Health Canada Santé Canada

Summary of Discussion
Science Advisory Board Meeting

September 30 - October 1, 2003

Canada

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Day 1 – September 30, 2003

Attendance

SAB Members

Judith Hall
Karen Grant
Keith Bailey
David Roy
Kathryn O'Hara
Ardene Vollman

By teleconference

Linda Lusby
Patricia Clements

Secretariat

Tammy Davies
Meggan Davis
Karoline Millson

Ex-officio members

Ian Green
Janice Charette
Kevin Keough
Diane Gorman
Scott Broughton
Helene Goulet
Marcel Nouvet
Patrick Borbey
Pierre-Gerlier Forest
Alan Bernstein
Janice Hopkins

Absent

Paul Paquin
Ian Potter
Ian Shugart

Opening Remarks

Dr. Judith Hall, Chair

The Chair welcomed members, including new ex officio members who were appointed as a result of the changes to the terms of reference made at the June meeting. She informed members that the appointment of new members and the approval of the terms of reference and guidance manual by the Minister are expected prior to the November meeting.

Invitations were extended to all in attendance to participate in the upcoming Health Canada Research Forum that will be held October 20 and 21, 2003.

Remarks from the Deputy Minster and Associate Deputy Minister

The Deputy Minister introduced Janice Charette as the new Associate Deputy Minister. Ms. Charette indicated that she has taken a direct interest and responsibility for many science-based issues in the Department, including BSE, the Office of the Chief Scientist, science capacity and the Framework for Science. She recognizes the role of science in the Department's mandate, particularly in areas of public health.

The Deputy Minister reiterated his appreciation for the work of the Board and its interest in making a solid contribution to ensuring the Minister has sound science advice to inform her decision making.

Given the events of the past six months, specifically SARS, BSE and West Nile Virus, public health has been foremost on the Department's agenda. The Deputy Minister provided an overview of the Department's surveillance, education, prevention, research, and response programs to combat these diseases. It has also made efforts to analyse and apply lessons learned.

Over the summer, the Public Policy Forum consulted with Health Canada stakeholders on the Therapeutics Access Strategy and ways to improve transparency and international cooperation in the regulatory process. Ms. Charette committed to keep the Board informed and to seek their advice on regulatory models.

In all of these events, there is a consistent public health orientation that is likely to grow in the future. Outside the Department, senior Health Canada officials have been working with their provincial and territorial counterparts, and with other federal government departments to improve the public health infrastructure and capacity at all levels. The Department and the Minister have used an inclusive definition of public health and the public health system, which encompasses the range of programs and services undertaken to protect, promote and restore the health of Canadians. This includes illness, injury and risk prevention, surveillance and product safety. Every Branch of Health Canada has a role to play in this regard. The Canadian Public Health Centre, as proposed by the Minister, would also be a primary contributor.

The convergence of so many issues in such a short time has underlined the importance of a long-range perspective on health and surveillance across the health system. Any decisions taken must be based on sound science and a solid evidence base. The Deputy Minister emphasized the opportunity for the Board to make an important contribution to this.

Discussion

- There needs to be a balanced focus on infectious and chronic diseases.
- There was interest in the pan-Canadian privacy framework as it relates to health data, electronic health records, research, and the collection of data in public health emergency situations. Data collection at the front lines of a health episode, particularly during the early stages, is essential. While it is essential to respect an individual's right to privacy, consideration should also be given to how health information can be accessed and used to contribute to the public good.
- In an age where electronic networks facilitate information exchange, careful attention should be paid to how personal health information and records are used and shared in different settings (e.g., Health Canada, hospitals). Electronic records and changes to standards for consent will affect research and the delivery of health care.
- The Canadian health care system is large and offers opportunities for Canadian firms to manufacture necessary goods. A strategy to "buy Canadian" would maximize economic benefits from investments in the health care system. Mechanisms to implement such a policy should be given further consideration.
- The Board is pleased to see further partnerships between Health Canada and CIHR such as the recent Prion Diseases International Research Conference in Edmonton.
- There was discussion about Health Canada's capacity to handle the coinciding issues described by the Deputy Minister and Associate Deputy Minister. The Board encouraged the Department's scientific capacity-building efforts.

Discussion on SARS and Public Health

Dr. David Naylor
Chair, National Advisory Committee on SARS and Public Health

Dr. Naylor spoke with the Board via teleconference and provided a summary of the forthcoming report of the National Advisory Committee on SARS and Public Health. He discussed the scope of the report and the nature of its recommendations with the Board.

The Board believes the framework presented by Dr. Naylor is excellent and looks forward to the release of the final report.

Public Health Overview

Scott Broughton, ADM, PPHB

Recent events such as SARS, West Nile Virus, food and water-borne diseases, increasing burden of diseases and injury, and the threat of bio-terrorism have placed public health issues at the forefront in the minds of Canadians. Given its mandate to maintain and improve the health of Canadians, Health Canada is a key player in the broader public health sector.

Health Canada has taken a public health approach that aims to improve the health of the entire population and to reduce the inequities among population groups. The Department's focus is on five determinants of health and their interactions as they affect populations in their environments: genetics; social and economic environment; bio-physical environment; individual behaviour; and the health care system.

Health Canada has identified its role in public health through three main functions (i.e., disease and injury prevention and control, health promotion, health protection) and four enabling functions (i.e., health surveillance; research, evaluation and knowledge translation; policy, legislation regulation and planning; and HR planning, development and training). These elements must be in place and working together for the public health system to be effective.

In addition to presenting the overall picture of Health Canada's role, Mr. Broughton outlined the individual public health responsibilities of the branches and PMRA in support of the various functions. Health Canada's roles are also complementary to those of many federal government departments (e.g., DND, CSC, CFIA, DFAIT), provincial, territorial and municipal jurisdictions, and international organizations and partners. In this context, Health Canada has a leadership role in public health programs, surveillance, guidelines and standards, specific national level expertise and research.

Discussion Summary

- Over the years, there has been limited understanding about public health among Canadians. The result is little interest in public health as a career choice, which has important implications for Health Canada as a key player in the public health system.

- In contrast to public awareness of Health Canada’s science, expertise and technologies, there is less awareness that Health Canada is not responsible for setting public health laboratory standards per se. The Board sees value in

communicating the responsibilities of the Department and distinguishing them from the roles of other jurisdictions. There are also opportunities to promote Health Canada's activities and leadership role in sharing technologies, information and best practices as part of a larger network.

- The Board suggested ways to increase awareness of public health issues (e.g., occupational health and safety) and Health Canada's role, including adopting a social marketing strategy, such as that used to promote the Canada Food Guide, healthy living, and smoking cessation.

- In order to ensure that Health Canada is fulfilling its public health responsibilities, the Board agreed that it would be useful to have national health goals. Clearly articulated goals would enable the Department to develop accurate performance indicators that would more fully measure the success of its actions and contribute to informed decision-making.

- The Board appreciated the overview of Health Canada's public health roles and responsibilities and felt it was informative in the context of setting the stage for the public health science panel presentations.

Surveillance and Outbreak Investigation

Dr. David Mowat, Director General, Centre for Surveillance Coordination and
Dr. Paul Gully, Senior Director General, PPHB

Drs. Mowat and Gully presented on the importance of an information architecture, data collection and design to support evidence-based decision-making. They identified opportunities and challenges, including the need for additional trained staff and greater partnerships between public health research, service, and training sectors. They also identified gaps in public health knowledge.

Discussion Summary

- Timely and accurate information is necessary for decision makers, including data that are easily accessible electronically. In some areas, this is lacking. It is also important to have knowledgeable individuals internally who can be called upon to provide information in various areas. Health Canada maintains networks of individuals with particular expertise that it can call upon when it does not have the in-house capability.

- In addition to collecting data at the front lines, Health Canada requires the capability to analyse and interpret findings to support decisions and responses in long-term and crisis situations.

- Health Canada has a role to play in facilitating training to support public health research and delivery.

Development and Licensing of SARS Vaccines and Immunotherapy Products: Regulatory Issues

Dr. Elwyn Griffiths, Associate Director General, Biologics and Genetic Therapies Directorate
Dr. Peter Ganz, Director, Biologics and Radiopharmaceuticals Evaluation Centre, and
Dr. Alan Mortimer, Director, Biologics Research and Genetic Therapies Directorate

Dr. Griffiths and his colleagues shared with the Board some of the challenges in developing and approving a vaccine for SARS, as well as the highlights of the Health Canada Regulatory Workshop, which aimed to facilitate the regulatory process by identifying key issues in product development and developing a scientific basis for decision-making concerning clinical testing and licensing of SARS vaccines and immunotherapy products.

Regulatory challenges regarding these products include the difficulty in undertaking clinical trials to evaluate product safety and efficacy if SARS does not reappear or remains local in nature.

Discussion Summary

- Board members were very interested in the science behind SARS, reactions to a potential vaccine, and the possibility of re-emergence of SARS.

- Members asked questions regarding the safeguards, criteria, models and clinical trials for testing, evaluating the efficacy, and approving an experimental vaccine for a disease such as SARS.

- There was discussion about how Health Canada can work with its stakeholders to facilitate or expedite the science in a manner that respects regulatory processes and safety to respond to SARS and other emerging infectious diseases.

- Lessons learned from the SARS experience in terms of dealing with stakeholders, transparency, and becoming proactive early in a situation, such as West Nile Virus, are broadly applicable.

- Consideration should be given to how public and scientific perception of risk may change in a crisis situation.

BSE: A Human Health and Public Health Issue

Dr. Paul Mayers, A/ Associate Director General, Food Directorate and
Dr. Robert Hills, Manager, TSE Secretariat, Food Directorate (HPFB)

Dr. Mayers and Dr. Hills provided an overview of events and response to the discovery of the case of BSE in May 2003. They described the processes used to detect BSE in Canada and the state of scientific knowledge about the disease.

In terms of the response to BSE, they provided detailed information about risk management strategies, restrictions on animal feed, and enhanced surveillance. They also identified some of the longer term challenges on this issue.

Lessons learned from this event were also shared, including the need for collaboration, communication with the public, and transparency with stakeholders.

Discussion Summary

- Board members were interested in the scientific aspects of BSE, its transmission, and testing methods as well as other TSEs.

- Discussion included how Canada's case of BSE differs from situations in other nations including the UK. The Board asked to be reminded of the situation in 2001 when Canada imposed a short-term ban on Brazilian beef. At that time, the history of some animals that might have been imported into Brazil from the UK could not be fully assessed by Canada. That situation was resolved and the temporary ban was lifted.

- There is pressure from the public and other countries to conduct more testing, despite the fact that there are difficulties in detecting BSE in animals less than a certain age. Board members noted the difficulty of risk management in a situation where the public perception of risk differs from the scientific perspective.

Environmental Influences on Public Health

Mr. Paul Glover, Director General, Safe Environments Program
Dr. David Blakey, Director, Environmental Health Science Bureau
Dr. Steve Clarkson, Director, Environmental Contaminants Bureau (HECS)

Environment is a powerful determinant of health. Mr. Glover provided an overview of some of the health outcomes that result from environmental degradation, as well as an assessment of HECS's strengths, challenges and possible directions to address them.

Discussion Summary

- The definition of environment can be expanded to include social, economic and physical factors that affect health outcomes. While the Branch has a specific mandate to address health and the physical environment, the Board was interested to hear about the work of HECS in areas such as vulnerable populations, children, and health determinants. It also stressed the importance of a population health based approach.

- Investing in upstream research, foresight activities and surveillance is necessary to direct research, inform decision making about the health effects of exposure, and help determine what aspects of the environment potentially damage health.

- Partnerships between Health Canada, provincial, territorial and municipal governments, other organizations, and Environment Canada are essential.

PMRA's Role in Regulating Products with Public Health Claims

Dr. Diana Somers, Director, Health Evaluation Division
Dr. Richard Aucoin, Acting Chief Registrar
Dr. Caje Rodrigues, Section Head, Environmental Re-evaluation (PMRA)

Dr. Somers and her colleagues provided an overview of PMRA's role in regulating pesticides for public health use and the types of products it regulates. PMRA must assess these products based on efficacy and value, human and environmental safety, and their quality. In each of these areas, the challenges to effective regulation were presented and discussed.

Discussion Summary

- Discussion focussed on the public's perception of the safety of natural and chemical products and how this has translated into greater use of natural products.

- The public needs accurate information about the efficacy and safety of natural

products. This will help the public make better decisions.

- The Board discussed acceptable levels of control. If standards are to be set, they should measure the efficacy of the product, its toxicity, and demonstrate a sensitivity to public perceptions and acceptance of risk.

- There is a need to better understand the cumulative effects of pesticide use (bio-accumulation).

Challenges in Public Health Infrastructure for First Nations and Inuit: An Overview

Ms. Kathleen MacMillan, Executive Director, Office of Nursing Services
Dr. RoseMary Ramsingh, Executive Director, Office of Community Medicine (FNIHB)

Ms. MacMillan and Dr. Ramsingh provided an overview of the role of FNIHB in delivering public health services to First Nations and Inuit. Some of the challenges FNIHB faces in this role are the complexities of public health services delivery to First Nations, health disparities, and remote communities.

One of the most pressing challenges is recruiting and retaining the human resources capacity. Medical officers of health, nurses and other public health professionals are needed to address a variety of public health issues.

Discussion Summary

- Recruiting and retaining qualified public health professionals is challenging, and in particular, ensuring that there is appropriate representation of First Nations and Inuit in the profession. The Board is pleased to see that work is taking place to attract more public health professionals.

- Multiple intervention projects that are initiated across communities and integrated with other programs are an opportunity to target public health issues (e.g., breastfeeding, prenatal care, fetal alcohol syndrome) in a meaningful way.

- There is a need to transfer the knowledge from public health professionals to the community so that the community can take ownership of issues and challenges and devise solutions.

Day 2 – October 1, 2003

Attendance

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Karen Grant
Keith Bailey
David Roy
Kathryn O'Hara

By teleconference

Linda Lusby
Patricia Clements

Secretariat

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Meggan Davis
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Ian Shugart
Alan Bernstein

Update from the Chief Scientist

Dr. Kevin Keough, Chief Scientist

Dr. Keough provided an update on the work of the Council of Science and Technology Advisors (CSTA) on their current study on linkages, as well as the progress on a government response to the CSTA's BEST, STEPS and EDGE reports.

SAB members were invited to participate in the upcoming Health Canada Research Forum, including the first Chief Scientist's Distinguished Lecture on the science of SARS by Dr. Donald Low and Dr. Frank Plummer. Members were also invited to attend the Amyot Lecture on November 6, 2003, which will be delivered by Dr. Sheela Basrur.

This fall, the Office of the Chief Scientist (OCS) will hold the second Postdoctoral Fellowship Program competition, the Innovative Science Competition, and four orientation seminars on research ethics and the procedures for obtaining an ethical review by the Research Ethics Board. The Framework for Science secretariat is continuing its roll-up of departmental science activities that will form the Departmental Science Plan. A 360 review of the activities of the Chief Scientist and the OCS is underway.

Health Canada continues to expand its partnership efforts with CIHR, including the recent Prion Diseases International Research Conference in Edmonton. Health Canada has also provided input to CIHR on its Blueprint 2007, which is its strategic plan for building an innovative health research enterprise over the next four years.

Discussion Summary

- There was interest in how the effectiveness of the SAB is evaluated and the types of advice that are most useful to senior departmental officials. While exit interviews and direct feedback from ADMs have been helpful in this regard, consideration could be given to more formal structures. Board members agreed that specific advice makes implementation and accountability easier for senior officials.

- The Board encourages departmental efforts to integrate Health Canada science among branches, with other departments, and with CIHR.

CIHR Institute of Infection and Immunity

Dr. Bagirath Singh, Director

Dr. Singh provided an overview of the structure, functions and recent challenges of the Institute of Infection and Immunity (III). He noted many of the Institute's partnerships with Health Canada, including AIDS, Hepatitis C, Safe Food and Water, prion diseases, and the SARS Research Consortium. He expressed appreciation for the OCS and the work it does in facilitating partnerships between the two organizations. He also outlined the focus of a newly proposed rapid research response steering committee, created in response to SARS, that will assist III respond to emerging infectious disease challenges.

Discussion Summary

- Board members were interested in the scientific findings presented at the recent Prion and Prions Diseases International Research Conference. Dr. Singh shared many of the highlights of the program with the Board.

- Discussion focussed primarily on rapid research response capacity and funding in emergency situations. The Board noted the importance of adequate funding to support the collection and analysis of data and clinical specimens.

- Health Canada and CIHR should meet periodically to exchange ideas and research directions that will support a rapid mobilization in the event of a health crisis. As part of this process, researchers should examine potential issues that they are likely to face. Social scientists should be included as part of this process.

Framework for Science

Dr. Mary L'Abbe, Framework Secretariat (OCS)

As part of the Framework for Science process, there has been work over the summer to compile an inventory of science activities that are ongoing and planned by the Department. This fall, a critical analysis of the data will be performed to identify current and future gaps, as well as strategic priorities for the future.

The Framework Secretariat has been compiling information from environmental scans and related activities. The Secretariat asked the Board for additional foresight on what science and related science activities Health Canada must have in five to ten years. Board members were

asked to specify whether the science would need to be performed in-house, require partnerships, or if the expertise exists elsewhere.

Some of the challenges and activities proposed by Board members:

- Human resources planning and training of professionals in key areas (e.g., public health, social sciences)
- Communicating the results and impact of science
- Privacy legislation
- Genetic predisposition and gene - environment interactions
- Drug interactions
- Vulnerable populations
- Social determinants of health
- Establish science priorities
- Surveillance, data analysis, interpretation, use, transparency and knowledge translation
- Assessment of environmental risks
- S&T excellence
- Bioterrorism
- Antibiotic resistance

Legislative Renewal

Mr. Mario Simard, General Counsel (HPCB)

At the June 2003 meeting, Board members requested a more detailed presentation and discussion on legislative renewal.

To facilitate discussion, Board members identified specific aspects of the proposal for discussion – health, surveillance and research; risk decision making; and health and safety related activities. Given the Board's interest in privacy issues at the June meeting, the manner in which the proposed legislation would affect privacy was also discussed. Overarching issues such as core values and how the new legislation will replace existing acts were presented to the Board.

Discussion Summary

- The Board agreed to meet again to discuss the legislative proposal and to provide input from a science perspective.

- There is concern that the core values that set the tone for the proposed legislation and its application may not adequately reflect the need for sound science, among other considerations and inputs, as a basis for evidence-based decision making.

- The Board noted the importance of the first principle of the proposed legislation, which states that the assessment of risk shall be based solely on science and objective observation. It also noted the need for appropriate recognition of the role of traditional knowledge.

- In terms of provisions in the health, surveillance and research portion of the proposal, there is a need to consider how to balance the importance of individual privacy rights with the benefit of sharing information that will ultimately contribute to the health of the population (e.g., reporting adverse drug reactions). Every effort should be made in the legislation to explicitly state the conditions required to disclose information that would identify one or more individuals. The mandate and structure of oversight committees (e.g., creation of a health information auditor) that would ensure Health Canada abides by these rules should be determined by the strength of the protection provided for privacy in the legislation. The Board wishes to devote more consideration to this issue.

- Additional consideration should be paid to the difference in the nature of commercial and personal information, and how this should affect rules for disclosure.