as the program matures.

Stakeholders consulted for the formative evaluation agree that there is still a need for the NHPRP to focus on projects related to NHP safety and efficacy, and on communicating tangible information/knowledge to the public.

2.33 Extent to which the NHPRP activities result in other organizations providing funds for NHP research: The partnership test

Given that the NHPRP is currently slated for five-year funding which will end in 2007/08, the program can have the most impact over the long-term by fostering and leveraging partnerships in the delivery of program funding (e.g., through its partnership with the CIHR to manage a portion of the grants envelope) and in encouraging other organizations – both public and private – to contribute to funding NHP research. The discussion of this evaluation question aligns with the outcomes identified in two key program areas, namely supporting the conduct of research and developing partnerships and community infrastructure.

Number of projects that obtained and/or obtained additional resources

Our review of the applications for project funding and the project reports indicated that funded researchers received in-kind contributions as well as funding from other organizations. This data was supported by the findings from the interviews with funded researchers who often clarified that their success at obtaining additional funds and/or in-kind support was due to their success in obtaining funds through the NHPRP. Specifically:

- About one-half (48%) of the NHPRP funded researchers who were interviewed as part of the formative evaluation reported that they received other sources of funding for their project;
- 40% relied solely on the NHPRP funding to complete their projects; and
- The remaining 12% further noted that in-kind support (such as time, equipment, materials, and space) had been received in addition to the NHPRP funding.

During the discussions with funded researchers, they noted that they often obtained additional funding through other agencies. Other reported funding sources included their organizations and/or sponsors, NSERC and CIHR (e.g., through academic researchers' or supervisors' existing grants), other Health Canada initiatives, private foundations, project team partner funding from other federal and provincial government sources (e.g., Agriculture Canada, Health Canada), industry (Natural Factors and CV Technologies), and other research foundations. Again, it is important to note that many interviewees indicated that additional funds for their projects were secured because of the NHPRP's funding commitment. The perceived reasons for their success at leveraging these additional resources have been reported elsewhere in this report and included, for example, the enhanced credibility and legitimacy of NHP research as well as the financial contributions from the NHPRP and the CIHR.

Funding contributions and additional funds estimates

In most cases, the interview respondent was unable to recall the approximate relative distribution between funding provided through the NHPRP and that provided by other sources.

For those who were able to respond to the question:

- Those who received funding for workshops and conferences (particularly the second in a series), received only about 10-15% of their total funding from the NHPRP. In other words, for every dollar spent by the NHPRP on projects such as workshops and conferences, an additional 8 or 9 dollars was leveraged.

- Those who had undertaken research projects indicated that they received approximately 50% of their total required funding from the NHPRP, suggesting that the program may be leveraging funds dollar-for-dollar for NHP research projects; and
- For those who received salary and training awards, almost all (80-100%) of their costs were covered by the NHPRP. In one case, the university covered the remaining tuition if the student was in receipt of a national fellowship.

It is important to note that these estimates do not include the in-kind contributions. If these in-kind contributions were factored into the equation, the estimates of additional funds obtained and funds leveraged would likely be much higher.

Other potential funders

The *Partnership Test* asks: What activities or programs should or could be transferred in whole or in part to the private/voluntary sector?

At this formative stage in the NHPRP's development, it is difficult to ascertain the scope of the impacts in each area of program activity, and consequently, difficult to assess where the most funding support is being or could be gained. At this point, it is important to note the feedback obtained from those consulted for the evaluation regarding potential sources of NHP project funding. A detailed list obtained from those consulted for the evaluation regarding potential partners and sources of NHP research funding is presented in Appendix I.

2.4 CONCLUDING STATEMENTS

Since the NHPRP was launched in June of 2003, funded researchers and internal and expert panel participants agree that substantial progress has been made to build the NHP research community. In particular, the efforts have paid off in identifying NHP research priorities, increasing the credibility of and interest in NHP research, connecting stakeholders from a variety of disciplines and sectors, and establishing a funding partnership with the Canadian Institutes of Health Research. However, this work is not done and still requires the coordination and support provided to date by the NHPRP.

The work done thus far was necessary to set the stage for more movement in fulfilling the mandate of the program: to support the NHPD in its regulatory role and to enable Canadians to make informed decisions regarding the safe use of NHPs. The consultations undertaken in the formative evaluation pointed to a number of lessons learned and potential strategies for program managers to use in their upcoming planning efforts. These are presented in the next section.

3.0 Lessons Learned and Recommendations: A Discussion of Effectiveness and Alternatives

In the following sections, a discussion of the lessons learned in each of the three areas of evaluation inquiry is presented, weaving in, as appropriate, information regarding effectiveness and alternatives. Each section concludes with the recommendations that have been developed based on these lessons and are proffered in the spirit of program improvement.

3.1 LESSONS LEARNED RE: ROLE AND RELEVANCE ISSUES

A solid base of credible NHP research is necessary to support the regulation of NHPs. In 1998, the Standing Committee on Health noted that there was little to no NHP research being conducted in Canada, yet the consumer demand for NHPs was increasing along with their production and importation. Now that the *NHP Regulations* are in place, it is even clearer that there are gaps in the knowledge of NHP safety, efficacy and quality – areas critical to the regulatory role.

As noted earlier, enabling Canadians to make informed choices about health care options is part of the program's mandate, yet a recent poll indicated that in general, more Canadians are unfamiliar (45%) than familiar (36%) with NHPs. The formative evaluation revealed that the program is challenged to communicate the findings and knowledge gained from NHPRP funded research to Canadians in a tangible manner.

Sustained efforts are required to bridge the ongoing gaps in NHP research and the regulatory environment in particular:

- Additional research on NHP safety, efficacy and quality;
- Timely response to the needs of the NHP regulatory environment; and
- Sustained dialogue between stakeholders and the dissemination of evidence-based information on NHPs.

Conclusion and recommendation re: role and relevance issues

It is clear that the NHPRP is still relevant and necessary in the bigger picture of the *NHP Regulations* and for enabling consumers to make informed choices about the safe use of NHPs.

In an effort to ensure the continued relevance of the program, it is recommended that the NHPD:

Recommendation 1: Develop a stronger relationship between regulators and the broad NHP community to ensure an integrated approach in addressing the knowledge gaps and challenges of the NHP regulatory environment.

Recommendation 2: Sustain and improve efforts in the generation of knowledge in the areas of quality, safety and efficacy and its dissemination to stakeholders, partners and the Canadian public.

3.2 LESSONS LEARNED RE: PROGRAM IMPLEMENTATION

In the first three years, the NHPRP funded a total of 60 projects, many of which cross program activity areas, disciplines, research themes, NHP products, and geographic locations. As of March 2006, 84% (or \$2.5M of the allocated \$3.0M) was spent across all three delivery mechanisms (i.e., grants, contributions and operating funds).

The program staff have responded to a number of challenges in program delivery. In terms of managing grants, the NHPRP has been able to use 100% of the allocated funds in the first year, 68% in the second year and 57% in the third year. Discrepancies in planned allocations versus actual expenditures have primarily been related to the challenges involved in coordinating the flow of funds with the timing of the CIHR funding calls, improving the timely identification of unused funds, and coordinating the timing of accounting within the CIHR and Health Canada. The NHPRP needs to continue to work with the CIHR to strategize around fine-tuning the process.

A total of 30 contributions agreements – with amounts of \$20K, \$25K, and \$75K – were signed during the first three program years. A total of 42 projects were screened positively by a peer review panel and recommended for funding, meaning that the NHPRP had resources to fund 71% of the eligible projects. In general, funding recipients are satisfied with the contributions funding process, with some suggested improvements including more time between requesting proposals and application due dates, earlier receipt of funds, increased funding amounts, and less stringent reporting requirements.

The operating funds have served a good purpose by providing a means to fund numerous consultations, priority setting meetings, conferences and workshops. As noted under Program Results, the work done to achieve consensus on NHP research priorities among a wide variety of stakeholder groups who have competing interests is particularly significant. Crucial to the success of moving forward in these areas is the importance to involve the right partners at the table – including NHPD staff – to be effective and constructive. Furthermore, the flexibility of the operating funds mechanism has allowed the NHPRP to fund projects that provided needed research data in a timely fashion. The formative evaluation also identified that there are still knowledge gaps regarding the NHPs typically used in the areas of homeopathy, naturopathy and essential oils/aromatherapy and that there would be benefits to having priority-setting exercises to further clarify the nature of these gaps. The present evaluation also indicated that the

technical workshop format for meetings and scientific symposia is the preferred approach for fostering networking and identifying gaps in NHP knowledge.

Conclusion and recommendations re: program implementation

The three delivery mechanisms require some tweaking in order to ensure that all available program funds are spent but have been working well in terms of furthering the program objectives. The diverse approach allows the NHPRP flexibility and the ability to exercise control where required.

For improvements to program implementation, it is recommended that the NHPD:

Recommendation 3: Improve the coordination of grant funding with the CIHR.

Recommendation 4: Improve the contribution funding process with respect to the launching and broadcasting of Call for Proposals, the timely availability of funds and reporting requirements.

Recommendation 5: Involve broader representation of various internal and external stakeholders in various priority-setting and knowledge-based activities.

3.3 LESSONS LEARNED RE: PROGRAM OUTCOMES

The NHPRP aims to impact six key beneficiary groups and to achieve results in four key areas.

Of the six beneficiary groups, the NHPRP has made notable progress in reaching the research community (for example, by increasing access to research funding through the CIHR, helping to increase the credibility of NHP research, and creating training opportunities through INCAM), industry (by building relationships via consultations and NHPD communication activities, and providing opportunities for participation in NHP research projects), and those involved with the development of the NHP regulations (by funding quality research in NHP safety, efficacy and quality; and holding consultations which identify gaps in NHP knowledge and reach consensus on technical regulatory issues and contribute to the development of technical documents and monographs).

Less is known about the program's impact on the other three beneficiary groups, namely, voluntary and not-for-profit organizations, health care professionals and the Canadian public – though preliminary data suggests that important first steps have been made to reach these groups.

The program has made significant strides with respect to building research capacity and is following the principles of capacity development that are evident in the literature. Of note is the program's partnership with the CIHR in the delivery of grants. This partnership has

allowed the NHPRP to gain credibility in the eyes of key stakeholders such as academics, industry and other funding organizations, as well as contributing to the increased credibility and legitimacy of NHP research as a whole.

The program has done well in a very short period of time in terms of supporting the conduct of research, resulting in the creation of sound and credible knowledge bases in areas such as EFAs and some NHPs used in CAHC/CAM. But there are also some areas – particularly the grey area between NHPs and functional foods and the NHPs typically used in homeopathy, naturopathy and essential oils/aromatherapy – that are imperative to address.

The partnerships with the CIHR and industry will be particularly important to nurture in order to ensure sustained credibility of NHP research, sustained affordability of NHP research, and the successful implementation of the *Regulations*. The literature notes that the development of infrastructure (i.e., physical, monetary, and human) within academic and research institutions is key to sustaining and building on this momentum.

The program has also facilitated the development of partnerships at other levels, in terms of the creation of research networks and multidisciplinary research teams. The creation of the research networks has evolved into the beginnings of research centres, which will be key to the sustainability of NHP research in Canada. However, the literature in the areas of network development and research capacity building remind us that it is just as important to foster continued innovation through the support of individual research through competitive research grants.

Multidisciplinary research teams such as those developed thus far by the NHPRP have been linked in studies of similar research programs to enhancing knowledge transfer and information dissemination. Anecdotal evidence of knowledge transfer is already appearing among researchers and between researchers and regulators, mostly during conferences or funded workshops. It is likely too soon to expect to see concrete examples of NHP knowledge being transferred to consumers and the Canadian public; however, this area cannot be ignored, as it is essential to the program's mandate.

Conclusion and recommendations re: program outcomes

Based on the findings of this evaluation, the NHPRP would not benefit from a reallocation of funding or a change of emphasis among key areas of activity, as all four are important to meeting the program's objectives.

In terms of improving its ability to achieve program results across all four key program areas, it is recommended that the NHPD:

Recommendation 6: Explore new funding opportunities and support efforts to further build the sustainability of the NHP research community.

Recommendation 7: Enhance knowledge transfer and dissemination of information on NHPs.

3.4 OTHER LESSONS RE: EFFECTIVENESS AND ALTERNATIVES

This section outlines additional lessons learned which could be used by NHPRP stakeholders and program managers to deliver the program in a more cost-effective way, while striving to ensure optimal reach and impact. The discussion is complemented by the *Efficiency Test*, as outlined by the Expenditure Review Committee (TBS, 2003).

The *Efficiency Test* asks whether the program exploits all options for achieving lower delivery costs through, for example, public-private partnership and third-party delivery mechanisms. The NHPRP has used both partnerships and third-party delivery mechanisms to deliver the program over its first three years, and key informants have noted the success of this approach.

In terms of its grants mechanism, the NHPRP was able to leverage research funds from the CIHR and as part of the NHPD/CIHR Partnership Program, the CIHR funded three researchers 100% over and above the three researchers who were awarded funding through the competition and another two applicants were awarded personnel training awards through the Canada Graduate Scholarship Award Program and the Clinical Research Initiative Award.

In the context of a new research program seeking to create interest and capacity in a new and evolving area of research, the contributions mechanism was effective at fostering the interest in NHP research within various institutions across Canada. Moreover, the support provided to some organizations helped them obtain further funding [e.g., the NHPRP funded Natural Health Products Research Society of Canada (NHPRSC) annual conferences were also funded by other sponsors, in part due to the NHPRP's commitment to provide financial support].

It is important to note that the return on investment (ROI) is not always in terms of direct financial benefits. Of significant importance in research and development programs such as the NHPRP are examples of more intangible benefits, like increased research capacity. As an example, the Canadian Institute of Chinese Medicinal Research (CICMR), a national organization for Chinese medicinal research, was formed after the 1st NHPRSC Conference in 2004. The CICMR later held a large conference on Traditional Chinese Medicine (TCM) in Vancouver and was successful in obtaining conference support funding from the NHPRP for this endeavour.

In comparison to grants, the contributions envelope is much more labour intensive for the NHPRP. The program dedicates one full-time staff person a full time manager while funding recipients dedicate administrative and staff support time. Thus, it is in the best interests of both the NHPRP and the funding recipients to engage in contributions

agreements that are of significant value. This suggestion was also made by the funding recipients (see the Implementation Issues section of this report) and further justified by the exploratory nature of the studies typically funded under this envelope, which inevitably run into unexpected costs.

Through its operating funds, the NHPRP funded background papers on key regulatory issues related to emerging NHP products such as fatty acids (FAs) and essential fatty acids (EFAs), probiotics and TCM. These background papers formed the basis for further exploration of issues related to these products and the conduct of priority-setting exercises to identify research gaps. The EFA consultation then led to consensus on three monographs for the NHPD, a concrete application in relation to the *NHP Regulations*.

Key to the success of these projects was the ability to use operating funds in a flexible manner to target research that is identified and needed in a timely fashion. In the case of the EFA consultation, the success was further facilitated by the involvement of industry and the NHPD, the technical nature of the venue which focused on specific regulatory challenges, and the ability to work through issues and challenges with expertise on hand and in one physical location.

Similarly, the priority-setting exercises were instrumental in bringing together groups of stakeholders who would otherwise not necessarily have the resources and/or capacity to organize and readily meet to explore common issues. Thus, the return on investment is not a dollar figure, but significant qualitative benefits in relation to the program's objectives.

One final item of note is a reminder to give consideration to a larger investment in building expertise within Health Canada for some NHP areas. Some key informants expressed a concern that the focus to date has been on building external research capacity at the expense of building the internal scientific and laboratory research capacity of the NHPD.

Conclusion and recommendations re: effectiveness and alternatives

All three delivery mechanisms have made important, yet different, contributions to the program's success to date in achieving results in four key areas, demonstrating significant returns on investment.

For improvement in the effectiveness of the delivery mechanisms, it is recommended that the NHPD:

Recommendation 8: Deliver program in a more cost-effective manner, maintaining balance between flexibility and effectiveness and further strengthening the research community infrastructure.

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Appendices

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APPENDIX I

List of Potential NHPRP Partners and Sources of NHP Research Funding (p. 85)

Appendix A: Evaluation Information Summary Table

The following table is reproduced from the Request for Proposal Reference # 4500115378.

Evaluation Questions	Indicators	Data Sources
Implementation Issues: What is the status of implementation of the research program? What progress has been made? Where are the gaps in implementation?		
Implementation Question 1: Is funding used fully, effectively and in keeping with plans and authorities?	Comparison plan to actual: <ul style="list-style-type: none"> ▪ Expenditures ▪ Allocation across funding mechanisms 	Systems, Applications and Products (SAP) Database; financial reports; project files
Implementation Question 2: What activities have been funded?	<ul style="list-style-type: none"> ▪ # of research grants, awards, curriculum development ▪ # and type of networks ▪ # and nature of research projects/ initiatives 	NHPRP annual reports; project files Interviews with funding recipients
Implementation Question 3: What groups are benefiting from the program interventions?	<ul style="list-style-type: none"> ▪ # and type of funded recipients ▪ Stakeholders involved in program activities 	Financial and administrative reports; NHPRP program files; project files Expert panel discussion Interviews with funding recipients
Implementation Question 4: Is the NHPRP delivering planned activities while being responsive to identified priorities and research areas?	<ul style="list-style-type: none"> ▪ Comparison of expenditures and outputs by activity area ▪ Scope and objectives of requests for proposals, priority setting exercises and funded research 	Financial and administrative reports; NHPRP program files; NHPRP annual reports Internal panel discussion

Evaluation Questions	Indicators	Data Sources
Implementation Question 5: Is the NHPRP implemented according to anticipated delivery mechanisms?	<p>Comparison of planned delivery approaches to actual:</p> <ul style="list-style-type: none"> ▪ MOUs with CIHR ▪ # of requests for proposals launched ▪ # of applications/ # funded ▪ Extent of multi-sectoral involvement ▪ # of responses to and results of competitions 	<p>NHPRP program files and record or applications received; contribution agreements and initial proposals; NHPRP Grants and Contributions Commitments Worksheet</p> <p>Internal panel discussion</p>
Program Results: What progress is being made towards the achievement of results?		
Results Question 1: To what extent is the program reaching the intended beneficiaries?	<ul style="list-style-type: none"> ▪ Intended vs. actual beneficiaries ▪ # of researchers and organizations associated with the funded NHPRP projects ▪ Reported barriers 	<p>Project reports</p> <p>Interviews with funding recipients</p> <p>Internal panel discussion</p>
Results Question 2: To what extent are NHPRP activities enhancing research capacity and partnership building?	<ul style="list-style-type: none"> ▪ Quantitative and qualitative data generated by grants and contributions programs ▪ Increase in # of researchers, research opportunities ▪ # of grants and salary and training awards ▪ Extent to which ability to conduct research has been increased ▪ Self-reported and perceived changes in research community infrastructure 	<p>NHPRP Grants and Contributions Commitments Worksheet; CIHR awards database; funded projects progress reports; CIHR applications database</p> <p>Expert panel discussion</p> <p>Interviews with funding recipients</p>
Results Question 3: Did NHPRP activities result in other organizations providing funds for NHPs research?	<ul style="list-style-type: none"> ▪ Knowledge of NHPs based on research conducted in specified areas and obtained through partnerships or co-sponsorship ▪ # of NHPRP projects in which other organizations contributed funding 	<p>Contribution agreements and initial proposals; CIHR files</p> <p>Expert panel discussion</p> <p>Interviews with funding recipients</p>

Evaluation Questions	Indicators	Data Sources
Results Question 4: Did NHPRP activities contribute to an improvement in the scientific and public understanding of NHPs?	<ul style="list-style-type: none"> ▪ Reported level of awareness ▪ Expert panel feedback ▪ NHPs-related issues reported in presentations, scientific publications, media reports 	<p>Funded projects progress reports</p> <p>Expert panel discussion</p> <p>Internal panel discussion</p> <p>Interviews with funding recipients</p>
Results Question 5: Did NHPRP activities contribute to the development and implementation of the regulatory framework?	<ul style="list-style-type: none"> ▪ Evidence of linkages with regulatory framework ▪ Identified gaps in specific regulatory research areas 	<p>NHPRP funding announcements</p> <p>Expert panel discussion</p> <p>Internal panel discussion</p> <p>Interviews with funding recipients</p>
Role and Relevance Issues: Does the NHPRP make sense in terms of the conditions, needs or issues it is intended to respond? Does it continue to serve the public interest and address an actual need?		
Role/Relevance Question 1: Is there a legitimate and necessary role for the NHPD in this program area?	<ul style="list-style-type: none"> ▪ Need expressed for ongoing support to the regulatory process ▪ Need expressed for ongoing support to informed choice by consumers ▪ Evidence and need expressed for evidence-based research in NHPs ▪ Status of body of research on NHPs 	<p>NHPD files and background documents (e.g., Report from the Standing Committee on Health in 1998, deliberations from Halifax consultation in 1999); probiotics, TCM and EFA meetings and AFMNet project reports</p> <p>Expert panel discussion</p> <p>Internal panel discussion</p> <p>Interviews with funding recipients</p>

Evaluation Questions	Indicators	Data Sources
<p>Role/Relevance Question 2: Is there demonstrated consistency between the program and the needs and priorities of primary beneficiaries?</p>	<ul style="list-style-type: none"> Alignment with needs of citizen, public policy response to program need Existence of new, emerging themes and issues Ability to engage new partners in NHP dialogue 	<p>NHPD files; HPFB Strategic Plan and other documents; results of consultations conducted by NHPRP, TCM, EFA and homeopathy consultations</p> <p>Expert panel discussion</p> <p>Internal panel discussion</p> <p>Interviews with funding recipients</p>
<p>Role/Relevance Question 3: Does the NHPRP complement, overlap, duplicate or conflict with other government or stakeholder NHPs initiatives?</p>	<ul style="list-style-type: none"> NHPD assessment of other government or stakeholder research activities conducted Direction and future needs 	<p>Report of meeting with funding partners in 2004; review of funded proposals budgets and contributing partners</p> <p>CIHR key informants</p> <p>Expert panel discussion</p> <p>Internal panel discussion</p> <p>Interviews with funding recipients</p>
<p>Effectiveness and Alternatives: Is the NHPRP employing the most appropriate and efficient means to achieve objectives, relative to alternative design and delivery?</p>		
<p>Effectiveness Question 1: Are key stakeholders involved in the delivery of the program?</p>	<ul style="list-style-type: none"> # of stakeholders consulted and sectors represented Better understanding of knowledge gaps and areas requiring priority research funding 	<p>NHPD program files and consultation reports</p> <p>Expert panel discussion</p> <p>Internal panel discussion</p> <p>Interviews with funding recipients</p>
<p>Effectiveness Question 2: Would the NHPRP benefit from a reallocation of funding and a change of emphasis between activities?</p>	<ul style="list-style-type: none"> Level of funding per project Comparison of actual expenditures by activity and results achieved Extent to which funded activities align with priorities and objectives of NHPRP 	<p>NHPRP and NHPD program files; MAC and EAC meeting reports</p> <p>Expert panel discussion</p> <p>Interviews with funding recipients</p>

Evaluation Questions	Indicators	Data Sources
Effectiveness Question 3: Are there more cost-effective ways of delivering the program?	<ul style="list-style-type: none"> ▪ Comparison of actual expenditures by activity and results achieved ▪ Staff resources required according to delivery mechanism ▪ Peer review process and infrastructure 	NHPRP program files Expert panel discussion Interviews with funding recipients
Effectiveness Question 4: What worked well in delivering the research program?	<ul style="list-style-type: none"> ▪ Reported enabling factors 	Expert panel discussion Internal panel discussion Interviews with funding recipients
Effectiveness Question 5: What are some of the challenges encountered?	<ul style="list-style-type: none"> ▪ Reported challenges 	Expert panel discussion Internal panel discussion Interviews with funding recipients

Appendix B: Detailed Evaluation Methodology

Both qualitative and quantitative data were collected from a variety of sources, as indicated in the table below:

Instrument/ method	Purpose	Respondents and sampling strategy	Procedure	Response
Review of key program and background documents	<ul style="list-style-type: none"> To provide background information for the NHPRP To examine program documents for evidence of activity/ outcome accomplishment To complement the information gathered through the interviews and panel discussions 	<ul style="list-style-type: none"> Selected in consultation with the NHPD 	<ul style="list-style-type: none"> An Excel spreadsheet was set up to capture relevant data for each indicator identified in the Evaluation Information Summary Table Documents related to the NHPRP, the regulatory function of the NHPD, as well as project proposals and reports were reviewed and evidence to support evaluation indicators was noted in the Excel spreadsheet 	83 documents reviewed (see List of Documents Reviewed for the Formative Evaluation on p. 88)
Interviews with NHPRP funded researchers	<ul style="list-style-type: none"> To assess how the program has been implemented with respect to projects funded through the 3 delivery mechanisms To assess the extent of progress made towards program outcomes, in particular, in the area of knowledge transfer To clarify information gathered through the review of program documents To provide collaborative evidence 	<ul style="list-style-type: none"> Selected in consultation with the NHPD using a set of criteria that included project status (ongoing and completed), type of funding (project, grants, awards), funding source (CIHR partnership and NHPRP alone), and geographic location 	<ul style="list-style-type: none"> Telephone interviews were conducted with recipients of NHPRP funded projects and of awards and grants funded in collaboration with the CIHR Interviews followed the interview guide approved by the NHPD and were conducted in accordance with the protocol approved in the ethics review All members of the research team conducted the telephone interviews and took notes of the discussion using a template that addressed key areas of inquiry Immediately following the interview, the notes were elaborated upon and an electronic version was sent to the interviewee for review and comment (with the permission of the interviewee) 	25 interviews conducted

Instrument/ method	Purpose	Respondents and sampling strategy	Procedure	Response
Internal review panel discussion	<ul style="list-style-type: none"> ▪ To focus on the evaluation areas of role and relevance issues and effectiveness and alternatives ▪ To shed light on the extent to which the NHPRP is (or can be) linked to the regulation of NHPs ▪ To provide collaborative evidence 	<ul style="list-style-type: none"> ▪ Selected in consultation with the NHPD in order to provide a broad representation at the managerial level of the many bureaus within the NHPD. In addition, representatives from the Marketed Health Products Directorate, the Health Products and Food Directorate, and a regional representative were invited. ▪ Staff from various bureaus within the NHPD and representatives from the Office of the Chief Scientist (OCS), the Health Products and Food Inspectorate (HPFI), and the Marketed Health Products Directorate (MHPD) attended. 	<ul style="list-style-type: none"> ▪ The consulting team facilitated a half-day Internal Review Panel session with NHPD staff. ▪ Participants were e-mailed an "Invitation to Participate" and the discussion guide in advance of the session ▪ The sessions were facilitated using small- and large-group mixed-method activities ▪ Since not all participants were familiar with the NHPRP, the afternoon began with an abbreviated overview of the NHPRP's mandate, key highlights, success, challenges, and findings from the document review, followed by an opportunity for questions ▪ Participants were then asked to engage in a number of small group discussions to work on the evaluation questions ▪ At the end of the discussion, participants were asked to come up with 3 strong recommendations that the NHPRP should consider in planning effectively for the future 	10 participants in total plus 3 key staff from the NHPRP for selected components of the discussion
Expert review panel discussion	<ul style="list-style-type: none"> ▪ To focus on the evaluation areas of role and relevance issues and effectiveness and alternatives ▪ To provide a broad picture of NHP research in Canada, the extent to which the NHPRP has impacted that state after its first two years in existence, ways to engage new partners and stakeholders in the NHP dialogue, ways to better understand knowledge gaps 	<ul style="list-style-type: none"> ▪ Selected in consultation with the NHPRP using a set of criteria that included: <ul style="list-style-type: none"> - Stakeholder category (research funders, research community, NGOs, practitioners, and industry/ consumer groups); - Involvement with the NHPRP (funded and not funded); - Research area (clinical, 	<ul style="list-style-type: none"> ▪ The consulting team facilitated a full-day Expert Panel session with representatives of key NHP stakeholder groups. ▪ Participants were e-mailed an "Invitation to Participate" and discussion guide questions in advance of the session. ▪ Participants also completed a short e-mail survey for completion and return before the session. This survey was intended to "allow for polling of the realities of a number of stakeholder representatives while minimizing group dynamics" (Barrington, 1986). It was 	12 participants in total plus 3 key staff from the NHPRP for selected components of the discussion

Instrument/ method	Purpose	Respondents and sampling strategy	Procedure	Response
	<p>and areas requiring priority research funding, and the fit of the NHPRP with other government or stakeholder NHP initiatives</p> <ul style="list-style-type: none"> To provide collaborative evidence 	<p>basic/biomedical, health systems and health services, and social science);</p> <ul style="list-style-type: none"> Scope of work (local/population groups, national and international); Area of expertise (e.g., clinical research, nutritional science); and Geographic location. <ul style="list-style-type: none"> Individuals who fit into a variety of categories were selected over those who represent just one desired area. Goal was to obtain a panel comprised of a cross section of stakeholders in NHP research. Participants included representatives (at the local and national levels) from research funding organizations, the research community, non-governmental organizations (NGOs), practitioner groups, industry groups, and consumer groups. 	<p>also intended to encourage some reflection prior to the session.</p> <ul style="list-style-type: none"> Since not all participants were familiar with the NHPRP, the day began with an overview of the NHPRP's mandate, key highlights, success, challenges, and findings from the document review, followed by an opportunity for questions. Participants were then asked to engage in a number of small group discussions to work on the evaluation questions. The day's session focused on identifying strengths, weaknesses, opportunities and threats (Turbo SWOT) for each of the program's 4 key areas At the end of the discussion, participants were asked to come up with 3 strong recommendations that the NHPRP should consider in planning effectively for the future. 	
Selected Literature Review	<ul style="list-style-type: none"> To provide collaborative evidence and present the trends in knowledge in the key areas of research capacity, partnerships and knowledge transfer. 	<ul style="list-style-type: none"> Articles were selected based on the identification of best resources identified through previous literature reviews and key references from academic and research institutions. 	<ul style="list-style-type: none"> Review of recent results of literature reviews conducted on these topics Consultation with academic and research institutions 	

All participants were informed of the purpose of the project, limitations to confidentiality, their rights as participants, and use of the data prior to their participation. An invitation to ask questions was also extended. Copies of all instruments used can be obtained from the NHPRP.

Appendix C: Suggested Ways to Reach Audiences Beyond the Research Community

NHPRP funded researchers who were interviewed made the following suggestions to better disseminate NHPRP research findings beyond the research community:

- Explore the expansion of the three current communication activities (i.e., the NHPD monthly Communiqué, the NHPD quarterly report, and the electronic bulletin) to include plain language summaries of project results and dissemination to a broader audience (e.g., health food stores, industry);
- Improve the NHPRP website (e.g., *“NHPRP website needs to be more transparent, searchable, and accessible. Reports and abstracts need to be available. Abstracts need to be in plain language...”*);
- Use the Natural Health Products Research Society as a gateway for research dissemination;
- Publish editorials in industry and trade magazines;
- Explore the approach used by the Canadian Arthritis Network (publication of journals for the general public);
- Explore dissemination activities/opportunities with university public relations and press offices;
- Share more information with the media/encourage media presentations to promote more public awareness;
- Promote awareness regarding existing online searchable websites (e.g., CamLine and Réseau Proteus);
- Provide more public information forums;
- Work with the Canadian Health Network (e.g., prepare abstracts in plain language, post on their website);
- Continue to fund high quality NHP research to increase credibility within the field (e.g., maintain partnership with CIHR);
- Offer training and information sessions;
- Deliver conference presentations for practitioners;
- Teach practitioners how to access and use research information; and
- Include stakeholders (e.g., NHP community, consumers, general public, Aboriginal communities, etc.) in the design of research projects.

Appendix D: NHPRP Funding Commitments 2003/04 – 2007/08

Title of Project	Organization	Request for Proposal/Type of Award
Contribution Dollars		
2nd Annual Natural Health Product Research Conference	Natural Health Product Research Society of Canada	Request for Proposal Sep 2004 Workshop & Conference Support
2nd National Growing an Industry: Linking Agriculture and Health from the Consumer to the Field - Canada's Place in the Herb, Spice and NHPs Industry	Saskatchewan Herb & Spice Association	Request for Proposal May 2005 Conference Support
3rd Annual Conference & Tradeshow - From Concept to Consumer	Natural Health Product Research Society of Canada	Request for Proposal May 2005 Conference Support
A Pilot Study to Evaluate: A Multi-disciplinary approach to study the anti-inflammatory property of NHPs - development of markers for product standardization	University of Western Ontario	Request for Proposal Jan 2004 Seed Funding
A Proposal to Support the Pilot Project of NHPs Analytical Laboratory Proficiency Program	British Columbia Institute of Technology	Request for Proposal Jan 2004 Seed Funding
Capacity-Building & Effective Knowledge Transfer - Developing a NHPs Curriculum for Integration into Canadian Undergraduate Medical Education Programs	University of Calgary	Request for Proposal Jan 2004 Seed Funding
Characterization of bioactive potency towards cancer cell cytotoxicity by triterpenoid containing North American medicinal plants	University of British Columbia	Request for Proposal April 2005 Bridging the Gap
Developing a Strategic Business Plan for the Natural Health Product Research Society of Canada	Natural Health Product Research Society of Canada	Request for Proposal April 2005 Bridging the Gap
Development of a Network for Research of Natural Health Products in HIV	Canadian College of Naturopathic Medicine	Request for Proposal Jan 2004 Seed Funding
Development of Good Wildcrafting Practice Guidelines and Wildcrafter Certification for the Harvesting of Wild Medicinal Botanicals	Royal Roads University	Request for Proposal April 2005 Bridging the Gap
Développement d'une expertise de pointe et de méthodes efficaces et rigoureuses en matière d'innocuité, qualité et efficacité des probiotiques / <i>Development of leading-edge expertise and effective and rigorous methods related to the safety, quality and effectiveness of probiotics</i>	L'Institut des nutraceutiques et des aliments fonctionnels (INAF) - Université Laval	Request for Proposal April 2005 Bridging the Gap
Enabling Natural Health Product Researchers: Building a Clinical Epidemiology Infrastructure	Children's Hospital of Eastern Ontario	Request for Proposal Jan 2004 Seed Funding
Establishing Canadian Network for NHP in Pregnancy and Lactation	Hospital for Sick Children - Motherisk Program	Request for Proposal Jan 2004 Seed Funding

Title of Project	Organization	Request for Proposal/Type of Award
Expanding the Network - Inclusion of conventional and CAHC health practitioners as participants in the knowledge exchange and transfer information on NHPs	University of PEI	Request for Proposal Sep 2004 Workshop & Conference Support
Feasibility Study - Applying Metabolomics to the Authentication and Quality Control of Natural Health Products (NHPs)	British Columbia Institute of Technology	Request for Proposal April 2005 Bridging the Gap
Fingerprinting Canadian Prairie Safflower and comparison with <i>Flos carthami</i>	University of Manitoba	Request for Proposal April 2005 Bridging the Gap
First Annual Forum on Complementary and Alternative Health Care and Paediatrics	The Hospital for Sick Children Foundation	Unsolicited
Integrating Traditional Chinese Medicine (TCM) Treatment into Clinical Practice	BC Cancer Agency	Request for Proposal May 2005 Conference Support
Modules d'auto-apprentissage à l'intention des praticiens alternatifs : lecture critique et gestion de l'information sur les PSN / <i>Independent learning modules for alternative practitioners: Critical reading and management of information on NHPs</i>	Chaire Lucie et André Chagnon pour l'avancement d'une approche intégrée en santé	Request for Proposal Jan 2004 Seed Funding
Native Plants & First Nations: How can we create research that is equitable, sustainable and beneficial to all?	Royal Roads University	Request for Proposal Sep 2004 Workshop & Conference Support
Natural Health Product Research Society Workshop	Natural Health Product Research Society of Canada	Request for Proposal May 2005 Conference Support
Natural Health Products in Primary Psychotic Disorders: Use and Attitudes	Centre for Addiction and Mental Health	Request for Proposal Jan 2004 Seed Funding
Oméga-3, santé cardiovasculaire et mentale : Les experts se prononcent! / <i>Omega-3, cardiovascular and mental health: The experts speak out!</i>	Chaire de l'Université Laval	Request for Proposal Sep 2004 Workshop & Conference Support
Programme intégré de soutien à la prise de décision en matière de PSN pour les femmes d'âge moyen vivant la transition ménopausique et celles ménopausées : étude des besoins / <i>Integrated program for supporting decision-making about NHPs for middle-aged women going through or having gone through menopause: requirement study</i>	Unité de recherche évaluative du centre Hospitalier Universitaire de Québec (CHUQ)	Request for Proposal Jan 2004 Seed Funding
Reporting Suspected Adverse Effects Associated with NHPs: Research Proposal Development	University of Toronto	Request for Proposal April 2005 Bridging the Gap
Symposium international sur les effets santé des fruits et légumes - FAV Health 2005 / <i>International Symposium on the Health Effects of Fruits and Vegetables - FAV Health 2005</i>	L'Institut des nutraceutiques et des aliments fonctionnels (INAF) - Université Laval	Request for Proposal May 2005 Conference Support
The use of Natural Health Products by Individuals with Type 2 Diabetes	University of Guelph	Request for Proposal Jan 2004 Seed Funding
Therapeutic Honey: Antibacterial activities of honey	Brock University	Request for Proposal April 2005 Bridging the Gap
Trial of Certain Herbal Combination Products such as Essiac to Ascertain its Effect in Women with Breast Cancer	Trial of Certain Herbal Combination Products such as Essiac to Ascertain its Effect in Women with Breast Cancer	Trial of Certain Herbal Combination Products such as Essiac to Ascertain its Effect in Women with Breast Cancer

Title of Project	Organization	Request for Proposal/Type of Award
US 2005 - Market For Functional Foods & NHPs - Regulatory & Marketing Perspective	US 2005 - Market For Functional Foods & NHPs - Regulatory & Marketing Perspective	US 2005 - Market For Functional Foods & NHPs - Regulatory & Marketing Perspective
Grant Dollars		
Interdisciplinary Capacity Enhancement Team (ICE) Grant Supporting Research in Complementary and Alternative Health Care (CACH)	University of Toronto	Interdisciplinary Capacity Enhancement Team (ICE) Grant Supporting Research in Complementary and Alternative Health Care (CACH)
NHPD/CIHR Partnership Program (training awards and operating grants):	NHPD/CIHR Partnership Program (training awards and operating grants):	NHPD/CIHR Partnership Program (training awards and operating grants):
<i>Antiviral activity and mechanism of vitamin A (retinoids) on measles virus and canine distemper virus in vitro and in vivo</i>	<i>The Research Institute of the McGill University Health Centre</i>	<i>Antiviral activity and mechanism of vitamin A (retinoids) on measles virus and canine distemper virus in vitro and in vivo</i>
Reliability and validity of guidelines for reports of controlled trials of botanical medicines	University of Toronto	Fellowship
Herbal Medicine Use and Older Adults: Social Networks and Information Exchange	University of Victoria	Doctoral Research Award
Conjugated linoleic acid and airway health in asthma	University of British Columbia	Operating Grant
Effect of the medicinal mushroom ganoderma lucidum on tumour cell activities	Sunnybrook and Women's College Health Sciences Centre	Operating Grant
Interactions of a standardized ginkgo biloba extract EGb 761 with pharmacological compounds, foods and NHPs	Institut national de la recherche scientifique (INRS) - Institut Armand Frappier	Operating Grant
Personnel Training Awards:		
Glucosamine sulphate in osteoarthritis of the knee: Long-term validity and cost effectiveness	University of Toronto	Fellowship
Functional characterization of vitamin-D and retinoid signalling in osteoblast differentiation	University of Western Ontario	Fellowship
Study of the mechanisms controlling the myeloid expression of the human NRAMPI gene in phagocytes: Transcriptional activation in response to the differentiation induced by vitamin D (model HL-60) and disturbances during infection by intracellular pathogens	Institut national de la recherche scientifique (INRS) - Institut Armand Frappier	Fellowship
Rigorous Scientific Evaluation of Selected Anti-diabetic Plants: Towards an Alternative Therapy for Diabetes in the Cree of Northern Quebec	Université de Montréal	NHPD/CIHR Grant
Study of Echinacea in Children with Upper Respiratory Tract Infections	University of Alberta	NHPD/CIHR Grant

Title of Project	Organization	Request for Proposal/Type of Award
Operating Funds		
Biodiversity & Health Symposium 2003.	Tropical Conservancy Council	NA
Canadian Botanicals Research Project – Microbiological Component	University of Ottawa Centre for Research in Biopharmaceuticals & Biotechnology	
Coordination of NHP Research in Canada	Mage Consulting	
Developing Collaboration Among Researchers and Research Users in Functional Foods and Natural Health Products	Advanced Foods and Materials Network (AFMNet)	
Essential Fatty Acids Discussion Paper	NutriTech Consulting	
Information for Decision-making Health Law and Ethics	Health Law Institute, University of Alberta	
Invitational workshop on Complementary Alternative Medicine (CAM) in Undergraduate Medical Education (UME)	University of Calgary, Dept of Community Health Sciences	
Legislative and Literature Review of Natural Health Product (NHP) Regulations for Canada's Primary NHP Trading Partners	JHR Toxicology	
Literacy Amongst Complementary and Alternative Health Care (CAHC) Practitioners Phase I and Phase II	Centennial College, Toronto	
Natural Health Products Directorate (NHPD) Consultation on Fatty Acids and Essential Fatty Acids (EFAs)	NutriTech Consulting	
Natural Health Products Directorate Consultation with Research Funding Agencies	Contract Theodore de Bruyn	NA
Perspectives on Natural Health Products: A Collection of papers from stakeholder consultation reports 2001-2002	Contract Publication	
Probiotics Discussion Paper	NutriTech Consulting	
Research Priority Setting Consultation on Homeopathic Medicine in Canada: An Invitational Roundtable	Trish Dryden	
TCM "Preparatory" Meeting	Luimandale Consulting	
The Natural Health Products Research Society of Canada's (NHPRSC) Natural Health Products Research Conference	Natural Health Products Research Society of Canada	
WHO's final Consultation on Safety Monitoring of Herbal Medicines	Department of Technical Cooperation for Essential Drugs and Traditional Medicine World Health Organization	
Workshop Modules and Practical Guides	Canadian AIDS Treatment and Information Exchange (CATIE)	

Appendix E: Recommendations from the Internal Panel Discussion

Panel participants expressed the sentiment that the NHPRP has done an excellent job to date. When asked to develop recommendations for the NHPRP based on their understanding of the program's activities and results, participants noted the following:

- **Increase consultations to identify directions for future research.** In particular, consult with the research community and with the public.
- **More focused rather than large range of funding initiatives.** It might be time to focus research funding in an effort to increase cost-effectiveness and to further build the credibility, importance and maturity of NHP research in the larger community. More focused funding may also help to “raise the bar” of the research and thus, help to improve Health Canada's reputation for participating in and promoting projects that are seen as credible. Suggestions included focusing by team, by year, or by the NHPRP's current interest topic. It was also suggested that the NHPRP have different categories of funding, e.g., large amounts of funding to large projects, smaller amounts to some smaller conferences, etc.
- **Increase collaborations with other funding organizations.** To increase the cost effectiveness of the projects to be funded, the NHPRP should collaborate with several funding organizations with similar objectives and projects [i.e., collaborate with “like” funders such as Agriculture and Agri-Food Canada (AAFC)].
- **Educate health professionals.** It was recommended that the NHPRP improve knowledge transfer with health professionals (e.g., physicians and pharmacists) regarding the *NHP Regulations*. This could perhaps be done through medical school curriculum and the education of existing professionals and may overlap with communicating the NHP research findings.
- **Develop a dissemination plan for the NHP research findings.** The findings should be disseminated around the world and, in particular, to NHPD staff, industries, health professionals, other NHP researchers, and the public to increase awareness of those initiatives and stimulate interest in this work. The findings can perhaps be disseminated through a central database model similar to a Clinical Trial Registry. Utilize technology (e.g., videoconferencing) for some education, networking, collaborating, etc. Give prominence to NHPRP research findings (panel participants felt that this is currently limited). Summarize NHPRP research findings in newsletters that are internal to the NHPD and have NHPD staff write summaries of their conference experiences and include these in an NHPD newsletter.
- **Obtain feedback from funding recipients.** Assess the extent to which, for example, funding levels and timing, application requirements and procedures are appropriate based on feedback from funding recipients. In addition, assess whether there were barriers to accessing NHP funding.

Appendix F: Recommendations from the Expert Panel Discussion

Building NHP research capacity

Recommendations:

1. Facilitate “research capacity” within Complementary and Alternative Medicine (CAM) practitioner groups (e.g., how to design a study; how to access funding; how to assess safety/efficacy of their NHP-related practices). This may involve, for example:
 - a. Salary support, i.e., fellowships for graduate training
 - b. Bridge support to the Canadian Institutes of Health Research (CIHR)
 - c. Mandating involvement of Complementary and Alternative Medicine (CAM) practitioners in NHPRP funded projects
2. Enhance awareness of NHPRP among key NHP stakeholders and the general public [e.g., via new and continued partnership/collaboration with practitioner organizations, industry organizations, the Canadian Interdisciplinary Network for Complementary and Alternative Medicine (INCAM) Research, the National Centre for Complementary and Alternative Medicine (NCCAM), the Cancer and Complementary/Alternative Medicine (CCAM) Research Team, and the NHP Research Society of Canada (NHPRSC), etc. and by improving the visibility of the NHPRP in the NHPD website]
3. Apply for additional funding to continue the NHPRP for at least 10 additional years. In the short-term (i.e., next two years), leverage additional funding via collaborating with the Canadian Institutes of Health Research (CIHR), the National Cancer Institute of Canada (NCIC), the Social Sciences and Humanities Research Council of Canada (SSHRC), the Natural Sciences and Engineering Research Council of Canada (NSERC), and not-for-profit organizations.
4. Continue to support existing, senior researchers so as to provide the mentors needed by more junior researchers

Supporting the conduct of NHP research

Recommendations for the short-term (next two years):

1. Fund more hard science:
 - a. By leveraging partnerships
 - b. That trains the next generation of NHP researchers
 - c. To inform product quality
 - d. In the areas of analytical and pre-clinical research
2. Encourage:
 - a. Constructing interdisciplinary teams
 - b. Leveraging/creating funding opportunities

Recommendations for the long-term:

1. Over the next five years, obtain additional money that will ensure sustainability and enhance partnerships
2. Support research that will produce results to inform the pre-market approval process. Start by identifying the knowledge gap through evidence-based reviews and use the information to build a clinical research program.

Developing partnerships and community infrastructure

Recommendations:

1. Keep improving at identifying the “right” practitioner representatives and “right” balance of groups at consultation and community meetings
2. Further develop credible national/regional/international researcher partnerships with funding agencies, practitioner organizations, health condition groups, consumer groups, industry, provincial government
3. Develop a database for researchers, practitioners and funders which indicates areas of expertise and contact information for researchers and practitioners as well as funding opportunities. An online searchable database has already been developed through the Canadian Interdisciplinary Network for Complementary and Alternative Medicine (INCAM) Research and the NHPRP could perhaps focus on its further development and consolidation.

Enhancing knowledge transfer

Recommendations for the short-term (next two years):

1. Develop a functional definition and strategic plan for knowledge transfer by:
 - a. Building on and/or adopting existing frameworks
 - b. Determining “what is evidence on NHPs?”
 - c. Articulating value-added role and decision criteria
 - d. Determining resource requirement, particularly with respect to the use of the Internet as a knowledge transfer tool
2. Continue to build on current strengths in knowledge transfer, for example by:
 - a. Linking stakeholders and networking
 - b. Sustaining close relationships with researchers and decision makers through a small, dedicated group of staff
 - c. Develop mechanism(s) to support NHP research synthesis and dissemination by exploring existing funding models [e.g., CIHR, Canadian Health Services Research Foundation (CHSRF)]

Recommendation for the long-term:

1. Facilitate dissemination of credible evidence-based information on NHPs via the Internet or other communication resources and tools

Other general observations and recommended actions

1. Panel participants commended the NHPRP on its tremendous success to date, particularly in setting up a new research program with a new structure, addressing a wide breadth of topics through research projects, facilitating a multidisciplinary approach to NHP research, making funding more accessible to research teams that include participants who are working outside of university settings (an important achievement that is not currently the norm in the United States), and developing a variety of partnerships that have helped to leverage NHP research funding and increase the credibility of NHP research.
2. There was a strong feeling articulated by panel participants that the one million dollar (\$1 M) annual budget for NHP research be increased at least tenfold in order to continue to build research capacity in the NHP sector. The momentum achieved to date by the work done through the NHPRP is significant and the need is urgent that this momentum be grown. Panel participants also expressed that the current level of NHP research funding is low given that, generally speaking, relatively little is known about NHPs and their safe and effective use and a large number of Canadians use NHPs. Many participants also indicated that the partnership between the NHPRP and the CIHR should continue around the distribution of some of the research funds.
3. Panel participants also expressed the need to more directly focus the NHPRP on enabling Canadian consumers to make more informed decisions regarding the use of NHPs. In particular, this would take the form of supporting research related to the safe and effective use of NHPs, disseminating information about the type of research that is underway, and transferring the resulting knowledge to consumers and other stakeholder groups.
4. Panel participants were unsure about the best approach to integrate knowledge transfer funding with funding to conduct NHP research (i.e., knowledge transfer as a component of projects to disseminate the findings from a specific investigation, versus knowledge transfer as a project unto itself) but provided suggestions regarding the approaches currently undertaken by other organizations.
5. Panel participants were unable to comment on the perceived quality of existing partnerships between the NHPRP and other organizations, in part, because they did not feel that they had enough information about the desired partnership outcomes for the NHPRP or about what constitutes an “effective” or “successful” partnership. That said, one participant described an existing report that referenced “the partnership between Health Canada and the CIHR as an example of a great partnership”. There was further discussion regarding the role of industry in partnership with the NHPRP. In particular, participants wondered to what extent partnership with industry could represent a conflict of interest, versus healthy cooperation. It was noted that in contrast to the system in the United States, which was perceived as adversarial, that there “seems to be a positive cooperation between government and industry in Canada”. It was further noted that the involvement of industry is important to support implementation of the *NHP Regulations* – to help assess what is feasible, etcetera.

6. Panel participants noted that the NHPRP does not duplicate efforts such as those by the Canadian Health Network (CHN) which also works to support people in making good health decisions, because the CHN cannot provide information about treating disease, for example.

Appendix G: Intended vs. Actual Impacts in Each Key Program Area

Table G1. A comparison of the intended vs. actual impact in building research capacity

Expected outcomes & guidance from the literature	Program strengths, weaknesses, opportunities and threats
<p>The NHPRP hopes to increase the:</p> <ul style="list-style-type: none"> ▪ Number of NHP researchers; ▪ Number of NHP research training opportunities; ▪ Awareness of NHP issues and challenges among students and practitioners; and ▪ Cooperation and interoperability between conventional health care and CAHC/CAM <p>From the literature:</p> <p>The capacity to undertake high quality and effective research can have a variety of different meanings but typically includes physical infrastructure, operational budgets, institutional mechanisms, people, skills, and motivation (DANIDA, 2000 in ODI, 2002).</p> <p>There is unclear evidence around the issue of whether – when trying to build research capacity – research have practical and policy relevance, or be of a fundamental nature (Killick, 2001 in ODI, 2002).</p> <p>Due to increasing research related costs, research funders now tend to fund regions and institutions with the highest concentration of talent in order to ensure impact and to optimize their investment – as opposed to scattering funding across a wide range of individual researchers. The result has been an increasing concentration of research funding among</p>	<p>Key strengths:</p> <ul style="list-style-type: none"> ▪ Increased networking (e.g., INCAM, NHPRSC conference) ▪ Research/project funding to a diversity of individuals, not only those who are affiliated with universities ▪ Increased research capacity of CAM practitioners ▪ Increased credibility and legitimacy of NHP research ▪ The impact of networking and relationship building. For example: <p><i>“What we’ve done over the last year has helped to form a good base for us to move forward and hopefully get additional multi-year funding. We recognized the limitations of what could be done in a year and are looking for a longer-term investment. We’ve put together a group of people who otherwise would not have been able to work together. Right now, there’s no educational program to train people in multi-disciplinary approaches to NHP research.”</i></p> <p>Key weaknesses:</p> <ul style="list-style-type: none"> ▪ Enhancing awareness of the NHPRP ▪ Securing additional funding for efforts aimed at building research capacity ▪ Helping the development of networks for homeopathy, naturopathy, essential oils/aromatherapy, and Traditional Chinese Medicine (TCM)

Table G1. A comparison of the intended vs. actual impact in building research capacity

Expected outcomes & guidance from the literature	Program strengths, weaknesses, opportunities and threats
<p>a shrinking number of leading regions (Mulholland Consulting, 2004).</p> <p>The World Bank undertook efforts to build research capacity by first establishing the networks and providing support to individual researchers through competitive research grants. "Once established, the focus will shift to institution-building, knowledge-sharing, and bringing researchers and policy makers together" (ODI, 2002).</p> <p>A recent study of 49 organizations involved in building research capacity revealed that: most are involved in networking, training, research partnerships, institution-building, their own research, providing funding for research and capacity-building to others, and policy development.</p> <p>"Research partnerships or twinning arrangements are generally regarded as effective if they are genuine, long-term, equitable relationships....There has been little analysis to date of the effectiveness of other forms of research capacity building" (ODI, 2002).</p>	<p>Key opportunities:</p> <ul style="list-style-type: none"> ▪ Encourage the involvement of CAM practitioners in research ▪ Create a practical bridge to the CIHR (e.g., how to apply and be successful; create pilot projects template to/with CIHR) ▪ Develop an international centre of NHP research <p>Key threats:</p> <ul style="list-style-type: none"> ▪ Not enough money to make a <u>real</u> difference (need an international contribution) ▪ The need to address the issue of NHPs vs. CAM <u>practice</u>/whole systems research (need to differentiate these appropriately) ▪ Still many are unaware that the NHPRP exists (both the public and key NHP stakeholders) ▪ The complexity of the situation (e.g., the availability of NHP products; disparaging of NHPs and practice; academic bias against NHP research)

Table G2. A comparison of the intended vs. actual impact in supporting the conduct of research

Expected outcomes & guidance from the literature	Program strengths, weaknesses, opportunities and threats
<p>The NHPRP hopes to increase the:</p> <ul style="list-style-type: none"> ▪ Knowledge of NHPs based on research conducted through partnerships or co-sponsorship; 	<p>Key strengths:</p> <ul style="list-style-type: none"> ▪ Training the next generation of peer reviewers, researchers, regulators ▪ Capitalizing on the CIHR program tools and leveraging funds for strategic research

Table G2. A comparison of the intended vs. actual impact in supporting the conduct of research

Expected outcomes & guidance from the literature	Program strengths, weaknesses, opportunities and threats
<p>and</p> <ul style="list-style-type: none"> ▪ Understanding of knowledge gaps and research priorities 	<ul style="list-style-type: none"> ▪ Addressing a broad content and breadth of NHP topics ▪ Engaging many practitioners/communities and researchers ▪ The majority of NHPRP funded researchers who were interviewed ($n = 18$; 72%) reported that the current NHPRP project had contributed to (or would contribute to) the development of future research or project activities. Some participants emphasized the role of team building that had been made possible by the NHPRP and how this would be helpful in future projects. <p>Key weaknesses:</p> <ul style="list-style-type: none"> ▪ Securing additional funding to support NHP research in a strategic manner ▪ Funding an internal NHPD research program in science <p>Key opportunities:</p> <ul style="list-style-type: none"> ▪ Create opportunities for consumer organizations to conduct conferences (outgoing public education) ▪ Create an opportunity for an NHP research network to support “cross pollination” of researchers, stakeholders and consumers ▪ Create and develop international opportunities ▪ Creating a more encouraging application process for NHPRP funds (Among the remaining interview participants, 28% reported that the process was encouraging and 20% reported that the process was not encouraging to those outside the academic and scientific research communities.) <p>Key threats:</p> <ul style="list-style-type: none"> ▪ The challenge of adapting research methodology to less conventional modalities ▪ Limited money in short- and long-term

Table G3. A comparison of the intended vs. actual impact in developing partnerships and community infrastructure

Expected outcomes & guidance from the literature	Program strengths, weaknesses, opportunities and threats
<p>The NHPRP hopes to:</p> <ul style="list-style-type: none"> ▪ Enhance understanding of NHP research issues; ▪ Expand the role and involvement of voluntary and not-for-profit organizations in NHP research; and ▪ Sharpen the focus on key areas of interest and concern across different sectors. <p>From the literature:</p> <p>Some research has demonstrated that the following elements – which are mutually dependent – effect the successful development and maintenance of partnerships: partner characteristics, external factors, communication, operations, and the reasons for partnering (Scott, 2000; Scott & Thurston, 1997). If any of these key pieces are missing, it is very likely that the partnership will fail.</p> <p>Furthermore, within each of these elements, a number of issues may arise. For example, the desire of one partner to maintain a strong organizational identity may impact their ability to fully participate in the partnership. Further</p>	<p>Key strengths:</p> <ul style="list-style-type: none"> ▪ Identifying the “right” practitioner representatives and the “right” balance of groups at consultation meetings ▪ Leveraging money and crystallizing funding/interest from other potential funders ▪ Achieving a level of international recognition ▪ Increased networking and partnerships (both formal and informal connections). The regulator (NHPD) is well positioned to facilitate networks. <p>Key weaknesses:</p> <ul style="list-style-type: none"> ▪ No “database” <u>for</u> researchers and <u>for</u> practitioners <u>for</u> collaborative opportunities and <u>about</u> funders ▪ The broad range of “interested” parties (too many people to invite to all the meetings) <p>Key opportunities:</p> <ul style="list-style-type: none"> ▪ Partner with: <ul style="list-style-type: none"> - Funding agencies - Health conditions groups (consumers) - Provincial government - International organizations - Other CAM groups ▪ Make partnerships a tool for addressing safety and efficacy – not by funding groups to initiate and develop a partnership – but by funding research in the area of safety and efficacy that will be conducted <u>through</u> a partnership effort (e.g., INCAM)

Table G3. A comparison of the intended vs. actual impact in developing partnerships and community infrastructure	
Expected outcomes & guidance from the literature	Program strengths, weaknesses, opportunities and threats
complicating the issue around networking and partnership building is that volunteer health organizations may not have the resources to become involved in activities related to NHP research activities.	<p>Key threats:</p> <ul style="list-style-type: none"> ▪ Conflicting aims of various partners ▪ Perception on the part of partners of a lack of meaningful input and decision-making ▪ Limited money to run the NHPRP

Table G4. A comparison of the intended vs. actual impact in enhancing knowledge transfer	
Expected outcomes & guidance from the literature	Program strengths, weaknesses, opportunities and threats
<p>The NHPRP hopes to increase:</p> <ul style="list-style-type: none"> ▪ Sharing across sectors of NHP information; ▪ Knowledge from literature reviews to inform research priorities and the development of the regulatory framework; and ▪ Accessibility of information on NHP research to stakeholders, including consumers <p>From the literature:</p> <p>Since the early 1990s, a number of studies have been undertaken in an attempt to demonstrate the benefits from publicly funded research (e.g., Buxton et al., 1999; Gastel, 2001) and to understand the relationships between health</p>	<p>Key strengths:</p> <ul style="list-style-type: none"> ▪ Conference sponsorship and networking (e.g., NHPRSC) ▪ Enabling close relationships between the small, dedicated group at NHPRP and NHP researchers and decision-makers ▪ Enhancing awareness of research for NHP practitioners ▪ Researchers are making significant progress in disseminating findings from their projects both within and outside the NHP research community. <p>Key weaknesses:</p> <ul style="list-style-type: none"> ▪ Securing additional funds and expertise within the NHPRP ▪ Ensuring that the program is funding research that is answering consumer needs

Table G4. A comparison of the intended vs. actual impact in enhancing knowledge transfer

Expected outcomes & guidance from the literature	Program strengths, weaknesses, opportunities and threats
<p>research and health policy (e.g., Gerhardus et al., n. d.). Generally speaking, the transfer of knowledge (beyond the dissemination of research findings) from health research to practice and policy is often limited. Specifically, researchers are not always able to disseminate their findings among their peers (via conferences and in peer-reviewed journals) yet alone to decision-makers and health practitioners.</p> <p>Studies have shown that this passive form of knowledge dissemination is not enough to facilitate its uptake. In fact, it appears that the transfer of research based information to practitioners requires attention to four critical details: the source, the content, the method, and the audience (Barwick et al., 2005). It is clear that the transfer of new knowledge is more successful when there is active collaboration and partnerships with all stakeholders from the beginning (Barwick et al., 2005), such as involving decision-makers and users of health information in the design and implementation of research projects. Furthermore, leadership, power, authority and resistance to change – from the system, the leaders and the practitioners – must be addressed in the knowledge transfer process.</p>	<p>Key opportunities:</p> <ul style="list-style-type: none"> ▪ Continue to develop a variety of partnerships ▪ Facilitate inter-professional dialogue and knowledge transfer re: NHPs ▪ Facilitate a climate of evidence-based practice ▪ Provide a rating of knowledge transfer resources (through the NHPD) ▪ Develop an international dissemination plan for the NHPRP research/project findings that: includes a central database model similar to the Clinical Trial Registry; includes the use of technology for education, networking, and collaborating; and highlights the prominence of NHPRP/NHPD work. <p>Key threats:</p> <ul style="list-style-type: none"> ▪ A lack of credible/reliable information available on NHPs (available information is often conflicting) ▪ Gap between the holders of public trust (conventional health care practitioners) and holders of NHP knowledge (non-conventional health practitioners)

Appendix H: Intended vs. Actual Impact on Program Beneficiaries

Table H1. A comparison of the intended vs. actual impact on the research community	
Intended impact	Notable progress to date
<p>Research community: NHPRP funding will help qualified Canadian investigators to develop and conduct research projects related to NHPs; potential new researchers to acquire knowledge and skills through subsidized education and training; and academic and research institutions to develop infrastructure related to NHP research.</p>	<ul style="list-style-type: none"> ▪ The NHP community is now better able to access research funding through the CIHR, due to increased awareness of these funding opportunities and success in obtaining CIHR funding for NHP research (i.e., there has been a culture change). ▪ Training opportunities have been created through INCAM (e.g., doctoral training awards). ▪ The NHPRP is recognized as having helped to increase the credibility and legitimacy of NHP research (for example, by securing funding through Health Canada and the CIHR).

Table H2. A comparison of the intended vs. actual impact on industry	
Intended impact	Notable progress to date
<p>Industry: Stakeholders in industry will benefit from the increased availability of NHP researchers, and from opportunities to obtain and exchange research information or to collaborate with other organizations, including the NHPD.</p>	<ul style="list-style-type: none"> ▪ Pharmaceutical industries are one of the many audiences who have been reached through the dissemination of findings from NHPRP funded projects, thus contributing to the exchange of research information. ▪ Stakeholder consultations have been conducted with a number of groups, including industry, on a number of issues to develop and refine NHP research priorities (i.e., Consultation on Homeopathic Medicine in Canada, January 2005; Collaboration Workshop on Functional Foods, February 2005; and a TCM meeting and background paper on research capacity in TCM research). ▪ Industry representatives: <ul style="list-style-type: none"> ○ Participated in 11 NHPD supported conferences and workshops; ○ Were members of advisory groups or steering committees for 5 NHPD supported research related projects; and ○ Were consulted in the preparation of 3 background papers.

Table H3. A comparison of the intended vs. actual impact on those involved with the NHP regulatory framework

Intended impact	Notable progress to date
<p>Individuals or entities involved with the development of the regulatory framework: Research based evidence generated by the NHPRP initiatives will better enable NHPD to develop an effective and appropriate regulatory framework for NHPs.</p>	<ul style="list-style-type: none"> ▪ The NHPRP has funded 16 projects in research in key areas that support the regulatory role, namely, NHP safety, efficacy, and quality. ▪ Consultations such as the Invitational Consultation on Essential Fatty Acids (EFAs) and Fatty Acids (FAs) that identify issues, priorities, and gaps in knowledge, as well as reach consensus on technical regulatory issues (i.e., 3 monographs were revised and/or developed in that same consultation) help NHPD staff to put the <i>NHP Regulations</i> into practice.

Table H4. A comparison of the intended vs. actual impact on voluntary and not-for-profit organizations

Intended impact	Notable progress to date
<p>Voluntary and not-for-profit organizations: These organizations will receive financial support for contributing to meaningful activities related to NHP research.</p>	<ul style="list-style-type: none"> ▪ Voluntary and not-for-profit organizations have been directly funded for a total of 7 projects to date.

Table H5. A comparison of the intended vs. actual impact on health care professionals

Intended impact	Notable progress to date
<p>Health Care Professionals: Of fundamental importance to health care professionals, research will enhance the evidence-base for medicinal use of NHPs. Furthermore, efforts to integrate the work of conventional and complementary health care practitioners and information retrieval specialists will benefit health care professionals and their allied institutions.</p>	<ul style="list-style-type: none"> ▪ Numerous projects have been funded in the areas of NHP use in CAHC/CAM and TCM and in linking practitioners in these areas with those in conventional medicine. ▪ Curriculum has been developed in NHPs for integration into Canadian Undergraduate Medical Education programs. ▪ A number of NHPs have been examined to date through the NHPRP funded projects including, for example, traditional medicine products and homeopathic medicines.

Table H6. A comparison of the intended vs. actual impact on the Canadian public	
Intended impact	Notable progress to date
<p>Canadian Public: The public will be the ultimate beneficiaries of research and the diffusion of information that relates to the safety and efficacy of NHPs.</p>	<ul style="list-style-type: none"> ▪ The public was involved in initial consultations to set NHP research priorities. ▪ Almost one-third (27%) of the projects funded to date were in the area of NHP product quality, safety and efficacy, areas particularly important to enable consumers to make informed decisions about the use of NHPs. ▪ The research program facilitated the dissemination of research information through sponsored conferences. ▪ A total of 6 projects were directly aimed at improving informed choices by consumers. Examples include practical guides for use of NHPs in HIV/AIDS and a study of the requirements for supporting decision-making about the use of NHPs for women of menopausal age.

Appendix I: List of Potential NHPRP Partners and Sources of NHP Research Funding

List of potential NHPRP partners and sources of NHP research funding based on feedback from NHPRP funded researchers and expert panel participants:

- Funding agencies [e.g., Fonds de recherche en santé du Québec (FRSQ), Sick Kids, CIHR, Michael Smith Foundation, Ontario HIV Treatment Network (OHTN), Lotte and John Hecht Memorial Foundation investigating and supporting Complementary and Alternative Medicine (CAM) in the treatment of cancer]
- Health conditions groups (consumers) (e.g., Canadian Arthritis Network, cancer agencies)
- Provincial government
- Other federal departments [e.g., Natural Sciences and Engineering Research Council of Canada (NSERC), National Research Council of Canada (NRC), Agriculture and Agri-Food Canada (AAFC)]
- International [e.g., the National Centre for Complementary and Alternative Medicine (NCCAM), the U.S. National Institutes of Health (NIH)]
- Other Complementary and Alternative Medicine (CAM) groups (e.g., INCAM)
- National and regional foundations (e.g., Sick Kids Foundation)
- Private foundations (e.g., Wellness West)
- Private donors
- Industry associations
- National and regional practitioner organizations
- National and regional researchers
- Academics and academic institutions (e.g., University of Exeter)
- Research institutes
- Chinese Medicine research groups

In addition, expert panel participants suggested that the NHPRP has a prime opportunity to:

- Create opportunities for consumer organizations to conduct conferences (outgoing public education);

- Create an opportunity for an NHP research network to support “cross pollination” of researchers, stakeholders and consumers;
- Create and develop international opportunities; and
- Develop partnerships with disease-specific funding organizations.

Data Collection Tools

List of Documents Reviewed for the Formative Evaluation (p. 88)

Funding Recipient Interview Protocol (p. 91)

Internal Panel Key Question Areas (p. 97)

Expert Panel Key Question Areas (p. 98)

Selected Literature Review Protocol (p. 99)

List of Documents Reviewed for the Formative Evaluation

A total of 83 documents were reviewed for the formative evaluation, as indicated below:

Background Documents

1. Treasury Board Submission Natural Health Products Research Program TB #829979; Annex A and Annex B; Results-Based Management and Accountability Framework; Risk-Based Accountability Framework (RBAF); Annex E (53 recommendations)
2. Natural Health Products: A New Vision. Report of the Standing Committee on Health
3. Natural Health Products in Canada: A History
4. List of projects funded through Grants and Contributions
5. List of projects funded through Operating funds - directed research projects
6. Memorandum of Understanding with Natural Health Products Directorate (Health Canada) and the Canadian Institutes of Health Research for the NHPD/CIHR Partnership Program.
7. Memorandum of Understanding with Natural Health Products Directorate (Health Canada); CIHR Institute of Musculoskeletal Health and Arthritis; CIHR Institute of Infection and Immunity; and CIHR Institute of Health Services and Policy Research in support of the Interdisciplinary Capacity Enhancement (ICE) Teams Grant Program application in Complementary and Alternative Health Care (CAHC).
8. Memorandum of Understanding with Natural Health Products Directorate (Health Canada) and the Canadian Institutes of Health Research - Institute of Aboriginal Peoples' Health to support the New Emerging Team (NET) that is conducting research in the area of Diabetes with the Cree of Northern Quebec.
9. Memorandum of Understanding with Natural Health Products Directorate (Health Canada) and the CIHR Randomized Controlled Trials Unit to support the pre-clinical work in preparation for the Clinical Pharmacology component of the research being conducted on Echinacea in children with upper respiratory tract infections.
10. Memorandum of Understanding between the Office of Natural Health Products and the Canadian Institutes of Health Research (CIHR) for the Health Research Partnership Fund
11. NHPRP Request for Proposals Announcements
12. NHPRP Request for Proposals Announcements: Application Guide, Screening form, Scoring sheet
13. CIHR request for Applications Interdisciplinary Capacity Enhancement (ICE) Teams Grant Program
14. CIHR request for Applications New Emerging Team Request for Applications
15. CIHR NHPD/CIHR Partnership Program – Announcements
16. Natural Health Products Research Priority-Setting Conference in Halifax, Nova Scotia, November 6-8, 1999
17. Health Promotion - Perspectives on Natural Health Products - A collection of reports from stakeholder consultations, 2001-2002
18. NHP Regulations Canada Gazette II
19. Strategic Plan 2004-07 for Health Canada's Health Products and Food Branch. Serving Canadians - Now and Into the Future
20. External Environmental Scan 2005
21. Internal Environmental Scan 2005
22. Baseline Natural Health Products Survey Among Consumers 2005
23. Benchmark Survey of Natural Health Products Directorate Stakeholders 2005

24. NHPD Monthly Communiqués

Proposals and status reports

1. Natural Health Products Directorate (NHPD) Consultation on Fatty Acids (FA) and Essential Fatty Acids (EFAs)
2. Rigorous scientific evaluation of selected anti-diabetic plants: Towards an alternative therapy for diabetes in the Cree of Northern Québec
3. Complementary and alternative health care (CAHC) research team
4. Conjugated linoleic acid and airway health in asthma
5. Effect of the medicinal mushroom ganoderma lucidum on tumour cell activities
6. Interactions of a standardized ginkgo biloba extract EGb 761 with pharmacological compounds, foods and NHPs
7. Reliability and validity of guidelines for reports of controlled trials of botanical medicines
8. Antiviral activity and mechanisms of vitamin A (retinoids) on measles virus and canine distemper virus in vitro and in vivo
9. Herbal medicine use and older adults: Social networks and information exchange
10. Development of a Network for Research of Natural Health Products in HIV
11. Natural Health Products in Primary Psychotic Disorders: Use and Attitudes
12. Establishing Canadian Network for NHP in Pregnancy and Lactation
13. Expanding the Network - Inclusion of conventional and CAHC health practitioners as participants in the knowledge exchange and transfer information on NHPs
14. Feasibility Study - Applying Metabolomics to the Authentication and Quality Control of Natural Health Products (NHPs)
15. Modules d'auto-apprentissage à l'intention des praticiens alternatifs: lecture critique et gestion de l'information sur les PSN
16. Programme intégré de soutien à la prise de décision en matière de PSN pour les femmes d'âge moyen vivant la transition ménopausique et celles ménopausées: étude des besoins
17. The use of Natural Health Products by Individuals with Type 2 Diabetes
18. Trial of Essiac to Ascertain its Effect in Women with Breast Cancer
19. US 2005 - Market for Functional Foods & NHPs - Regulatory & Marketing Perspective
20. Symposium international sur les effets santé des fruits et légumes - FAV Health 2005
21. Natural Health Product Research Society of Canada Workshop
22. Natural Health Product Research Society of Canada Conference & Tradeshow
23. Characterization of bioactive potency towards cancer cell cytotoxicity by triterpenoid containing North American medicinal plants
24. Feasibility Study - Applying Metabolomics to the Authentication and Quality Control of Natural Health Products (NHPs)
25. Developing a Strategic Business Plan for the Natural Health Product Research Society of Canada
26. Fingerprinting Canadian Prairie Safflower and comparison with Flos carthami
27. A Proposal to Support the Pilot Project of NHPs Analytical Laboratory Proficiency Program
28. Reporting Suspected Adverse Effects Associated with NHPs: Research Proposal Development
29. Therapeutic Honey: Antibacterial activities of honey
30. Development of Good Wildcrafting Practice Guidelines and Wildcrafter Certification for the Harvesting of Wild Medicinal Botanicals
31. Capacity-Building & Effective Knowledge Transfer - Developing a NHPs Curriculum for Integration into Canadian Undergraduate Medical Education Programs
32. Integrating TCM into Clinical Practice

33. Développement d'une expertise de pointe et de méthodes efficaces et rigoureuses en matière d'innocuité, qualité et efficacité des probiotiques
34. 2nd National Growing an Industry: Linking Agriculture and Health from the Consumer to the Field - Canada's Place in the Herb, Spice and NHPs Industry

Completed reports

1. 2nd Annual Natural Health Product Research Conference
2. Native Plants & First Nations: How can we create research that is equitable, sustainable and beneficial to all?
3. Omega-3, cardiovascular and mental health: The experts speak out!
4. First Annual Forum on Complementary and Alternative Health Care and Paediatrics
5. Enabling NHP Researchers: Building a Clinical Epidemiology Infrastructure
6. Study of Echinacea in children with upper respiratory tract infections (SECURTI)
7. Glucosamine sulphate in osteoarthritis of the knee: Long-term validity and cost effectiveness
8. Functional characterization of vitamin-D and retinoid signalling in osteoblast differentiation
9. Study of the mechanisms controlling the myeloid expression of the human NRAMP1 gene in phagocytes: Transcriptional activation in response to the differentiation induced by vitamin D (model HL-60) and disturbances during infection by intracellular pathogens
10. Developing Collaboration Among Researchers and Research Users in Functional Foods and Natural Health Products
11. Coordination of NHP Research in Canada
12. Essential Fatty Acids Discussion Paper
13. Probiotics Discussion Paper
14. TCM "Preparatory" Meeting
15. Research Priority Setting Consultation on Homeopathic Medicine in Canada: An Invitational Roundtable
16. The Natural Health Products Research Society of Canada's (NHPRSC) Natural Health Products Research Conference Inaugural Conference
17. Natural Health Products Directorate Consultation with Research Funding Agencies
18. Developing A National Vision for Complementary Alternative Medicine (CAM) in Undergraduate Medical Education (UME)
19. Literacy Amongst Complementary and Alternative Health Care (CAHC) Practitioners Phase I and Phase II
20. Canadian AIDS Treatment and Information Exchange (CATIE) Practical Guides
21. WHO Pharmacovigilance – Report
22. Biodiversity & Health Symposium 2003 – Proceedings
23. Canadian Botanical Research Project
24. International regulations of Natural Health Products – Report
25. Information for Decision-making Health Law and Ethics – Report

Funding Recipient Interview Protocol

FORMATIVE EVALUATION OF THE NATURAL HEALTH PRODUCTS RESEARCH PROGRAM (NHPRP)

TELEPHONE INTERVIEWS WITH FUNDING RECIPIENTS

Note. Interview questions may need to be adapted depending on the project type and status. The following lists represent general lines of questioning across all types of NHPRP projects.

Some interviewees may have received funding for more than one project. Clarify project(s) at start of interview.

Proposed interview time is 30 – 60 minutes.

Interviewer probes are in italics.

Introduction

Panoptik Research and Consulting is conducting an evaluation of Health Canada's Natural Health Products Research Program (NHPRP). We are speaking with a number of groups in order to evaluate the program, including practitioners, industry, and consumer groups, as well as Health Canada staff and NHP researchers such as you.

As indicated in an e-mail that was recently sent to you, we would like to ask you a few questions about your NHPRP-funded project. Specifically, we would like to learn your views about the funding process, how the findings from your project may have been disseminated, and how your project may have already impacted the broader community, such as NHP research, industry, consumers and/or health practitioners. Your name was randomly sampled from our list of funded researchers.

This interview could take up to an hour. Participation in this interview is voluntary, and you do not have to answer questions that you choose not to. You are also free to withdraw from the interview at any time. We would appreciate and value your frank input, and assure you that any opinions expressed will not be attributed to a particular organization or individual without your express written permission. Findings will be shared in summary form only.

Do you have any questions for me?

Are you ready to begin?

Dissemination of Research Findings

The first few questions are about dissemination of your research findings. (Note: Ask ongoing projects if they have disseminated findings or if they have plans to do so, as indicated below.)

1. a) Have you or your project team members **presented** the findings from your NHPRP project at any conferences? Symposia? Meetings? Workshops? Have you distributed the findings within or outside your organization? *[If so, try to obtain detail on the type of presentation and to what type of audience (other NHP researchers, practitioners, policy makers, industry, etc)]*

b) Are any other presentations resulting from your project planned or anticipated? Please comment and provide detail.

2. a) Have the findings been **published**? [Note. This could include publications by you or others on your research team.] *[If so, try to obtain detail on the type of publication (peer-reviewed and non peer-reviewed journals, published abstracts, books, book chapters, reviews, editorials, reports, professional educational materials, public education materials (e.g., videos, brochures), etc]*

b) Are any other publications resulting from the NHPRP project planned? Please comment and provide detail.

3. a) What, if anything, has **hindered publication/dissemination** of the findings of this NHPRP project? *[e.g., Do not know how to disseminate findings beyond the research community, submission(s) rejected after peer review, insufficient time has passed since research was completed, no (or insufficient) funding to publish research]*

b) In what ways could dissemination of NHPRP research findings beyond the research community be improved?

c) In your experience, have you seen examples of research dissemination **beyond the research community** that the NHPRP could use? *(Get specific suggestions.)*

Sources of Project Funding

4. In order to understand the impact of NHPRP funding on your project, we need to know the full **scope of resources** applied to your project.
 - a) Did you receive any other funding for this project? *(If there were no other funding sources, skip to Q. 6)*
 - b) Approximately what percentage of your total project funding was from the NHPRP?
 - c) Which other funders provided you with resources?
5. a) If you **had not** received funding through the NHPRP initiative, where else might you have sought funding for your project? *[Canadian Institutes of Health Research (CIHR), Industrial Research Assistance Program (NRC-IRAP), National Sciences and Engineering Research Council (NSERC), Social Sciences and Humanities Research Council (SSHRC), Canadian Health Services Research Foundation (CHSRF), other federal program or department, provincial/territorial program or department, university, teaching hospital, medical research foundation, pharmaceutical company, non-governmental organization, don't know, would not have sought out other sources]*
 - b) Would your project have been initiated and/or completed without NHPRP funding? Please comment.

Project Team Composition

6. a) Was any member of your NHPRP project team (including yourself) a member of a stakeholder group **other than the NHP research community**? (e.g., health care professionals and their allied institutions, voluntary health organization, industry, etc) *(Note to interviewers. We are looking for examples of team members who might help to disseminate findings and/or link the research findings to people/organizations outside the research community.)*
 - b) What was their role in your NHPRP project?
7. Were any students, health professionals or community members **trained in conducting**

research as a result of this NHPRP project? (*What groups? How many?*)

Funding Process

8. How did you hear about the NHPRP?
9. How would you rate your satisfaction with the **scope and objectives** outlined in the RFPs? Were the scope and objectives clear? (Provide satisfaction rating scale)

1 = Very dissatisfied; 2 = Dissatisfied; 3 = Neither satisfied nor dissatisfied; 4 = Satisfied; 5 = Very satisfied
10. a) How would you rate your satisfaction with the **timing of the application due dates**? (Provide satisfaction rating scale)

b) With the **timing of the receipt of funding**? (Provide satisfaction rating scale)

c) With the **funding amount** provided by the NHPRP? (Provide satisfaction rating scale)
11. a) In your opinion, is the **funding process** encouraging NHP researchers/practitioners to apply for funding? In what ways? [*Is the current process welcoming to those who may not have traditional credentialing (e.g., Masters/Doctorates) but who are skilled in an area of NHP research? The "process" could include the funding announcements, the application requirements, the review process, the amount offered, the funding institutions, etc*]

b) How can this process be made **more encouraging**?
12. a) In your opinion, **is the review process fair**? In what ways?

b) In your opinion, was the **feedback you received on your proposal informative or useful**? In what ways? (e.g., *Did it help you to restructure your application? Did it clearly explain why you were or were not chosen? Will it help you with future applications?*)

13. Would you **apply for NHPRP funding again**? Please elaborate.

Research Outcomes

We'd also like to take this opportunity to ask you about any preliminary outcomes from your NHPRP project.

14. a) First, at the time you applied for your NHPRP funding, who were the **intended users or targets** of the findings?

b) Do you know if the findings reached those people? If so, do you know how they used the findings?

15. Have any of the following **future research/research use activities** resulted from your NHPRP project? *[e.g., other research (conducted by you and/or team members) that builds on your NHPRP project; research (conducted by those not on the research team) that builds on your NHPRP project; leveraging of additional funding to conduct further research; journal citations of your work; your NHPRP project findings summarized in a source such as online medical resources, newsletters etc.; your NHPRP project findings highlighted in the media]*
16. Has participation in the research led to (or is it expected to lead to) **additional qualifications** (e.g., post-grad qualification) for any members of your NHPRP project team?
17. Are you aware of any ways in which your NHPRP project findings have been **incorporated or taken into account by decision makers, policy makers**, etc? Examples? *[e.g., statements by national/provincial/regional/local policy makers; impact on policy documents/business plans; Impact on clinical practice; establishment of a working group to examine the implications or implementation of the research findings; improved information for political and executive decisions; etc]*

18. Are you aware of any ways in which your NHPRP project findings have led to any **changes in the awareness, attitudes or practice of practitioners, consumers, industry, research funders or others?** Examples?
19. Are you aware of any **health services benefits** that have occurred from the application of your NHPRP project's research findings? *[e.g., new/improved treatments; improved service delivery; improved health; cost savings; etc]*

Ways to Maximize Impact of NHPRP Research

20. Are there ways that the NHPRP could **strengthen linkages** between research and practice?
21. Is the **knowledge** gained from NHPRP research being disseminated? Being linked to practice? *(Note to interviewers: This is different than just dissemination of research findings.)*

Closing Comments

22. Is the NHPRP **providing a needed service** to the NHP community? In what ways?
23. Is the NHPRP **duplicating the efforts** of other funding agencies? Examples?
24. Are there any additional comments you would like to make about the impact of your NHP project that have not already been covered?
25. Do you have any questions for me?
26. May I send you a summary of my notes from our conversation via e-mail for your review and comment? *[If yes, set date to send comments and for return of feedback. If no, ask if you may contact the participant for clarification, if needed.]*

Thank you.

Internal Panel Key Question Areas

INTERNAL PANEL

Key Question Areas

for the

Formative Evaluation of the Natural Health Products Research Program (NHPRP)

1. To what extent are you aware of (or understand) the mandate, role, activities and results of the NHPRP?
2. a) In your opinion, have there been any positive changes or benefits realized within the NHP community over the past two to three years? (Positive changes or benefits might be for you, your bureau, NHP researchers, industry, health care professionals, etc.). If so, please describe briefly.

b) Are these benefits linked to the NHPRP? Examples?
3. What is your (or your bureau's) priority issue or concern with respect to the regulation of NHPs in Canada? (e.g., development of product monographs, post-market assessment, number of products to be assessed, Health Hazard Evaluations, communication with industry, capacity of researchers, involvement of practitioners, supporting the lines of evidence, policies, site licensing, good manufacturing practices, adverse reaction reporting, etc.)
4. What do you perceive to be the barriers to linking the NHPRP to the regulatory framework? Challenges to applying research knowledge?
5. To date, how (looking for specific examples) has the NHPRP supported research in the area of NHP:
 - a) Safety?
 - b) Efficacy?
 - c) Quality?
 - d) Access?

External Panel Key Question Areas

EXPERT PANEL

Key Question Areas

for the

Formative Evaluation of the Natural Health Products Research Program (NHPRP)

1. What changes (if any) have you noted in... NHP research capacity/ supporting the conduct of research/ developing partnerships and community infrastructure/ enhancing knowledge transfer... over the past two to three years? Has the NHPRP contributed to that change? If so, how? If not, how can/should the NHPRP be involved? How does the operating environment of the NHP regulations contribute to this change?
2. Strengths:
 - a. Where has the NHPRP been most effective in terms of reaching its stated objectives? Where has the NHPRP made the most significant progress to date? How? Why? (List specific examples)
 - b. What is working well within the NHP research community? (Looking for assets within the research community)
3. Weaknesses:
 - a. In what ways has the NHPRP been least effective? How? Why? (List specific examples) How can the NHPRP improve in these areas?
 - b. What is not working well within the NHP research community?
4. Opportunities:
 - a. In your opinion, how can the NHPRP best move forward in this area? (List specific examples)
 - b. Where do we need to be? How can we get there?
 - c. What should be the role of the NHPRP?
5. Threats:
 - a. What might challenge the NHPRP's ability to move forward in this area? (List specific examples)

Selected Literature Review Protocol

The literature reviewed in the formative evaluation was selected from recently conducted literature reviews and research on the topics of research capacity development, the development of partnerships and community infrastructure, and knowledge transfer and/or discussions with researchers and research foundations that are currently doing work in these areas.

The consultant queried academic/research contacts (e.g., at the University of Calgary and the Alberta Cancer Board) as well as contacts at research foundations (i.e., Canadian Health Services Research Foundation, Alberta Heritage Foundation for Medical Research) and asked them for key references. Other key literature was already known to the consulting team based on their current and previous work and was deemed to best assist the NHPRP formative evaluation.

This approach was determined to give the best value in terms of quickly accessing the key research in these topic areas. A formal literature review conducted specifically for the NHPRP evaluation would have been costly, duplicative, and would not necessarily result in the identification of the best resources.