Health Canada Policy Making in a Complex World: Accessing and Assessing Evidence

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Outline

- Federal-Provincial Jurisdiction
- About Health Canada
- Policy Making:
  - Federal Government policy making process
  - Managing health risks and public policy development
  - Health Canada’s “Decision Making Framework”
- Importance of scientific evidence
- Illustrating complexity through three examples
- Assessing Evidence
- Concluding remarks
Federal-Provincial Jurisdiction

- Constitutional division of powers:
  - Federal government has: criminal law, trade/commerce, quarantine, matters of peace, order and good governance
  - Provincial governments have jurisdiction for hospitals, property, civil rights, matters of a “merely local or private nature”

- Thus, the majority of jurisdiction over “healthcare” has been deemed to fall within provincial jurisdiction

About Health Canada

Helping the people of Canada maintain and improve their health through:

- Regulating products and substances to protect health and safety
- Providing health services to First Nations and Inuit
- Working with our partners to support the health care system and administer the Canada Health Act
- Encouraging Canadians to take an active role in their health
- Generating and sharing knowledge and information, on which personal decision-making, regulations and standards, policy development, and innovation in health rely
- Contributing to global health
Federal Government Policy Making

Speech from the Throne, Budget outline policy agenda of the elected government

Mandate & Report on Plans and Priorities also relevant

Bureaucracy supports direction of the PM and also provides advice on policy directions often with a view of the longer term

PM makes policy decisions through consensus at Cabinet Committees

Legislation that is approved to move forward is read in the House of Commons and Senate.

Risk Management in Public Policy

Broader Context:
- Legal considerations
  - Duty of care
  - International obligations

Problem/Hazard Identification - scientific evidence

Development of Policy Options
- Cost/benefit
- Jurisdiction
- Instrument choice

Decision - political advice and input
- Cabinet/Parliament approval as required

Implementation and Evaluation - results of effectiveness

Scientific evidence is one of many considerations in public decision making

Adapted from Risk Management and Canadians Report of the ADM Working Group on Risk Management, (PCO), Annex A
Importance of Scientific Evidence

Health Canada’s legislated mandate requires a strong foundation of scientific evidence for policy, regulation, and program delivery.

As a science-based department, Health Canada employees:

- Provide leading-edge science, sound policy research, and effective program and service development, including within the health care system.
- Provide knowledge to Canadians, health care workers and other public and private sector stakeholders to enable them to make sound choices to protect health and the environment.
- Monitor and research the health threats from environmental factors such as toxic substances, air and water pollution, climate change.
- Access scientific evidence to foster sound decision-making and policy-development by all stakeholders to help reduce health risks.
- Fulfill regulatory obligations on tobacco, medicines and medical devices, pesticides, consumer chemicals and products, nuclear and radiological safety, illicit drugs and food.

Health Canada Vision for Scientific Evidence

Health Canada is trusted to make effective decisions through innovative approaches to access, conduct, assess and share quality scientific evidence required to help promote and protect health of Canadians.
Policy Development to Manage Health Risks


- The framework is intended to provide a common basis for risk management decision-making throughout the Department and is intended to be applicable to the range of health risks that fall within Health Canada’s mandate.

- These health risks include: **diseases** (both communicable and noncommunicable); **substances** (chemicals, radiation, microbes); and **products** (food, medical devices, drugs, tobacco, and consumer products).

*Taken from: Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks, August 1, 2000*
Identifying, Assessing and Managing Risks

Scientific Risk Assessment Process

Evidence Base: Access, Conduct, Assess and Share

DMF Map and Sources of Scientific Evidence

- Health issues can be proactively or reactively identified
- Issues often cross disciplines & responsibility centres
- Sources of evidence are diverse
- Include toxicology studies, epidemiological studies, public health research, surveillance, results of validated standardized tests, etc

Bisphenol A: A Complex Regulatory Decision

In April 2008, Canada was the first country in the world to complete a risk assessment of bisphenol A as part of the Chemicals Management Plan.

In June 26, 2009, the Government of Canada announced it is developing regulations to prohibit the advertisement, sale and importation of polycarbonate plastic baby bottles that contain bisphenol A.

Not without some controversy

Challenge to regulators to validate and use new data and new science in decisions

Precautionary to more susceptible populations - newborns and infants

Image taken from www.rsc.org/chemistryworld/Issues/2008
Obesity: Multitude of factors complicates policy making

Figure 1. International Obesity Task Force (IOTF) Causal Web

Taken from: Obesity In Canada, Identifying Policy Priorities
Proceedings of a Roundtable, Ottawa, Ontario, June 2003
Part of the Canadian Institute for Health Information
Institute of Nutrition, Metabolism and Diabetes (CIHR-INMD)

Drug Development and Authorization

Global Product Development

Pre-Market

Post-Market

Access by providers and patients through the healthcare system

Surveillance, inspection, investigation for safety and regulatory compliance

Pre-Clinical Studies

Clinical Trials

Regulatory Product Submission

Marketing Decisions by Drug Companies

Price Review (PMP Price)

Public and private drug plans/policies

Patient Access

Real World Use

Provider Interactions

Therapeutic & cost-effectiveness studies (published research, etc.)

Information for clinicians and patients

Collection and communication of ADRs and other postmarket information

Withdrawal of products from marketplace by regulator or company

Health Canada Authority

Under specific conditions, Health Canada’s Special Access Program may authorize the use of drug not currently approved for sale or authorized for sale but not marketed in Canada
Complexity in the Drug Review Process

- Health Canada Authority: Clinical Trial Application, Submission Review, Post-market
- Evaluate drug safety, efficacy, and quality
- Hundreds of volumes of scientific and clinical information
- Health care delivery is provincial

Orphan drug policy review requires multiple perspectives and jurisdictions...

Key Challenge: Too much information?

The data deluge
Businesses, governments and society are only starting to tap its vast potential

Feb 25th 2010 | The Economist

1200 exabytes of digital data will be generated this year – 1 exabyte equals 10 billion copies of The Economist
Assessing Evidence: Fitness for Use

Six dimensions of “fitness for use”:

1. **Relevance** - degree to which the statistical information meets the real needs of users.

2. **Accuracy** - degree to which the information correctly describes what it was designed to measure.

3. **Timeliness** - the delay between the reference point to which the information pertains, and when the information becomes available, influences its relevance.

4. **Accessibility** - ease it is obtained by users (how ascertained, cost, suitability of the form it is accessed).

5. **Interpretability** - availability of supplementary information necessary to interpret and utilize it.

6. **Coherence** - degree to which it can be successfully brought together within a broad analytic framework and over time.

For drug submissions, Health Canada has adopted the International Conference on Harmonization Common Technical Document format and issues guidances regarding content (data) requirements in regulatory program areas.

*Taken from: Statistics Canada Policy on Informing Users of Data Quality and Methodology, 2000

Assessing Evidence: Data Quality Processes

Processes that contribute to data quality:

- Governance, including priority setting and ethics review
- Research design and methodology
- Peer review, publication, results dissemination
- Continuous learning, training and mentoring
- Standards development & application, certification, accreditation

Adequate infrastructure, skills, IM/IT tools, networks, access to experts, content and critical data appraisal expertise* also important.

*Taken from CHSRF A self assessment tool And discussion guide for health services management and policy organizations
Improving the Science Policy Interface

Science Policy Interface (SPI) is the juncture at which the technical world of describing evidence and the world of decision makers interact

- Activities undertaken at Health Canada to improve integrating science into policy include:
  - Implementing the Health Canada’s Science and Technology Strategy through the Health Canada Science Plan
  - The annual Health Canada Science Forum
  - Health Portfolio SPI Workshops
  - Series of Health Canada-Canadian Institutes of Health Research (CIHR) Best Brains Exchanges
  - Development of a Health Canada-CIHR Science Policy Fellowships Program
  - Implementation of Health Canada S&T Foresight Program
  - Developing a science and regulatory program IM/IT strategy

Closing Remarks

- Effective regulation of food, health and consumer products and substances in the environment across the product lifecycle (R&D – market – disposal) contributes to health promotion and an effective health care system

- Regulators are challenged to rapidly incorporate new knowledge into decisions – SPI activities can help

- Improving our ability to access quality external evidence while targeting internal scientific studies to fill priority knowledge gaps will lead to better informed decisions (Health Canada Science Plan)
Closing Remarks, con’t

- Raising public awareness of important data sources so individuals can make effective health and lifestyle decisions is a common challenge given the current deluge of information.

- Processes such as publication and programmatic peer review, as well as continuous learning & mentoring contribute to data quality.

- Public policy involves many data sources, jurisdictions, and perspectives - partnerships and collaborative models are essential.