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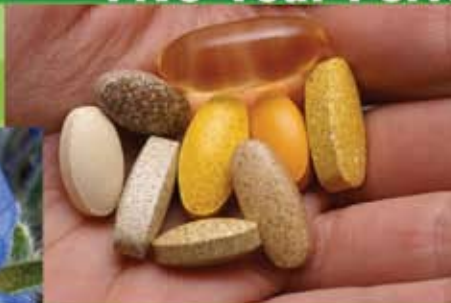



# Natural Health Products Research Program

Natural Health Products Directorate  
Health Products and Food Branch  
Health Canada



## Five-Year Performance Report 2003-2008





**“Our mission is to help the people of  
Canada maintain and improve their health,  
while respecting individual choices  
and circumstances.”**

**– Health Canada**

Également offert en français sous le titre :

*Programme de recherche sur les produits de santé naturels:*

*Rapport quinquennal sur le rendement 2003-2004 à 2007-2008*

This publication is also available electronically at the  
following address: [www.healthcanada.gc.ca/nhprp](http://www.healthcanada.gc.ca/nhprp)

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Cat. H164-74/2008E-PDF

ISBN 978-0-662-47969-7



## **Natural Health Products Research Program**

Five -Year Performance Report

2003/04 - 2007/08

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# EXECUTIVE SUMMARY

*This report is a review of the activities funded and progress achieved between 2003/04 and 2007/2008 through the research program of the Natural Health Products Directorate of the Health Products and Food Branch at Health Canada.*

*In addition to its role as a regulatory authority, the Natural Health Products Directorate's mandate was extended to support research and help bridge the gap in research-based knowledge on natural health products, as identified by the Standing Committee on Health's Advisory Panel on Natural Health Products.*

*The Natural Health Products Research Program was launched in June 2003. The objective was to contribute to improved knowledge of natural health products to enable Canadians to make informed choices about their safe and effective use. In support of this objective, the program focussed on four key areas: building research capacity, supporting quality research, developing partnerships and community infrastructure, and promoting knowledge transfer.*

## **Building research capacity**

A variety of initiatives and activities were supported to help build research capacity. This included funding for fellowships and doctoral research awards in collaboration with the Canadian Institutes of Health Research (CIHR); the development of education or training programs and curriculum development; funding of workshops to strengthen capacity among researchers in various areas of research methodology; and support for the development of national research networks and research infrastructure.

## **Supporting research**

A number of initiatives were carried out by the program and its partners to support the conduct of quality research. This included supporting and encouraging research in various disciplines

including biomedical, clinical, health services and health systems, and population health. Support was provided in partnership with the CIHR to build capacity and sponsor the conduct of research; with academic and community partners to expand and encourage their role in research and assist in the development of research projects and initiatives; and through complementary activities to build knowledge and gather data and information required for timely and effective regulatory decision-making.

## **Developing partnerships and community infrastructure**

The research program set out to encourage research into natural health products through partnerships and community infrastructure development, and through stakeholder involvement and consultations on research priorities and activities.

Key work achieved in this area includes the support provided for the development of national research networks such as the Canadian Interdisciplinary Network on Complementary and Alternative Medicine, the Natural Health Products Research Society of Canada and the Chinese Institute of Chinese Medicinal Research. These networks promote research on natural health products and /or complementary/traditional medicine research as well as serving as forums for education, communication and networking across stakeholder groups, research disciplines and the conventional and complementary health care sectors.

During its mandate, the research program facilitated dialogue, discussions and the development of new collaborations on natural health product related issues, both domestically and internationally. The program played an important role in bringing stakeholders together, increasing the credibility of natural health products research and making funds more accessible to research teams.



Consultations were conducted with a number of groups to develop and refine natural health products research priorities or to obtain consensus on technical regulatory issues. Examples include the 2005 Research Priority Setting Consultation on Homeopathic Medicine in Canada, the 2005 Invitational Consultation on Essential Fatty Acids and Fatty Acids, and the 2005 World Health Organization (WHO) Working Group Meeting on International Regulatory Cooperation for Herbal Medicines.

### **Enhancing knowledge transfer**

The research program sought to contribute to improvement in scientific and public understanding of natural health products and help Canadians make informed choices about natural health products. This was done mainly through promoting dialogue and knowledge transfer among stakeholders and by disseminating information on natural health product related issues.

Support was provided for national research conferences, such as the Natural Health Products Research Society of Canada annual research conference and the annual scientific symposia hosted by the Canadian Interdisciplinary Network on Complementary and Alternative Medicine as well as for a number of smaller or issue specific workshops or seminars.

Achievements also included the publication of peer reviewed articles, technical documents, practical guides developed to provide information to consumers and numerous presentations at national and international conferences and venues.

### **Conclusion**

The initial investment in research and knowledge-based activities was for a period of five years. The research program helped to create conditions for the generation, exchange and application of knowledge on natural health products.

The Natural Health Products Directorate will be building on the partnerships and collaborations developed through the research program to further advance the generation of scientific information in support of regulatory process and to create a better understanding of the use of natural health products for informed decision-making.



## PURPOSE OF THE REPORT

*This report presents the activities conducted and the results achieved by Health Canada's Natural Health Products Research Program (the research program) in the period 2003-04 to 2007-08. The research program created opportunities for support and investment in research on natural health products. This report serves to communicate the evolution of the natural health products research environment as a result of these efforts.*

## RESEARCH PROGRAM AT A GLANCE

The research program was an initiative of the Natural Health Products Directorate, the primary regulatory authority for natural health products for sale in Canada. The mandate of the Natural Health Products Directorate 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.

The research program was established to direct funding to natural health product research and related initiatives. Its objective was to bridge knowledge gaps and generate evidence-based information in support of regulatory processes and informed decision-making by consumers, through support of community initiatives and partnerships.

The Directorate used grants to leverage funding with other funding agencies, notably the Canadian Institutes of Health Research (CIHR). The grant mechanism allowed the Directorate to work jointly with the CIHR to support a number of larger initiatives requiring extensive management and expertise in the review of proposals.

Additional projects were implemented as funding contribution agreements between Health Canada and project recipients (i.e., external organizations) to accomplish work which would further the objectives of the research program.

The Directorate also directly managed a number of complementary activities, including priority-setting exercises, workshops, forums facilitating discussion between stakeholders and information gathering.

Program activities were initiated in June 2003 and ended March 2008. While \$5 million was the total earmarked for this program, funding pressures resulted in funding reductions in years four and five to support the Directorate's regulatory commitments and primary mandate.

Appendix A provides a list of the projects funded through the research program by funding type.

## DEVELOPMENT OF THE RESEARCH PROGRAM

As part of its mandate to protect the health of Canadians, the federal government responded to the increased popularity and use of natural health products by Canadians by taking steps to better understand the issue. In October 1997, the Standing Committee on Health undertook a study on natural health products and made recommendations regarding a legislative and regulatory regime for these products.

In March 1999, the Minister of Health accepted all 53 Standing Committee recommendations, outlined in the report titled *A New Vision: Report of the Standing Committee on Health*, and announced the creation of the Office of Natural Health Products (now the Natural



Health Products Directorate). The primary aim was to create a regulatory framework for natural health products. *The Natural Health Products Regulations* (the NHP Regulations) came into force on January 1, 2004. The NHP Regulations include provisions on product labelling, good manufacturing practices, clinical trials, product and site licensing, and provisions for a full range of health claims that must be supported by evidence.

In addition to its role as a product regulator, the Standing Committee on Health identified the need for Health Canada to support natural health product research. The work of the Standing Committee also identified the need to provide consumers with information that would better enable them to make informed choices about natural health products and the need to base regulatory decisions on objective and credible scientific information.

It was further identified that there was limited research being conducted on natural health products and that there were few organizations and resources available in the natural health product industry and academia for research into these products. It was deemed unlikely that market forces alone would generate sufficient research investment to bridge these gaps in a timely manner.

The Natural Health Products Directorate launched the research program in June 2003 after holding a series of consultations with stakeholders to determine how best to fulfill this research mandate.

### **Objectives**

The objective of the research program was to contribute to improved knowledge of natural health products, including their safe and effective use, by supporting research and by making information accessible to stakeholders and consumers. Eligibility for funding support was based on the terms and conditions developed for the research program and included educational, health, medical,

social policy and research organizations, institutions, agencies or individuals; researchers, scholars and health professionals affiliated with Canadian post secondary institutions and their affiliated institutions; Canadian voluntary and not-for-profit organizations with a role or interest in natural health product research; and provincial and territorial governments and agencies.

To meet this objective, the research program focussed on four key areas: building research capacity; supporting the conduct of quality research; fostering collaboration, community infrastructure and partnership building; and enhancing information retrieval and knowledge transfer.

### **Accountability**

A formative evaluation of the research program was conducted for the period June 2003-March 2006 with the final report submitted in October 2006.

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, and the effectiveness of the methods used to deliver the program.

The report and related management action plan were approved by the Departmental Audit and Evaluation Committee and the Treasury Board of Canada Secretariat Centre of Excellence for Evaluation.

Appendix B provides Annual Performance Report summary tables for research program activities.





## Chart 1: Allocation of funds

Research capacity  
\$1,369,278

43.4%

Conduct of research  
\$896,255

28.4%

Knowledge Transfer  
\$527,260

16.7%

Partnerships \$363,089

11.5%

## Total funding \$3,1 million

*The above chart represents the number of projects funded according to their primary area of activity. Most funded projects addressed more than one of the program's identified key areas.*

## KEY ACHIEVEMENTS

While many of the activities and projects funded over the five year period addressed more than one key program area, projects are presented below according to their main area of focus.

### I. Building Research Capacity

Under this activity, the research program provided funds to educate or train researchers and to develop education or training programs that would encourage research in natural health products or build awareness about natural health product research. The need to build research capacity was addressed in a number of specific ways:

- ▶ Support for the development of the Canadian Interdisciplinary Network on Complementary and Alternative Medicine. Funding was provided through the Interdisciplinary Capacity Enhancement initiative in partnership with the CIHR and three CIHR institutes, namely the Institute of Health Systems and Policy Research, the Institute of Musculoskeletal Health and Arthritis and the Institute of Immunity and Infection. The aim was to build capacity within the complementary and alternative health care sector through the development of a national interdisciplinary network.
- ▶ The Natural Health Products Directorate and the CIHR entered into a collaborative agreement: the Natural Health Products Directorate/CIHR Partnership Program. Under this multi-year funding agreement, the Directorate contributed approximately \$260,000 for fellowships and doctoral research awards.
- ▶ Support for exploring research literacy among complementary and alternative health care practitioners. A contract was awarded to complete an environmental scan of complementary and alternative health care educational institutions, continuing education opportunities and research initiatives within training institutions.



- ▶ Facilitation of an invitational workshop to develop a national vision for complementary and alternative medicine in undergraduate medical education. The workshop was organized in response to the increasing concurrent use of conventional and complementary and alternative medical services and the resulting need for physicians to be better informed on the interdisciplinary nature of health care and the variety of services and natural health products their patients may be using.
- ▶ Support for the development of a comprehensive curriculum on natural health products for integration into Canadian undergraduate medical education programs. The project built on results from the above invitational workshop. It was led by the University of Calgary Research Chair in Complementary Medicine. Competency-based student learning objectives and curriculum content specific to natural health products were developed and strategies identified for the integration of natural health products content into undergraduate medical education.
- ▶ Funding of three workshops designed to strengthen training and research capacity of Canadian natural health product researchers using different forms of research design including epidemiological studies, clinical trials and systematic reviews.
- ▶ With the support of research program contribution funding, the Royal Roads University's Centre for Non-Timber Resources hosted a small invitational workshop designed to bring together Aboriginal and non-Aboriginal participants to initiate dialogue regarding indigenous medicinal plants and Aboriginal contributions and approaches to alternative health care research priorities.
- ▶ Training of a University of Toronto graduate student to develop a research proposal on practitioner perceptions related to reporting suspected adverse reactions associated with natural health products compared to drugs.
- ▶ Development of a strategic business plan for the Natural Health Products Research Society of Canada to enhance and improve natural health products research in Canada including a strategy for sustainable funding and appropriate membership services.
- ▶ Funding for the second annual meeting of the Canadian Institute of Chinese Medicinal Research to promote the safe and responsible use of Traditional Chinese Medicine (TCM) products through the generation of reliable evidence from fundamental and clinical research and to foster knowledge exchange and collaboration between TCM practitioners, scientists and clinical investigators.

## **Chart 2: Natural Health Products Directorate/ CIHR Research and Training Awards**

### **Operating Awards Starting 2005**

- Delbert Dorscheid  
University of British Columbia
- Burton Yang  
Sunnybrook and Women's College  
Health Sciences Centre
- Charles Ramassamy  
Institut national de la recherche scientifique (INRS) -  
Institut Armand Frappier



## **Fellowships Starting 2005**

- Kathryn Rodeheffer  
The Research Institute of the McGill University  
Health Centre
- Joel Gagnier  
University of Toronto

## **Starting 2003**

- Etienne Richer  
Institut national de la recherche scientifique (INRS) -  
Institut Armand Frappier
- Arthur Sampaio  
University of Western Ontario

## **Doctoral Research Awards Starting 2005**

- Kristine Votova  
University of Victoria

*As presented in the above chart, the research program partnered with several CIHR institutes to support the conduct of research and training opportunities.*

## **II. Supporting Research**

Directly and in partnership, the research program provided funding for natural health product research projects in order to contribute to the evidence base required to support the regulatory framework and to facilitate informed choice by consumers.

The research which was supported and the findings achieved include:

- ▶ A multi-year financial contribution of \$230,000 for operating grants through the Natural Health Products Directorate/CIHR Partnership Program.
- ▶ A grant supporting the pre-clinical work required to conduct randomized control trials investigating the use of Echinacea in children with upper respiratory tract infections. The study was led by the University of Alberta. The funds for this research were awarded jointly by the Directorate and the CIHR and total funds amounted to \$115,000 for 2003-04.
- ▶ Support for conducting research on ethical approaches to the conduct of comparative clinical trials. The research was conducted by the Health Law Institute at the University of Alberta.
- ▶ Support for the Canadian Botanicals Project led by the University of Ottawa on natural health products and antimicrobial activity and drug interactions. Twenty native Canadian medicinal plant species were sourced for a collaborative study of their potential for interaction with antibiotics and level of enzyme inhibition activity.
- ▶ Funding for the British Columbia Institute of Technology to support the Analytical Laboratory Proficiency Program pilot project to explore natural health product quality. The three areas of concern under research were test methodology, reference materials and laboratory proficiency.



## **Profile: A Grant for Research into Herbal Medicines**

Support for the creation of a multi-disciplinary network conducting research into the use of herbal medicines for Type 2 diabetes by the Cree Nation of Northern Quebec.

The project was co-funded by the CIHR Institute of Aboriginal People's Health and the Natural Health Products Directorate.

Through this CIHR New Emerging Team grant initiative, research work was supported at the universities of Montreal and Ottawa. Over a three-year period, researchers and members of the Cree Nation identified and investigated herbal medicines used in the management and prevention of diabetes.

- ▶ A pilot project initiated by the University of Western Ontario to evaluate and advance research on the anti-inflammatory effects of natural health products. The main objective of the project was the development of markers for product standardization for the anti-inflammatory properties of natural health products. Through this pilot project, attempts were made to further the knowledge and evidence base for product quality and standardization and provide guidance to establish more effective harvesting practices, processing and manufacturing procedures.
- ▶ Support provided to the University of Guelph to conduct an investigation of the specific use of natural health products in individuals with Type 2 Diabetes. The project partnered with local diabetes education organizations, hospitals and health care practitioners.
- ▶ Funding to the University of Toronto for a research project on specific herbal combination products to ascertain their effect in women with breast cancer. This study, led by a multi-disciplinary research team,

included researchers from the National Institutes of Health Research Center at the University of Michigan. The project led to a more comprehensive understanding of the potential role of herbal products in the control of breast cancer related symptoms.

- ▶ Funding to the Canadian College of Naturopathic Medicine to establish a research network for evaluating the safety, efficacy and use of natural health products by the HIV/AIDS community. Through their work, the network successfully published several articles in peer reviewed journals, presented research findings at the Canadian Association for HIV Research, and disseminated information to AIDS Service Organizations and the Ontario HIV Treatment Network.
- ▶ Support provided to a research initiative led by the Centre for Addiction and Mental Health. The project brought together a multi-disciplinary network of investigators with the aim to evaluate the prevalence of use of natural health products in patients suffering from schizophrenia and related primary psychotic disorders attending psychiatric clinics within the Centre for Addiction and Mental Health.
- ▶ Development of Good Wildcrafting Practices (GWP) by the Royal Roads University Centre for Non-Timber Resources through the creation of a series of fact sheets for selected Canadian wildcrafted medicinal botanicals. The fact sheets included specific plant identification, harvesting, processing and ecological information on each of the species in order to harvest the species safely and to high quality standards.
- ▶ A critical review of current approaches to quality control of traditional medicines. The study proceeded with an assessment of bioinformatics software applications and the determination of the feasibility of using this data mining technique to authenticate botanical raw materials and set quality specifications for traditional natural health product formulations.



- ▶ Support to the University of Manitoba to perform an assessment of the quality of selected traditional Chinese herbs by chromatographic fingerprinting. Comparison with purified standards, biological and chemical assays were performed to associate peak fractions with activity. The methodologies and assessment strategies derived from this study can be extended to other medicinal herbs.
  
- ▶ A detailed analysis of the scientific literature on the development of methods for determining the functionality of probiotics in terms of quality, effectiveness and safety. This study led by the Institute on Nutraceuticals and Functional Foods (INAF) at the Université de Laval established parameters by comparatively analyzing the methods and methodologies described in the scientific documentation necessary to determine the effectiveness of probiotics as natural health products in order to standardize protocols.
  
- ▶ Comprehensive screening of the chemical analysis of triterpenoid content in North American dandelion root, devils club and ginseng root. This study was initiated to determine potential structural bioactive relationships between the active components present in these medicinal plants and to describe the mechanisms of cytotoxicity evoked in different model cancer cells.
  
- ▶ The development of a business case for future research studies on the efficacy of the topical use of therapeutic honey to identify the antibacterial properties of Canadian honey. This Brock University study examined whether these properties were similar to those of honeys currently assessed from other jurisdictions, and provided a basis for evaluating whether Canadian honeys might be ready for a form of clinical trials to confirm their health and antibacterial properties.

**Chart 3: Type of Research Supported  
2003-04 to 2007-08**

Product quality, safety and efficacy	<b>25.0%</b>
Information and knowledge transfer	<b>21.8%</b>
Health systems and health services research	<b>18.8%</b>
Clinical areas and population groups	<b>14.0%</b>
Bioethics, policy and regulatory issues	<b>12.5%</b>
Issues related to the conduct of research and research methodologies	<b>7.8%</b>

### III. Developing Partnerships and Community Infrastructure

The research program encouraged others to become involved in natural health product research by developing or facilitating the development of partnerships with and among stakeholders, by promoting the involvement of not-for profit organizations in natural health product research and by consulting with stakeholders for their input on the development of research priorities and activities. Progress in this area has been accomplished through the following:

- ▶ At the onset of the research program, a report was commissioned on the coordination of natural health product research in Canada. This report included a consultative process held over a six-month period with natural health product research stakeholders. The process resulted in the development of key issues and elements for a strategic plan for natural health product research and the elaboration of a process required to advance its development.




- ▶ A consultation was held with national and international research funding agencies on their interests and capabilities with regard to research on natural health products. The consultation was attended by representatives from the National Research Council of Canada, the Industrial Research Assistance Program (NRC-IRAP), the Natural Sciences and Engineering Research Council of Canada (NSERC), several institutes of the CIHR, program areas with responsibility for research and science in Agriculture and Agri-Food Canada and Health Canada, several Canadian research foundations and one research foundation from the United States. The objective of this consultation was to strengthen relationships between research funders and the Natural Health Products Directorate in order to facilitate the potential leveraging of funds in support of future projects.

### **Profile: World Health Organization (WHO) Consultations**

- ▶ In February 2004, the Natural Health Products Directorate and the Marketed Health Products Directorate hosted the WHO Final Consultation on Safety Monitoring of Herbal Medicines resulting in the publication *WHO Guidelines on Safety Monitoring of Herbal Medicines*. This consultation was followed by a two-day WHO Working Group meeting held to continue discussions on the quality control of herbal medicines.
- ▶ The 2005 WHO Working Group Meeting on International Regulatory Cooperation for Herbal Medicines was hosted by the WHO with support from the Natural Health Products Directorate on November 28 – 30, 2005 in Ottawa. Twenty-nine participants from 16 countries attended the meeting held to explore specific issues related to the needs and feasibility of international regulatory cooperation for the safety and quality control of herbal medicines. Representatives of regional bodies and groups on herbal medicines were also invited to attend the meeting.

The WHO Working Group agreed by consensus to establish a network for international regulatory cooperation for herbal medicines. The International Regulatory Cooperation on Herbal Medicines (IRCH) network, consisting of 16 member states and regional organizations, was created and Health Canada was identified as the Preliminary Secretariat for a two year period.

- ▶ The research program acted as expert resource to other funding agencies exploring the area of natural health product research. One such funding agency was the Hospital for Sick Children Foundation. Priorities and strategies to support the Hospital for Sick Children Foundation complementary and alternative health care and natural health products program were identified and developed at two priority-setting workshops hosted by the foundation and the Natural Health Products Directorate.
- ▶ With the support of research program funding, the Motherisk Program at the Hospital for Sick Children created a collaborative Canadian Research Network for the study of neonatal outcomes after natural health products exposure during pregnancy and lactation. In an effort to provide objective and evidence-based information to pregnant and lactating women, the research team developed several research protocols for prospective follow-up of specific natural health products use in pregnancy. The network successfully published the results in a peer-reviewed scientific journal and disseminated the information generated by the study through various family physician information sources.
- ▶ Support was provided to the Atlantic Canada Network on Bioactive Compounds (ACNBC), based in the University of Prince Edward Island, to hold a forum promoting greater awareness of natural health products and a better understanding of the interface between research in functional foods and natural health products or “nutraceuticals”. This network included researchers and representatives from the four



Atlantic provinces. The forum extended participation to health care providers and practicing health professionals in an effort to encourage the exchange of ideas and potential collaborative partnerships in natural health products research for product use.

### **Profile: Consultation on Homeopathic Medicine in Canada**

A research priority-setting consultation on homeopathic medicine in Canada was initiated by the research program.

Representatives from diverse stakeholder groups within the homeopathic medicine community in Canada were invited to participate in a research priority setting consultation held in Ottawa, January 2005.

The objectives of the consultation were to identify research priorities and foster partnerships within the homeopathic sector – including research, practitioners and industry – and to facilitate the development of strategies in which research priorities can be addressed.

- ▶ Support for the preparation of discussion papers on Canadian fatty acids and essential fatty acids (EFAs) research and issues, probiotic research and TCM product research in preparation for future work in this area. These discussion papers formed the basis for further exploration of issues relating to the above mentioned products and for priority-setting to identify research gaps and needs. As an example, the Invitational Consultation on Fatty Acids and EFAs was held in October 2005 to identify issues with the potential to be a regulatory challenge and explore options to facilitate research in this area.
- ▶ In collaboration with the Advanced Foods and Materials Network (AFMNet), support was provided for a two-day meeting to support increased collaboration and partnerships within the natural health

products community. The meeting brought together researchers, suppliers and trade associations working in the area of natural health products and functional foods to develop collaboration among researchers and research users, foster dialogue and explore common areas of research.

- ▶ The research program invited representatives from various stakeholder groups to participate in a focussed research meeting held in Toronto March 1-2, 2006. The research meeting was organized to identify and explore the concerns and opportunities in regards to herbal product and natural health product research in Canada.
- ▶ Support for and presentation at the North American Research Conference on Complementary and Integrative Medicine and Natural Health Products in Edmonton May 24-27, 2006. At this event, Canadian and international experts presented leading edge research and shared knowledge by disseminating scientific evidence currently available. The conference also supported Health Canada's leadership role in the regulation of natural health products and in the building of science capacity in this field by participating in discussions and debate about the role of science and research in the regulatory decision making processes.

### **Profile: Natural Health Products Research Society of Canada (NHRPSC)**

The NHRPSC is a national research network created in 2003 which supports and promotes scientifically rigorous research and education on natural health products. The research program provided start-up funding for their inaugural 2004 conference and for the development of a business case and strategic plan and has supported the 2005 and 2006 national conferences.



There have been numerous positive outcomes resulting from the formation of this national research network. These include:

- ▶ Increased collaboration of academic, industry and government researchers from across Canada on natural health product related issues, and
- ▶ National knowledge transfer and forum for education, communication and networking through its annual scientific conference.

#### **IV Enhancing Knowledge Transfer**

The research program contributed to an improvement in the scientific and public understanding of natural health products by promoting dialogue and knowledge transfer among stakeholders, by disseminating and synthesizing published information on a given area in natural health product research, and by providing financial support to workshops, seminars and conferences. A number of activities were conducted in support of this effort, including:

- ▶ An extensive literature and legislative review initiated on Canada's primary natural health product trading partners. The review presented a comparison of related regulatory frameworks among Canada's trading partners as part of a comprehensive effort to develop and transfer knowledge on international natural health products regulatory agencies and initiatives.
- ▶ Support for the dissemination of the proceedings of the Biodiversity & Health Symposium 2003. The symposium's conclusions and recommendations were published in the *Biodiversity Journal of Life on Earth* June 2004 issue. Important values and principles in the area of health and biodiversity were identified including: the importance of supporting the formal recognition that traditional medicine has a

role to play in primary healthcare provision; the importance of the validation of the safety and efficacy of traditional treatments; and the value of biodiversity to human health.

#### **Profile: Canadian AIDS Treatment and Information Exchange (CATIE)**

Information resources were produced for people living with HIV/AIDS to increase the capacity of patients and caregivers to access and make informed decisions about complementary and alternative health care and natural health products. These publications include:

- ▶ A workshop module on Complementary and Alternative Health Care Use in People Living with HIV/AIDS
- ▶ A fact sheet on Herb-Drug Interactions
- ▶ A revised edition of the Practical Guide to Herbal Therapies for People Living with HIV
- ▶ A revised edition of the Practical Guide to Complementary Therapies for People Living with HIV.

- ▶ The First Annual Forum on Complementary and Alternative Health Care and Paediatrics sponsored by the Hospital for Sick Children Foundation was held December 2-3, 2004, in partnership with the Canadian Pediatric Complementary and Alternative Medicine Network, the Canadian Interdisciplinary Network on Complementary and Alternative Medicine, the Department of Community Health Sciences at the University of Calgary and the Natural Health Products Directorate. The Foundation organized the first of what has become an annual forum to profile research in the area of complementary and alternative health care and paediatrics.
- ▶ Funding provided for the development of independent learning modules for alternative practitioners in support of critical reading and management of information on natural health products.





In collaboration with international experts in the field of alternative and complementary medicine, the research team led by the Chaire Lucie et André Chagnon developed self-learning modules for complementary and alternative health care providers to allow acquisition of knowledge and skills in searching for information and critical analysis of scientific information.

- ▶ The Chaire de l'Université Laval held a conference on Omega-3 fatty acids, Cardiovascular and Mental Health. This conference was an opportunity for experts to take stock of the current state of knowledge and research on omega-3 fatty acids and cardiovascular and mental health. As well, recommendations on public health and future directions were discussed during the conference.
- ▶ A research team led by the Unité de recherche évaluative of the Centre Hospitalier Universitaire de Québec was awarded funding for an integrated support program to help in decision-making on the use for natural health products in women at mid-life in the pre- and post-menopausal period. The study identified priorities related to the needs of establishing a decision-making framework, as well as the strategies to disseminate this framework to provide support and informed use of natural health products in this population. A decision-making tool was developed.
- ▶ A number of conferences, such as the NHRSC 2<sup>nd</sup> and 3<sup>rd</sup> annual conferences were supported, contributing to knowledge transfer and information dissemination by showcasing leading edge natural health product research in the basic, clinical and social sciences and by increasing awareness of current natural health product research capacity and expertise.
- ▶ The Institute on Nutraceuticals and Functional Foods (INAF) in collaboration with the International Society for Horticultural Sciences (ISHS), sponsored the International Symposium on the Health Effects of Fruits and Vegetables – FAV Health 2005. The goal of this symposium, which included a discussion of nutraceuticals, was an opportunity for experts to receive current scientific knowledge on the health effects of bioactive compounds contained in fruits and vegetables.
- ▶ The Saskatchewan Herb and Spice Association hosted a national conference entitled “2<sup>nd</sup> National Growing an Industry: Linking Agriculture and Health from the Consumer to the Field – Canada's Place in the Herb, Spice and Natural Health Products Industry” October 27-29, 2005, in St. John's, Newfoundland. The conference sought to connect the industry across regions and sectors to advocate for national standards for quality and to influence research directions to benefit the Canadian industry and the Canadian public and avoid duplication of effort.
- ▶ Support for the 4<sup>th</sup> International Conference of the British Columbia Functional Food and Nutraceutical Network (November 4, 2005, Vancouver). The conference showcased the regulatory frameworks of the United States Food and Drug Administration (USFDA) and Health Canada's Natural Health Products and Food Directorates with the aim to provide information and to promote and facilitate increased communications and business activities among members of the Canadian industry.
- ▶ The Natural Health Products Directorate hosted a scientific workshop titled “The Global Regulation of Natural Health Products: A Scientific Perspective”. While in recent years there has been a move towards regulatory cooperation, especially with regards to herbal medicines, many countries and jurisdictions have developed regulatory frameworks specific to their individual needs. This session comprised of presentations from international experts in the area of natural health products science-based regulation and subsequent discussions with the participants. For this session, the research program hosted three international experts in this area from Australia, the United Kingdom and the WHO.



#### **Chart 4: Activities supported to encourage knowledge transfer and exchange of information**

Publications in peer reviewed journals	<b>25</b>
Conferences /Scientific Symposia & Workshops	<b>17</b>
Literature reviews, Background papers	<b>5</b>
Resource Development	<b>5</b>
Curriculum Development	<b>4</b>

## **CHALLENGES AND OPERATIONAL ISSUES**

The rapid growth of the Natural Health Products Directorate and the need to implement the regulatory framework in the most timely fashion provided challenges in the early stages of implementation of the research program. Specific challenges and operational issues are discussed below together with actions taken to address them or mitigate their impact.

### **Implementation and late fiscal year start**

The research program was launched in June 2003, later than anticipated. This created challenges in a few areas: initiation of a partnership with the CIHR and generation of requests for proposals managed directly by the research program.

### *Partnership with the CIHR*

Implementation of the research program began mid-year and outside of the established CIHR research cycle making it difficult for the Natural Health Products Directorate to participate in funding initiatives. In response to these challenges, operational changes were made by both partners to facilitate the future working relationship. A lead CIHR institute, the Institute of Health Systems and Policy Research, was identified as the primary liaison and a program officer was assigned by the CIHR to assist in developing future funding collaborations.

### *Generation of Requests For Proposals*

The late start impacted on the ability of the program to launch a request for proposals using contribution transfer payments in the first fiscal year of the program. Administrative and financial processes had to be developed prior to launching a call for proposals and given the diverse nature of the natural health product research sector, allowing sufficient time to respond was particularly important.

In response to these challenges, the process of requesting proposals was deferred and the contributions funding was converted to operating dollars for fiscal year 2003-04. Measures were taken to ensure that the required mechanisms would be in place for 2004-05. Projects were identified which could be supported through operating dollars instead of contribution funding.

### **Infrastructure and Expertise Challenges**

As with all new processes, the implementation of procedures and identification of roles and responsibilities within the Directorate affected the initial operations of the research program. For the management of grants and contributions, the research program was initiated when Health Canada and the federal government



was reviewing the way it managed grants and contributions. The ensuing changes in standard operating procedures, together with the limited experience within the Health Products and Food Branch with contributions programs, meant the management of projects supported by these transfer votes required specialized expertise.

In response to these challenges, other program areas with expertise in grants and contributions management were consulted, staff members with experience in grants and contributions were hired, training was provided to staff and the relationship with Branch and Department financial areas were strengthened, notably with the Branch Senior Financial Officer and the Health Canada Centre of Expertise for Grants and Contributions.

### **Dealing with regulatory boundaries**

There are a number of products which can fall under various regulatory frameworks, with absolute classification possible only through an application for a product licence. Such products include those that share characteristics of natural health products and food or drugs, as defined under the *Food and Drug Act*. The research program received and peer-reviewed proposals dealing with natural health products whose attributes placed them at the interface of two or more regulatory frameworks, requiring further investigation before the proposals could be screened positively.

In response to these challenges, on an as-needed basis, technical advice was solicited from scientists within the Natural Health Products Directorate's Bureau of Product Review and Assessment; the CIHR was provided with a background document on natural health products for circulation to peer review members to ensure a common understanding of the types of products included in the NHP Regulations; and the research program developed a comprehensive definition of natural health products in the application and eligibility review forms for the requests for proposals.

### **Ensuring relevance to regulatory framework**

The research program was created to fund the promotion of research in support of the regulatory functions of the Natural Health Products Directorate. Linking the research program to the regulatory framework was sometimes challenging because new issues came up as the regulatory framework was implemented and also because the natural health products community had many diverse interests, some of which were peripheral to the NHP Regulations. The research program had to ensure that in reviewing research proposals and initiatives, there was a clear link with issues emanating from the application of the NHP Regulations.

In response to these challenges, the research program required from researchers that they demonstrate a clear and strong link to the natural health products regulatory framework and a request for proposals targeting product quality, safety and efficacy was launched. The issue of relevance also figured prominently in the evaluation of the research program and was part of the expert panel discussions conducted as part of the evaluation.

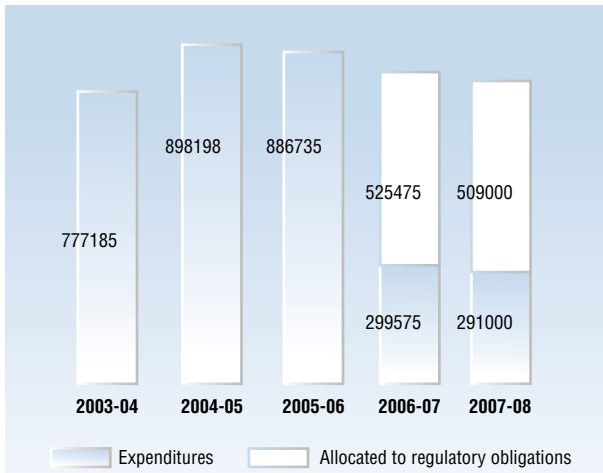
### **Funding levels and regulatory commitments**

In year four, funding levels for the research program were revised due to funding pressures and to allow the Directorate to invest additional resources to fulfill its core mandate and regulatory obligations.

In response to these challenges, the Directorate informed its external advisory committees, research stakeholders and funding recipients of the change in available funding levels for years four and five and efforts were made to direct researchers to other funding opportunities inside and outside government.



**Chart 5: Funding levels 2003-2008**



The above chart presents funding levels from 2003-04 to 2007-08. A portion of the funds were directed to regulatory activities in the last two years, .

## MAKING A DIFFERENCE IN THE NATURAL HEALTH PRODUCTS COMMUNITY

### Building a stronger research community

During its mandate, the research program worked with several natural health product stakeholder groups, including scientific and academic communities, government, industry, consumers and practitioners from both the conventional and the complementary health care sectors to stimulate interest in natural health product research. This created conditions for the generation, exchange and application of knowledge in the regulatory context and an environment where science contributed to regulatory development and decision-making.

A total of 60 projects were funded through the research program (see Appendix A). Approximately half of these were research projects or knowledge-based initiatives aimed at enhancing knowledge and understanding of natural health products. A large proportion

(60%) of funding recipients were researchers, scholars, or health professionals affiliated academic institutions such as hospitals and research institutes. The research program also supported smaller research projects conducted by not-for profit educational, health or medical research organizations.

With the support provided by the research program, the natural health product research community is more organized and there are major national networks now in place. Communication of risk information is strengthened through these networks and there is evidence of the emergence of multi disciplinary research teams and new partnerships. Collaboration with partners in the research community has helped to build a critical mass of researchers and research infrastructure.

### Leveraging funding for natural health products research

While natural health product research is supported by other research funding agencies, at the time of implementation of the regulatory framework there were no agencies supporting work specific to the regulation of natural health products. The research program partnered with large funding bodies such as the CIHR and the Hospital for Sick Children Foundation as well as with other program areas within Health Canada to support related research. In addition, consultations were initiated with research funding agencies to identify common areas of interest and capabilities with regards to research on natural health products.

The research program successfully leveraged resources through the five collaborative agreements with the CIHR which contributed over \$1.2 million in funds for natural health product related research and training.

Organizations who received funding through the research program were better able to leverage funds from other sources. Researchers have commented that their success in obtaining additional funds and/or in-kind support was due to their success in obtaining funds through the research program.



## **Reaching out across sectors**

A priority identified in the consultation process carried out to determine the direction of research program activities was the need for communication between stakeholder groups to foster partnerships and facilitate information sharing.

National research conferences supported by the program were successful in bringing together scientists, health practitioners, government and industry. This served as a means to initiate dialogue and promote partnerships between stakeholder groups and provide the building blocks for development of a strong natural health product research community in Canada.

Support for multi-disciplinary networks resulted in the creation of communication links and fostered dialogue between groups such as complementary and alternative health care practitioners and natural health product researchers. The research program supported multi-sectoral involvement in the projects it supported with the aim of enhancing the sharing and dissemination of information across disciplines, sectors and audiences.

Workshops, consultations and priority-setting exercises bringing together health care practitioners, industry, government and researchers took place throughout the duration of the program to encourage discussion and dialogue on key issues in the context of the regulation of natural health products.

## **Better understanding of natural health products**

A public opinion survey conducted by the Natural Health Products Directorate in 2005 to determine behavioural patterns, attitudes and beliefs of the general public in relation to natural health products identified that 71% percent of Canadians have used a natural health product. Yet 45% of respondents indicated that they were unfamiliar

with these products; seven in ten (69%) agreed that they needed more information on natural health products.

Priority-setting workshops and consultations were held both at the onset, to assist with the establishment of the research priorities, and throughout the mandate of the program. Discussions among experts and stakeholders led to the identification of gaps requiring most attention, the development of measures to address these gaps and a better understanding of issues.

In addition, through the research program, there has been support for conferences, scientific symposia and other national venues to facilitate a better understanding of regulatory issues, share the current state of knowledge on natural health products and facilitate the development of research directions to benefit regulators, Canadian industry and consumers.

## **CONCLUSION**

The investment of resources in extramural research facilitated the learning, knowledge transfer and capacity-building for the natural health product and complementary and alternative health care research communities. Opportunities were created to expand the knowledge and understanding of natural health products.

Efforts will be maintained by the Natural Health Products Directorate to further build Canada's capacity for research on natural health products.

As well, enhanced collaboration with the science and technology community will be encouraged both domestically and internationally with a view to developing a strong and sustainable research environment capable of generating the required information on risks and knowledge to inform regulatory decisions.



## Appendix A: List of funded projects

### Contribution funding

2 <sup>nd</sup> Annual Natural Health Product Research Conference	Natural Health Product Research Society of Canada
2 <sup>nd</sup> National Growing an Industry: Linking Agriculture and Health from the Consumer to the Field – Canada's Place in the Herb, Spice and Natural Health Products Industry	Saskatchewan Herb & Spice Association
3 <sup>rd</sup> Annual Conference & Tradeshow – From Concept to Consumer	Natural Health Product Research Society of Canada
A Pilot Study to Evaluate: A Multi-disciplinary approach to study the anti-inflammatory property of natural health products – development of markers for product standardization	University of Western Ontario
A Proposal to Support the Pilot Project of Natural Health Products Analytical Laboratory Proficiency Program	British Columbia Institute of Technology
Capacity-Building & Effective Knowledge Transfer – Developing a Natural Health Products Curriculum for Integration into Canadian Undergraduate Medical Education Programs	University of Calgary
Characterization of bioactive potency towards cancer cell cytotoxicity by triterpenoid containing North American medicinal plants	University of British Columbia
Developing a Strategic Business Plan for the Natural Health Product Research Society of Canada	Natural Health Product Research Society of Canada
Development of a Network for Research of Natural Health Products in HIV	Canadian College of Naturopathic Medicine
Development of Good Wildcrafting Practice Guidelines and Wildcrafter Certification for the Harvesting of Wild Medicinal Botanicals	Royal Roads University
Development of leading-edge expertise and effective and rigorous methods related to the safety, quality and effectiveness of probiotics	Institute on Nutraceuticals and Functional Foods (INAF) – Université Laval
Enabling Natural Health Product Researchers: Building a Clinical Epidemiology Infrastructure	Children's Hospital of Eastern Ontario
Establishing Canadian Network for Natural Health Products in Pregnancy and Lactation	Hospital for Sick Children – Motherisk Program
Expanding the Network – Inclusion of conventional and CAHC health practitioners as participants in the knowledge exchange and transfer information on natural health products	University of Prince Edward Island
Feasibility Study – Applying Metabolomics to the Authentication and Quality Control of Natural Health Products	British Columbia Institute of Technology
Fingerprinting Canadian Prairie Safflower and comparison with <i>Flos carthami</i>	University of Manitoba
First Annual Forum on Complementary and Alternative Health Care and Paediatrics	The Hospital for Sick Children Foundation

## Appendix A: List of funded projects

### Contribution funding (continued)

Integrating Traditional Chinese Medicine (TCM) Treatment into Clinical Practice	British Columbia Cancer Agency
Independent learning modules for alternative practitioners : Critical reading and management of information on natural health products	Chaire Lucie et André Chagnon pour l'avancement d'une approche intégrée en santé
Native Plants & First Nations: How can we create research that is equitable, sustainable and beneficial to all?	Royal Roads University
Natural Health Product Research Society Workshop	Natural Health Product Research Society of Canada
Natural Health Products in Primary Psychotic Disorders: Use and Attitudes	Centre for Addiction and Mental Health
North American Research Conference on Complementary and Integrative Medicine	University of Alberta
Omega-3, cardiovascular and mental health: The experts speak out!	Chaire de l'Université Laval
Integrated program for supporting decision-making about natural health products for middle-aged women going through or having gone through menopause : requirement study	Unité de recherche évaluative du centre Hospitalier Universitaire de Québec (CHUQ)
Reporting Suspected Adverse Effects Associated with Natural Health Products: Research Proposal Development	University of Toronto
International Symposium on the Health Effects of Fruits and Vegetables – FAV Health 2005	Nutraceuticals and Functional Foods Institute (INAF) – Université Laval
The use of Natural Health Products by Individuals with Type 2 Diabetes	University of Guelph
Therapeutic Honey: Antibacterial activities of honey	Brock University
Trial of Certain Herbal Combination Products such as Essiac to Ascertain its Effect in Women with Breast Cancer	University of Toronto
US 2005 – Market For Functional Foods & Natural Health Products – Regulatory & Marketing Perspective	University of British Columbia BC Functional Food & Nutraceutical Network Society (BCFN)



## Grant funding

Interdisciplinary Capacity Enhancement Team (ICE) Grant Supporting Research in Complementary and Alternative Health Care (CACH)	University of Toronto
Natural Health Products Directorate/CIHR Partnership Program (training awards and operating grants)	Natural Health Products Directorate/CIHR
Antiviral activity and mechanism of vitamin A (retinoids) on measles virus and canine distemper virus in vitro and in vivo	The Research Institute of the McGill University Health Centre
Reliability and validity of guidelines for reports of controlled trials of botanical medicines	University of Toronto
Herbal Medicine Use and Older Adults: Social Networks and Information Exchange	University of Victoria
Conjugated linoleic acid and airway health in asthma	University of British Columbia
Effect of the medicinal mushroom ganoderma lucidum on tumour cell activities	Sunnybrook and Women's College Health Sciences Centre
Interactions of a standardized ginkgo biloba extract Egb 761 with pharmacological compounds, foods and natural health products	Institute on Nutraceuticals and Functional Foods (INAF) – Institut Armand Frappier
Glucosamine sulphate in osteoarthritis of the knee: Long-term validity and cost effectiveness	University of Toronto
Functional characterization of vitamin-D and retinoid in osteoblast differentiation	University of Western Ontario
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	Institut national de la recherche scientifique (INRS) – Institut Armand Frappier
Rigorous Scientific Evaluation of Selected Anti-diabetic Plants: Towards an Alternative Therapy for Diabetes in the Cree of Northern Quebec	Université de Montréal
Study of Echinacea in Children with Upper Respiratory Tract Infections (SECURITI)	University of Alberta





## Operating funds

Biodiversity & Health Symposium 2003.	Tropical Conservancy Council
Canadian Botanicals Research Project – Microbiological Component	University of Ottawa Centre for Research in Biopharmaceuticals & Biotechnology
Coordination of Natural Health Products Research in Canada	Natural Health Products Directorate/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
Focussed Meeting with Western Herbalists and Researchers	Natural Health Products Directorate/Trish Dryden Consultant
Global Regulation Session : North American Research Conference	Natural Health Products Directorate
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 (Natural health products) Regulations for Canada's Primary Natural Health Products Trading Partners	JRH Toxicology
Literacy Amongst Complementary and Alternative Health Care (CAHC) Practitioners Phase I and Phase II	Centennial College, Toronto
Natural Health Products Directorate Consultation on Fatty Acids and Essential Fatty Acids (EFAs)	NutriTech Consulting
Natural Health Products Directorate Consultation with Research Funding Agencies	Natural Health Products Directorate/Theodore de Bruyn Consultant
Perspectives on Natural Health Products: A Collection of papers from stakeholder consultation reports 2001-2002	Natural Health Products Directorate Publication
Probiotics Discussion Paper	NutriTech Consulting



### Operating funds (continued)

Research Priority Setting Consultation on Homeopathic Medicine in Canada: An Invitational Roundtable	Natural Health Products Directorate/Trish Dryden Consultant
TCM "Preparatory" Meeting	Luimandale Consulting
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
WHO Working Group Meeting on International Regulatory Cooperation for 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 B: Summary Table - Annual Performance Report

Table 1: Year 2003-2004

Expected Outputs	Performance Indicator	Progress Year: 2003-2004
Personnel Training Awards, Training Centre Awards, Curriculum Development	<ul style="list-style-type: none"> <li>• Number of awards</li> <li>• Total &amp; average dollars per award</li> <li>• Funding by source</li> </ul>	<p><b>3 personnel training awards</b></p> <ul style="list-style-type: none"> <li>• \$35,000 awarded in 2003-04.</li> <li>• Awards granted for 3 years: 2001-02 to 2003-04.</li> <li>• Two grants over \$8,000 and one of \$17,000.</li> </ul> <p><b>Report on research literacy</b></p> <ul style="list-style-type: none"> <li>• Phase I report completed on research literacy among complementary and health care practitioners.</li> </ul>
Research Networks	<ul style="list-style-type: none"> <li>• Number and type of initiative</li> <li>• Participants - number and groups represented</li> <li>• Total and average dollars per award</li> <li>• Funding by source</li> </ul>	<p><b>Interdisciplinary network</b></p> <ul style="list-style-type: none"> <li>• Support for interdisciplinary networks such as the Canadian Interdisciplinary Network on Complementary and Alternative Medicine.</li> <li>• \$150,000 awarded in 2003-04.</li> <li>• Multi-year grant extending to FY 2006-07</li> <li>• Three (3) CIHR institutes partnering and providing funding.</li> </ul> <p><b>Invitational workshop on Complementary and Alternative Medicine (CAM) in Undergraduate Medical Education (UME) September 2003</b></p> <ul style="list-style-type: none"> <li>• 14 Canadian medical schools represented as well as CAM stakeholders.</li> </ul>
Research grants awarded and findings achieved	<ul style="list-style-type: none"> <li>• Number and type of research grants awarded</li> <li>• Total and average dollars per award</li> <li>• Funding by source</li> </ul>	<p><b>New Emerging Team Grant</b></p> <ul style="list-style-type: none"> <li>• Research into use of herbal medicines for Type 2 Diabetes – Cree Nation of Northern Quebec</li> <li>• \$140,000 in 2003-04 and total Natural Health Products Directorate contribution is \$290,000 over 2 years.</li> <li>• Partners include CIHR Institute on Aboriginal People's Health.</li> </ul> <p><b>Grant Echinacea in children</b></p> <ul style="list-style-type: none"> <li>• One (1) grant for pre-clinical work required to conduct randomized control trials investigating the use of Echinacea in children. Total amount was \$115,000 with Natural Health Products Directorate contribution of \$75,000.</li> </ul> <p><b>Comparative clinical trials</b></p> <ul style="list-style-type: none"> <li>• Research on ethical approaches to the Conduct of Comparative Clinical trials.</li> <li>• Report completed in March 2004.</li> </ul> <p><b>Botanicals Project</b></p> <ul style="list-style-type: none"> <li>• Support of the Canadian Botanicals Project - \$40,000.</li> </ul>



**Table 1: Year 2003-2004 (continued)**

Expected Outputs	Performance Indicator	Progress Year: 2003-2004
<p>New collaborations, networks or partnerships, increased involvement of voluntary organizations, stakeholder involvement</p>	<ul style="list-style-type: none"> <li>• Number and type of initiatives</li> <li>• Participants - number and groups represented</li> <li>• Outcome of initiatives</li> <li>• Total and average dollars per award</li> </ul>	<p><b>Consultation with research funding agencies, November 3-4, 2003</b></p> <ul style="list-style-type: none"> <li>• 25 participants from various Canadian research foundations, NSERC, NRC-IRAP, CIHR.</li> </ul> <p><b>Natural Health Products Directorate hosted WHO Consultation on Safety Monitoring of Herbal Medicines February 2-6, 2004</b></p> <ul style="list-style-type: none"> <li>• Consultation on safety monitoring of herbal medicines and the WHO working group on quality control of herbal medicines.</li> <li>• Amount awarded was \$98,500.</li> <li>• 54 participants, international representation including Canada.</li> </ul> <p><b>NHPRSC National Research Conference in Montreal, February 20-22, 2004</b></p> <ul style="list-style-type: none"> <li>• Amount awarded for this conference was \$35,000.</li> <li>• Groups represented included scientists, clinicians, government and industry from wide range of fields including: clinical science, botany, medical science, clinical pharmacology, pharmacy, social sciences and health services research.</li> <li>• Steering committee national in nature, including several key research community leaders. Plenary speakers included university researchers and CIHR scientific directors.</li> </ul> <p><b>Co-ordination of natural health products research in Canada</b></p> <ul style="list-style-type: none"> <li>• Two (2) consultations held and strategic plan developed.</li> </ul>
<p>Literature Reviews, Electronic Information</p>	<ul style="list-style-type: none"> <li>• Number and type of reviews or web pages supported</li> <li>• Total and average dollars per award</li> </ul>	<p><b>Literature review</b></p> <ul style="list-style-type: none"> <li>• Extensive literature and legislative review on natural health products (NHPs) for Canada's primary NHP trading partners and comparison of regulatory frameworks.</li> <li>• Completed March 2004. Amount awarded \$38,200.</li> </ul> <p><b>Biodiversity and Health Symposium</b></p> <ul style="list-style-type: none"> <li>• Support for dissemination of proceedings of the Biodiversity &amp; Health Symposium 2003. Amount awarded: \$9,950.</li> </ul> <p><b>Support of health promotion initiatives</b></p> <ul style="list-style-type: none"> <li>• One (1) workshop module, one (1) fact sheet and two (2) practical guides developed by CATIE to enhance access for Canadians on information on NHPs.</li> <li>• Publication and dissemination of Perspectives on Natural Health Products. Dissemination to stakeholders and posting on website.</li> </ul>

**Table 2: Year 2004-2005**

Expected Outputs	Performance Indicator	Progress Year: 2004-2005
<p>Personnel Training Awards, Training Centre Awards, Curriculum Development</p>	<ul style="list-style-type: none"> <li>• Number of awards</li> <li>• Total &amp; average dollars per award</li> <li>• Funding by source</li> </ul>	<p><b>Personnel training awards</b></p> <ul style="list-style-type: none"> <li>• \$23,250 extension for one fellowship.</li> </ul> <p><b>Report on research literacy</b></p> <p>Phase II report completed.</p>
<p>Research Networks</p>	<ul style="list-style-type: none"> <li>• Number and type of initiative</li> <li>• Participants - number and groups represented</li> <li>• Total and average dollars per award</li> <li>• Funding by source</li> </ul>	<p><b>HIV Research Network</b></p> <ul style="list-style-type: none"> <li>• Network for evaluating the safety, efficacy and use of natural health products (NHPs) by the HIV/AIDS community.</li> <li>• \$24,000 awarded in 04-05. Total contribution is \$44,000</li> </ul> <p><b>Canadian network for natural health products in pregnancy and lactation</b></p> <ul style="list-style-type: none"> <li>• Research network exploring neonatal outcomes after exposure to NHPs.</li> <li>• \$37,500 awarded in 04-05. Total contribution is \$75,000.</li> </ul> <p><b>Workshop to foster greater awareness within the Atlantic Canada Network on Bioactive Compounds (ACNBC) in the area of natural health products</b></p> <ul style="list-style-type: none"> <li>• \$25,000 allocated</li> <li>• Multi-stakeholder group including members of the research community, natural health products industry and provincial government in Atlantic Canada.</li> <li>• Conventional health care providers and complementary and alternative practitioners represented for a total of 40 participants.</li> </ul> <p><b>Advanced Food and Materials Network (AFMNet) Workshop February 2005</b></p> <ul style="list-style-type: none"> <li>• Two-day workshop to develop collaboration among researchers and research users in functional foods and NHPs.</li> <li>• 20 participants bringing together researchers, suppliers, trade and government. Represented organizations included: the BC Food Network, the Institute on Nutraceuticals and Functional Foods, (INAF), the Canadian Health Food Association, and the Alberta Natural Health Agricultural Network.</li> <li>• \$45,000 provided to AFMNet to host this session.</li> </ul>



**Table 2: Year 2004-2005 (continued)**

Expected Outputs	Performance Indicator	Progress Year: 2004-2005
<p>Research grants awarded and findings achieved</p>	<ul style="list-style-type: none"> <li>• Number and type of research grants awarded</li> <li>• Total and average dollars per award</li> <li>• Funding by source</li> </ul>	<p><b>Contributions</b></p> <ul style="list-style-type: none"> <li>• 16 projects supported through two funding calls and a total of \$400,000 awarded.</li> <li>• 11 projects: \$75,000/ proposal for seed funding.</li> <li>• 5 projects: \$25,000/ proposal for conference and workshop support.</li> </ul>
<p>New collaborations, networks or partnerships, increased involvement of voluntary organizations, stakeholder involvement</p>	<ul style="list-style-type: none"> <li>• Number and type of initiatives</li> <li>• Participants - number and groups represented</li> <li>• Outcome of initiatives</li> <li>• Total and average dollars per award</li> </ul>	<p><b>Hospital for Sick Children Foundation: First Annual Forum on Complementary and Alternative health Care and Paediatrics, December 2-3 2004</b></p> <ul style="list-style-type: none"> <li>• Event organized in partnership with PedCAM, the Canadian Interdisciplinary Network on Complementary and Alternative Medicine, and the Department of Community Health Sciences at the University of Calgary.</li> <li>• \$20,000 awarded.</li> <li>• 120 participants from conventional and complementary and alternative medicine research communities, clinicians and government officials working in the area of child health.</li> </ul> <p><b>2<sup>nd</sup> NHRSC National Natural Health Products Research Conference, Vancouver, February 11-13 2005</b></p> <ul style="list-style-type: none"> <li>• Amount awarded was \$21, 845.</li> <li>• Included 250 participants: basic, clinical and social scientists; graduate and post-doctoral students interested in field of NHPs; industry, government and health professionals.</li> <li>• Conference included plenary sessions on topics such as Aboriginal health, cancer, diabetes, ethnopharmacology, mental health, pediatrics and product quality and standards.</li> <li>• Opportunity to showcase leading edge NHP research and foster ongoing national dialogue on research.</li> </ul> <p><b>Developing Curricula on Complementary Practices and Products for Integration into Canadian Undergraduate Medical Education: A Second National Invitational Workshop March 11-12, 2005</b></p> <ul style="list-style-type: none"> <li>• Following first Invitational Workshop in September 2003, the National Working Group and curriculum development working groups developed a framework for the proposed CAM/NHP curriculum.</li> </ul>



**Table 2: Year 2004-2005 (continued)**

Expected Outputs	Performance Indicator	Progress Year: 2004-2005
Literature Reviews, Electronic Information	<ul style="list-style-type: none"> <li>• Number and type of reviews or web pages supported</li> <li>• Total and average dollars per award</li> </ul>	<p><b>Background papers</b></p> <ul style="list-style-type: none"> <li>• Discussion paper presenting on overview of probiotics research issues and opportunities in Canada.</li> <li>• \$7,500 awarded and project completed March 2005.</li> <li>• Discussion paper presenting on overview of essential fatty acids (EFAs) research issues and opportunities in Canada.</li> <li>• \$7,500 awarded and project completed March 2005.</li> </ul> <p><b>Traditional Chinese Medicine (TCM) background paper and preparatory meeting</b></p> <ul style="list-style-type: none"> <li>• Overview document identifying current research capacity in TCM at Canadian universities and challenges faced by researchers in this area of research.</li> <li>• Followed by meeting held March 2005 which gathered approximately 10 prominent TCM researchers.</li> <li>• Priorities established and recommendations developed.</li> <li>• \$6,500 awarded in total.</li> </ul>

**Table 3: Year 2005-2006**

Expected Outputs	Performance Indicator	Progress Year: 2005-2006
Personnel Training Awards, Training Centre Awards, Curriculum Development	<ul style="list-style-type: none"> <li>• Number of awards</li> <li>• Total &amp; average dollars per award</li> <li>• Funding by source</li> </ul>	<p><b>Personnel training awards</b></p> <ul style="list-style-type: none"> <li>• 3 awards granted for 3 years:</li> <li>-2 Fellowships: value of \$45,000 and \$55,000 per year (amount awarded less in first year as researchers started later than anticipated).</li> <li>-1 Doctoral research award: value of \$22,000 per year (amount awarded less in first year as researchers started later than anticipated).</li> </ul> <p><b>Good Wildcrafting Guidelines</b></p> <ul style="list-style-type: none"> <li>• \$20,000 awarded to develop a series of fact sheets for selected Canadian wildcrafted botanicals and including specific plant identification, harvesting, processing and ecological information.</li> </ul>



**Table 3: Year 2005-2006 (continued)**

Expected Outputs	Performance Indicator	Progress Year: 2005-2006
<p>Research Networks</p>	<ul style="list-style-type: none"> <li>• Number and type of initiative</li> <li>• Participants - number and groups represented</li> <li>• Total and average dollars per award</li> <li>• Funding by source</li> </ul>	<p><b>Natural Health Products Research Society of Canada Quality Network Business Plan</b></p> <ul style="list-style-type: none"> <li>• \$19,000 allocated for development of business plan.</li> </ul> <p><b>Interdisciplinary network</b> (continuation)</p> <ul style="list-style-type: none"> <li>• Canadian Interdisciplinary Network on Complementary and Alternative Medicine multi year grant:\$50,000 awarded in 05-06.</li> </ul> <p><b>HIV Research Network</b> (continuation)</p> <ul style="list-style-type: none"> <li>• Nationally and internationally recognized network has successfully presented research findings at the Canadian Association for HIV Research and disseminated information at the Ontario HIV Treatment Network, AIDS Service Organizations and 4 local hospital grand rounds.</li> <li>• Amount of \$20,000 awarded in year 2.</li> </ul> <p><b>Canadian network for natural health products in pregnancy and lactation</b> (continuation)</p> <ul style="list-style-type: none"> <li>• \$37,500 awarded in year 2 of this project.</li> </ul>
<p>Research grants awarded and findings achieved</p>	<ul style="list-style-type: none"> <li>• Number and type of research grants awarded</li> <li>• Total and average dollars per award</li> <li>• Funding by source</li> </ul>	<p><b>Operating grants</b></p> <ul style="list-style-type: none"> <li>• 3 operating grants for 3 years.</li> <li>• Award amounts are: \$49,915 (Sunnybrook and Women's College Health Sciences Centre); \$25,910 (INRS- Institut Armand Frappier); and \$37,720 ( St- Paul's Hospital) in 2005-06.</li> </ul> <p><b>Contributions</b></p> <ul style="list-style-type: none"> <li>• 14 projects supported through 2 funding calls and a total of \$517,790 awarded.</li> <li>• 8 projects: max. of \$20,000/proposal for research projects.</li> <li>• 6 projects: max. of \$20,000/proposal for conference support.</li> </ul> <p><b>New Emerging Team Grant (continuation)</b></p> <ul style="list-style-type: none"> <li>• \$250,000 awarded in 2005-06.</li> </ul>





**Table 3: Year 2005-2006 (continued)**

Expected Outputs	Performance Indicator	Progress Year: 2005-2006
<p>New collaborations, networks or partnerships, increased involvement of voluntary organizations, stakeholder involvement</p>	<ul style="list-style-type: none"> <li>• Number and type of initiatives</li> <li>• Participants - number and groups represented</li> <li>• Outcome of initiatives</li> <li>• Total and average dollars per award</li> </ul>	<p><b>Consultation on Fatty Acids and Essential Fatty Acids (EFAs) in St. John's Newfoundland on October 30 – 31, 2005</b></p> <ul style="list-style-type: none"> <li>• Participants (25) included key academics and researchers from across Canada. Also in attendance were representatives from the natural health product (NHP) industry focussed upon development and marketing of EFAs in dosage and food form. Key EFA research funders were present.</li> <li>• Issues discussed and addressed included: FA and EFA related issues with the potential to be regulatory challenges; options for facilitating research in this area; and ways to facilitate dialogue between various sectors working in EFAs.</li> </ul> <p><b>2005 WHO Working Group Meeting on International Regulatory Cooperation for Herbal Medicines, November 28 – 30, 2005 in Ottawa, Canada</b></p> <ul style="list-style-type: none"> <li>• Hosted by the WHO with the support of the Natural Health Products Directorate .</li> <li>• 29 participants from 16 countries attended meeting held to explore specific issues related to needs and feasibility of international regulatory cooperation for safety and quality control of herbal medicines</li> <li>• A network for International Regulatory Cooperation for Herbal Medicines (IRCH) consisting of 16 member states and regional organizations created; Health Canada is Preliminary Secretariat for a two year period.</li> </ul> <p><b>3<sup>rd</sup> NHRSC National Natural Health Products Research Conference, Toronto, February 17–19, 2006</b></p> <ul style="list-style-type: none"> <li>• 3rd Annual Conference &amp; Tradeshow - From Concept to Consumer</li> <li>• \$20,000 provided in support of well-attended event</li> </ul> <p><b>Focussed meeting with herbalists and researchers, Toronto, March 4 –5, 2006</b></p> <ul style="list-style-type: none"> <li>• Western herbalists identified as a sector of particular interest, given the issues related to herbal medicines.</li> <li>• Participants (20) met to identify key technical challenges, foster and support dialogue and partnership building between the NHP research community and the Western herbal practitioner community.</li> </ul>



**Table 3: Year 2005-2006 (continued)**

Expected Outputs	Performance Indicator	Progress Year: 2005-2006
<p>New collaborations, networks or partnerships, increased involvement of voluntary organizations, stakeholder involvement (continued)</p>	<ul style="list-style-type: none"> <li>• Number and type of initiatives</li> <li>• Participants - number and groups represented</li> <li>• Outcome of initiatives</li> <li>• Total and average dollars per award</li> </ul> <p>(continued)</p>	<p><b>National Conferences</b></p> <ul style="list-style-type: none"> <li>• Supported 4 other national conferences, providing \$50,000 in funds:</li> <li>• 2nd National Growing an Industry: Linking Agriculture and Health from the Consumer to the Field - Canada's Place in the Herb, Spice and Natural health products Industry sponsored by the Saskatchewan herb and Spice Association</li> <li>• International Symposium on the Health Effects of Fruits and Vegetables - FAV Health 2005 sponsored by Institute on Nutraceuticals and Functional Foods (INAF)</li> <li>• US 2005 - Market For Functional Foods &amp; Natural Health Products - Regulatory &amp; Marketing Perspective sponsored by BC Functional Food &amp; Nutraceutical Network Society - University of British Columbia</li> <li>• Integrating Traditional Chinese Medicine (TCM) Treatment into Clinical Practice sponsored by CICMR and the BC Cancer Agency.</li> </ul>
<p>Literature Reviews, Electronic Information</p>	<ul style="list-style-type: none"> <li>• Number and type of reviews or web pages supported</li> <li>• Total and average dollars per award</li> </ul>	<p><b>Development of monographs</b></p> <ul style="list-style-type: none"> <li>• Development of monograph on fish oil.</li> <li>• Revisions to monographs on flaxseed and evening primrose oil.</li> </ul> <p><b>Publications of findings</b></p> <ul style="list-style-type: none"> <li>• 12 articles in peer reviewed journals in first three years.</li> </ul>

**Table 4: Year 2006-07 and 2007-08**

Expected Outputs	Performance Indicator	Progress Year: 2006-07 and 2007-08
<p>Personnel Training Awards, Training Centre Awards, Curriculum Development</p>	<ul style="list-style-type: none"> <li>• Number of awards</li> <li>• Total &amp; average dollars per award</li> <li>• Funding by source</li> </ul>	<p><b>Personnel training awards</b></p> <ul style="list-style-type: none"> <li>• 3 awards granted for 3 years:</li> <li>- 2 Fellowships:(research program contribution reduced in 06-07 due to budgetary constraints. CIHR increased its share. Full contribution of \$45,000 and \$55,000 in 07-08)</li> <li>- 1 Doctoral research award: (research program contribution reduced in 06-07 due to budgetary constraints. CIHR increased its share. Full contribution of \$22,000 in 07-08)</li> </ul>



**Table 4: Year 2006-07 and 2007-08 (continued)**

Expected Outputs	Performance Indicator	Progress Year: 2006-07 and 2007-08
Research Networks	<ul style="list-style-type: none"> <li>• Number and type of initiative</li> <li>• Participants - number and groups represented</li> <li>• Total and average dollars per award</li> <li>• Funding by source</li> </ul>	<p><b>Interdisciplinary network</b> (continuation)</p> <ul style="list-style-type: none"> <li>• Canadian Interdisciplinary Network on Complementary and Alternative Medicine – last year of multi year grant.</li> <li>• \$50,000 awarded in 06-07</li> </ul>
Research grants awarded and findings achieved	<ul style="list-style-type: none"> <li>• Number and type of research grants awarded</li> <li>• Total and average dollars per award</li> <li>• Funding by source</li> </ul>	<p><b>Publications</b></p> <ul style="list-style-type: none"> <li>• At end of five years, a total of 25 publications were published.</li> <li>• Peer reviewed journals include: the Annals of Internal Medicine, New Scientist, the Journal of Biological Chemistry and the Canadian Journal of Clinical Pharmacology.</li> </ul>
New collaborations, networks or partnerships, increased involvement of voluntary organizations, stakeholder involvement	<ul style="list-style-type: none"> <li>• Number and type of initiatives</li> <li>• Participants - number and groups represented</li> <li>• Outcome of initiatives</li> <li>• Total and average dollars per award</li> </ul>	<p><b>North American Research Conference on Complementary and Integrative Medicine (CAM) and Natural Health Products (NHPs) Edmonton, May 24-27, 2006</b></p> <ul style="list-style-type: none"> <li>• Over 600 participants from across North America and from around the world.</li> <li>• Venue represented the largest collaboration in North America on natural health products and complementary and alternative medicines (CAM), bringing together researchers from across disciplines, networks and countries.</li> </ul> <p><b>Global Regulation Session</b></p> <ul style="list-style-type: none"> <li>• Held during North American Research Conference on Complementary and Integrative Medicine (CAM) and Natural Health Products (NHPs) and hosted by the research program.</li> <li>• Over 60 participants attended this regulatory focussed session.</li> <li>• Panel included leading experts of regulatory agencies from Australia, the United Kingdom, the United States, Canada and the World Health Organization.</li> </ul>

