Activities of Health Canada's Science Advisory Board
Annual Report to the Minister of Health
2004-2005

Table of Contents

MESSAGE FROM THE CHAIR

The Science Advisory Board (the Board) had a very busy year in 2004-2005, with a number of key issues being brought before the Science Advisory Board (SAB) for discussion, a great deal of involvement by members and significant personnel changes. Throughout, the Board focused on strengthening Health Canada's role in protecting the health and safety of Canadians, while underlining the need for defining initiatives that increase public awareness and confidence. In the pages that follow you will find a listing of topics that came before the Board during the year as well as a summary of our discussions.

I would like to take this opportunity to thank the distinguished Board members for their dedicated service throughout the last year. We had a number of changes in the Board membership during this term and I would like to say a special word of thanks to those whose terms expired in 2004-2005. Their contributions will be remembered not only in the context of this present report but also in the wealth of expertise and experience they brought to Board discussions throughout their respective terms. New appointments refurbished the Board and insured that we will continue to be able to fulfill our mandate and provide advice to the Minister with respect to health issues that affect all Canadians. Membership on the Board represents a wealth of diversity in terms of area expertise, demographic representation and public involvement and I have been honored to serve as Acting Chair during this period.

I would also like to thank the Chief Scientist of Health Canada for his continued contribution to the Board, the Science Advisory Board Secretariat for their dedicated service and the many members of Health Canada who have helped the Board by providing information, presentations and feedback. The report presented here is indeed the work of many individuals working as a team to further the mandate of Health Canada.

On behalf of the Board, I am pleased to provide you with our report, which summarizes the Board's work for 2004-2005.

Linda Lusby
Acting Chair, Science Advisory Board

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Stanley Vollant (2003-2006)
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BACKGROUND

In 1997, Health Canada created the Science Advisory Board to contribute to the Department's mission to help the people of Canada maintain and improve their health. Since then, the Board has been responsible for providing a valued source of expert, independent and strategic advice to the Minister of Health on the science performed and used by Health Canada.

The Board holds a number of responsibilities, including providing advice on the relevance and effectiveness of the science performed and used by Health Canada and reviewing and advising on emerging health sciences, scientific trends, challenges and opportunities in national and global contexts. Among other things, the Board is also responsible for providing broad strategic advice on the communication of the science performed and used by Health Canada as well as on scientific partnerships and linkages.

The Board is comprised of individuals, appointed by the Minister of Health, who are external to the federal government and have scientific knowledge, experience and expertise that is relevant to the Department's mandate. The Board includes a Chair, Vice Chair and up to 16 members; allowing for a maximum of 18.

The Board is supported, both substantively and administratively, by a Secretariat, which is housed within the Office of the Chief Scientist (OCS). The Chief Scientist acts as a liaison between the Board and senior departmental officials, facilitating coordination and communication.

OVERVIEW OF DISCUSSIONS

Over the past year, the Board has been presented with a number of different issues that cover a wide range of topics including health and the environment, Health Canada's role in research and regulation, public health, science management and other overarching issues. Below are some examples of the topics addressed by the Board.

HEALTH AND THE ENVIRONMENT

A special joint session was held with Environment Canada's Science Advisory Board and the Pest Management Advisory Committee (PMAC) for a multi-disciplinary and multi-departmental approach to examine the cross-cutting issues related to environment and human health. While there are many cross-

cutting issues between environment and human health, there are priority areas where Canada has special needs, where Canada could assume a regional or international leadership role, or where specific gaps exist in the knowledge base. It is in these areas that scientists at Health Canada and Environment Canada could make their contributions.

The success of ongoing collaboration between scientists at Health Canada and Environment Canada requires common goals and champions. Benefit could also be derived from formal management and implementation arrangements. Increasingly, key issues facing the Government of Canada require Science &Technology (S&T) expertise found in various parts of the government as well as externally. Integration, including the ability to manage budgets across departments, is critical to the success of federal S&T endeavours.

Scientific challenges, growing public expectations with regard to disease prevention, health protection and greater access to health information as well as transparency in decision-making, are increasing the need for coordinated government action, horizontality, partnerships and collaboration. Towards this end, Health Canada has been developing a *Health and Environment Strategy.* The Board supports improved data resources and surveillance mechanisms on the economic and social burden of illness directly linked to health and environment interactions. The Board suggests that linkages should be made to health care professionals and databases to provide baseline data on adverse health events linked to environmental exposure. Capacity development initiatives are needed that address the lack of highly qualified personnel and limited funding opportunities to support interdisciplinary science.

As part of the discussions on the *Health and Environment Strategy*, a focus was placed on the Global Earth Observation System of Systems (GEOSS) and the link between earth observations and public policy on health. It is recognized that GEOSS is a valuable technology that could be adapted to protect and maintain human health and the environment. The Board believes that the use of this technology could be expanded from the focus on radioactive detection and prediction to include the monitoring of air quality and its relationship to temperature, airborne mercury, and industrial smokestack and nuclear plant emissions.

The Health Canada and Environment Canada's advisory boards discussed the review of the *Canadian Environmental Protection Act*; the Government of Canada's principal legislative tool for pollution prevention and the protection of the environment and human health. Health Canada was commended for taking into account the hazard level, as well as exposure, in its priority setting. Work by both Health Canada and Environment Canada in this area is commended and demonstrates an excellent example of organizational and functional connection between health and environment. Attention continues to be needed in assuring that the specific target endpoints of each department are taken into account.

The joint session was also an opportunity to review the background and agenda for the June 2005 Health and Environment Ministers of the Americas (HEMA) meeting in Argentina and discuss the potential for Canada to show strategic leadership. Collaboration across sectors, cooperative linkages between scientists, and the development of a science agenda are critical to problem solving on human health and environment issues.

This joint session demonstrated the need for this type of discussion on a continuing basis in order to effectively facilitate science across federal government departments. The Board wishes to engage other science departments and their respective advisory boards at future meetings to discuss cross-cutting science and research issues that may affect human health.

REGULATORY SCIENCE AND RESEARCH

Over the past year, a number of the Board's discussions focused on Health Canada's regulatory science and research. These topics include:

- quality assurance in genetic testing;
- cells, tissues and organs;
- transparency in clinical trials;
- post-market safety and therapeutic effectiveness assessments of health products;
- Medical Marijuana Research Program; and
- research and monitoring to support regulatory decisions with regard to pesticides.

Quality Assurance in Genetic Testing
The Board's views were solicited on the priorities for quality assurance in molecular genetic testing (MGT) and the national and international linkages in this area. The Board recognizes this as a vitally important issue for Canada and notes the potential to assume an international leadership role.

This role requires the development of appropriate national and international networks and a critical step is the re-establishment of the Federal/Provincial/Territorial Genetic and Health Task Group. The Board notes the importance of Canada's active involvement in the Organization for Economic Cooperation and Development's work on a guidance framework for quality assurance in this field. The Department may also benefit from collaborating with and utilizing the work of other related international initiatives (e.g., the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, the International Organization for Standardization, and the World Health Organization).

Cells, Tissues and Organs
Health Canada is proposing a new regulatory framework under the *Food and Drugs Act* to regulate all establishments and individuals in Canada that handle and/or process human cells, tissues and organs for transplantation.

An issue of concern to the Board is the need to ensure accurate and timely reporting of adverse events. Consideration should be given to an electronic reporting system whereby health care professionals can directly provide information to Health Canada, with supplemental and simultaneous reporting to the source establishment. The type of system to be used should be informed by appropriate research and evaluation to facilitate the cooperation of health care professionals and ensure the utility of the information that is collected.

Transparency in Clinical Trials
The Minister of Health has committed to increased transparency in clinical trials. One of the approaches to achieve this is the development of a single, comprehensive database or registry that contains a list of randomized clinical trials.

The SAB supports efforts in this area and the contribution it would make to the evaluation of real-world safety and effectiveness of drugs. While the ultimate goal would be an international registry, the development of a Canadian registry would be a valuable first

step. Health Canada is encouraged to take a leading role in developing the standards for the registry and ensuring its implementation. It is noted that since all clinical trials must receive the approval of research ethics boards, such boards should be engaged in this effort.

Post-Market Safety and Therapeutic Effectiveness Assessments of Health Products

Health Canada seeks to improve its efforts in monitoring the safety, effectiveness and quality of health products after they reach the marketplace. In this context, the Board considered the types of evidence that would be most useful in a post-market setting, how to address gaps in knowledge and methods to improve scientific rigour in post-market decision making.

Provincial electronic drug databases are collecting drug effectiveness and safety data and these are linkable to relevant health outcome data. Linkages between the Department and academic health centres are also encouraged to build on relevant health outcomes knowledge in population-based drug exposure studies. A path forward in this area could include the development of a framework for collecting drug effectiveness and safety data; based on conditional licensing of selected drugs. Standards for such a framework would be set by government and responsibility for submitting information would fall to industry.

Marijuana Research Program

The Board reviewed the status of Health Canada's Medical Marijuana Research Program. The Board recognizes the challenges of developing a standard scientific evidence base and encourages an overall review of this strategy. Issues to explore include: defining research questions and synthesizing existing literature; the creation and use of an effective peer review mechanism; and the development of an appropriate instrument to administer the program.

Research and Monitoring to Support Pesticide-related Regulatory Decisions

The regulatory system for pesticides and its related challenges were also presented to the Board for consideration. The Board determined that there is a need to develop a research agenda with key scientific questions and priorities around the effects of pesticides on humans, wildlife and the environment, and to incorporate Canadian values and goals into any agenda that is developed. The Board also believes that this agenda would be furthered through networking with other research-based

organizations such as the Canadian Institutes for Health Research (CIHR), Social Science and Humanities Research Council of Canada, and the Natural Science and Engineering Research Council of Canada.

PUBLIC HEALTH

Indigenous Health Research

The Board reviewed indigenous health research priorities in the context of the First Nations and Inuit Health Branch (Health Canada), the Institute of Aboriginal People's Health (Canadian Institutes of Health Research), and the United States/Canada Indigenous Peoples' Health Research Roundtable.

The Board believes that valuable lessons could be drawn from other experiences and models of agreements with vulnerable populations to ensure that cultural sensitivities and data ownership issues are adequately addressed. Emphasis should be placed on the community's role in developing research priorities and ensuring that research benefits the health of the population being studied. Health Canada has an opportunity to play a leadership role in knowledge transfer and community implementation of indigenous health research. The Board considers this an important issue which it will continue to review.

SCIENCE MANAGEMENT AND OTHER OVERARCHING ISSUES

Performance/Tracking Science and Research Activities

The Board encourages the Department to adopt a more coordinated approach to the management of science. Greater transparency and clarity is needed on intramural and extramural science research activities, as are more coherent rationales for programs and performance measurement approaches to ensure the most effective use of resources.

A coordinated approach is also needed across departments. The Board welcomes opportunities to collaborate with other departmental science advisory boards in order to contribute to the development of a national science strategy, as well as to address issues that cut across more than one federal department.

The Board is particularly interested in linking health goals with funding streams for research to avoid duplication and waste.

Health Information Privacy and Confidentiality Framework
There is an expectation of privacy and confidentiality when it comes to dealing with the personal information of Canadians, and this is especially critical in the health sector. Under the auspices of the Federal/Provincial/Territorial Conference of Deputy Ministers of Health, the Advisory Committee on Information and Emerging Technologies was tasked with developing a *Pan-Canadian Health Information Privacy and Confidentiality Framework*.

The Board acknowledges that tension exists between the privacy of individuals and the use of information to benefit scientific discovery. The knowledge derived from electronic networks of health information brings with it the potential for misuse. A strong emphasis needs to be placed on transparency and great care should be given to deciding who will be responsible for the custody of this information and the limitations that that will govern their powers. The issue of consent is critically important and measures need to be taken to ensure that patients, families and citizens are adequately informed about policies that will allow for the sharing of their health-related information without their explicit consent. There is a need for sustained public education about the collection and use of such information.

International Regulatory Cooperation
The Board was informed of approaches taken within the Department on international regulatory cooperation in relation to the recommendations made by the Expert Advisory Committee on Smart Regulations. While the Board recognizes that additional work is required in this area, it believes that the Department's focus should remain on the need for strong scientific evidence as the basis of decision-making. Consideration should be given to adopting a case study approach, for example the issue of food fortification may be an appropriate area to better examine the use of science in formulating domestic and international regulatory policy.

Public Health Agency of Canada, National Collaborating Centres
The Public Health Agency of Canada's (PHAC) National Collaborating Centres (NCC) aim to foster linkages among provinces, territories, academia and non-governmental organizations, as well as to accelerate the development and implementation in public health practice of new research findings and best practices.

The Board is particularly interested in the PHAC's proposed collaborating centres. It believes that successfully achieving these requires the engagement of the public health and social science communities. Efforts should be made to avoid duplicating existing structures and focusing on building on and enhancing existing capacity. Elements to focus on include the development of strategic targets, objectives and measurable outcomes. A "program logic" model detailing activities and relationships, with built-in accountability and evaluation mechanisms would strengthen the work of the NCCs. The Board anticipates built-in evaluation mechanisms and looks forward to hearing about the structure and priorities of NCCs and linkages to Health Canada. Upon completion, these centers could serve as a national blueprint for connecting health activities between the provincial and federal levels.

YEAR IN REVIEW

This past year provided the Board with an opportunity to evaluate its current roles and how to build on its contributions to the Department. The Board achieved this, in part, through the completion of exit interviews and the examination and implementation of several of the recommendations that came from them. The Board revised its terms of reference to better reflect its mandate, provide effective advice to the Department, and help the Board members fully understand their roles and responsibilities. The terms of reference, membership and meeting records for the Board can be found at www.healthcanada.gc.ca/sab.

In addition to the discussions on issues brought forward to the Board and regular updates from the Deputy Minister and Associate Deputy Minister, the Chair and Vice Chair addressed certain topics of importance to the Board, such as the Health Canada Science Forum and the need for co-operation between departments, the federal government and its stakeholders.

Several Board members attended the Health Canada Science Forum and the Board would like to congratulate the Department on the successful organization and execution of this event. The Forum provided an excellent opportunity to meet with a wide cross-section of Health Canada's scientists, as there were over 600 individuals in attendance. It was quite extraordinary to see the breadth of the work conducted by the Department and its staff. The Board was also pleased to have seen the evidence of some of its advice, particularly in the field of social science.

The Board has encouraged the Deputy Minister to strive for collaboration in science programs across the Department. Members have also discussed how the Board's mandate, in terms of providing advice on science and policy, allows for interaction with the proposed PHAC collaborating centres and the Canadian Institutes for Health Research. The Board members also believe that the health-related National Centres of Excellence are good models for connection and integration across the research sectors.

The Board welcomed the appointment of Pierre-Gerlier Forest as Health Canada's Chief Scientist. Given the Board's role in advocating the creation of a Chief Scientist position at Health Canada, it continues to take an active interest in the role of Chief Scientist. The Board supports the efforts of the Office of the Chief Scientist (OCS) to integrate science perspectives into policy advice to the Minister. One of the key areas identified by the Board is the need for Health Canada to strengthen its relationships, both within the health portfolio and with other departments. The Board believes that the Chief Scientist will play a key role in facilitating this goal and the Board will contribute to the identification of key areas for enhanced collaboration.

There is continued interest by Board members in tracking the impact of the Board's advice and receiving feedback from departmental officials. Informal discussions with presenters, such as representatives from Health Canada, indicate that consultations with the Board continue to provide objective and expanded points of view.