

Industry/Government Collaboration in Health Innovation February 17<sup>th</sup>, 2015

Summary report and recommendations



### **Preface**

The Federal Minister of Health, the Honourable Rona Ambrose, announced the creation of the Advisory Panel on Healthcare Innovation (Panel) on June 24, 2014, to examine innovative health care ideas and approaches that exist in Canada and internationally. The Panel's mandate is to identify promising innovations, here and internationally, which could help Canada reduce growth in health spending while improving the quality and accessibility of care<sup>1</sup>. It will also provide advice on how the federal government can better support those innovations.

The Institute of Health Economics (IHE), in partnership with the Healthcare Innovation Secretariat (which is supporting the Panel), held a roundtable in Toronto on February 17<sup>th</sup>, 2015, to help inform the Panel's recommendations. The purpose of the roundtable was to gather key informants from industry and the public sector to engage in informative discourse around the topic: Industry/Government Collaboration in Health Innovation.

"Access to high quality care is important to all Canadians. We need to work together across all sectors of society to harness the tremendous potential of innovation in healthcare and improve the responsiveness and sustainability of the healthcare system."

Rona Ambrose, Minister of Health

A survey was sent to participants prior to the meeting, and responses were summarized in a background document<sup>2</sup>, as a basis for further discussion. Respondents indicated a number of ways the federal government could help overcome barriers to the entry of needed innovation including improving legislation, increasing transparency, and incenting better provincial coordination and opportunities for system reform. Several examples of successful industry/government collaboration to facilitate the introduction of innovation were also outlined.

The meeting was held under the Chatham House rule, allowing ideas from the meeting to be used without attribution. This document summarizes key points and concrete recommendations from participants but does not represent a consensus view.

The roundtable hosted by the Institute of Health Economics was supported by, developed and delivered in partnership with Health Canada. The views expressed herein do not necessarily represent the official policy of Health Canada.

<sup>&</sup>lt;sup>1</sup> For more information on the Advisory Panel on Healthcare Innovation, please see the following link: http://news.gc.ca/web/article-en.do?nid=860909.

<sup>&</sup>lt;sup>2</sup> Please see Appendix A for a copy of the background document for this roundtable.



The objectives for the roundtable were to:

- Discuss the current and potential use of federal levers to support healthcare innovation.
- Deliberate opportunities and barriers for the federal government in engaging in the further development and application of healthcare innovation.
- Identify some directions and recommendations for the Advisory Panel on Healthcare Innovation's consideration.

The structure of the roundtable was as follows:

#### **Opening and Opening Remarks**

- Moderator: John Sproule, Senior Policy Director, Institute of Health Economics.
- Dr. Neil Fraser, President, Medtronic and Member for the Federal Advisory Panel on Healthcare Innovation.

**Topic 1:** How can governments and industry work better together to address key healthcare challenges?

**Topic 2:** How can the economic opportunities provided by a strong healthcare system be strengthened through greater government/industry collaboration?

**Topic 3:** What do you see as the main barriers to enabling industry and government to work more collaboratively to ensure that the most appropriate innovations are adopted/diffused by the healthcare system in a timely manner?

**Topic 4:** What would be the top three recommendations that you would like reflected in the Panel's report and why?

#### **Summary of Discussion**

#### **Closing Remarks**

#### **Roundtable Participants:**

Joshua Liu – Founder and CEO, Seamless MD

Sandy Schwenger – Co-Owner and CEO, Patient Care Solutions and M-Health Solutions

Shirley Sharkey – President and CEO, St. Elizabeth Hospital

Andrea Englert-Rygus – Vice-President, Operations, Plexxus

David O'Neil – General Manager, Zimmer

Geoff Fernie – Founder and CEO, Apnea Dx

Adalsteinn Brown – Director, Institute of Health Policy, Management, and Evaluation, University of Toronto

Jeff Ruby, Founder and CEO, Newtopia

William Falk, Managing Partner and National Leader of the Healthcare Services Group at PwC

Heather Chalmers, General Manager, GE Health Canada

Susan Fitzpatrick – Associate Deputy Minister, Health System Delivery & Implementation, Ministry of Health and Long-Term Care, Government of Ontario

## Advisory Panel on Healthcare Innovation:

Neil Fraser, Member of the Advisory Panel on Healthcare Innovation

Toby Jenkins, Member of the Advisory Panel on Healthcare Innovation

#### **Healthcare Innovation Secretariat:**

Marcel Saulnier, Executive Secretary to the Panel

David Clements, Executive Director, Healthcare Innovation Secretariat



### **Executive Summary**

Innovation is critical to ensuring a modern, efficient, patient-focused, quality directed healthcare system. Although the provincial/territorial governments are primarily responsible for the administration and delivery of healthcare services, the federal government has many levers that could facilitate an environment conducive to innovation development, implementation and utilization, including through legislative and policy levers such as intellectual property law, taxation, and regulation. The federal government is also both responsible for and the predominant funder of research and development across Canada.

To support forthcoming recommendations by the Advisory Panel on Healthcare Innovation<sup>3</sup>, the Institute of Health Economics (IHE) <u>www.ihe.ca</u>, in partnership with the Healthcare Innovation Secretariat, brought together a small group of Canadian industry and healthcare leaders in Toronto, Ontario on February 17<sup>th</sup>, 2015. The meeting was held under the Chatham House rule, which encouraged a free exchange of ideas by ensuring attribution of comments was not revealed

This document summarizes key points and provides high-level recommendations arising from discussions but does not represent a consensus view.

The Roundtable recommendations focus on key areas where the Federal government has levers for change:

#### Regulation:

- Remove barriers to personalized medicine Canada does not have legislation like the
  US Genetic Information Nondiscrimination Act (GINA) of 2008 that would assist in
  removing barriers to innovators in personalized medicine as it addresses concerns from
  patients around risks of discrimination or inappropriate use of genetic data.
- Incent value-based healthcare The federal government is in a position to create
  nationwide value-based standards including interoperability and data capture standards
  for information and communication technology, care pathways, outcomes from and
  prices for new services. The implementation of value-based standards can be attached
  to conditions within the Canada Health Transfer.
- Provisions for prototyping Making amendments and additions to existing device regulation to accelerate certain types of innovation. The introduction of a 510(k)-like provision, (premarket notification which allows faster regulatory approval) for example, could reduce barriers to prototyping and in-health-system testing.

#### **Coordination and Support for SMEs:**

 Monitoring and navigational support for industry - The Federal government should extend its efforts to help industry, including assisting small and medium-sized enterprises understand how healthcare is delivered across Canada and how innovation

<sup>&</sup>lt;sup>3</sup> For more information about the Panel, its terms of reference and its mandate please see Appendix A.



can be adopted and scaled within them (e.g., Concierge program, clear roadmaps and system navigation tools).

- Coordinating regional efforts to accelerate innovation The Federal government can
  provide support to the provinces to create innovation councils/coordinating mechanisms
  and programs similar to what is seen in Ontario and Alberta, while also creating
  standards, additional coordination or other types of needed support for these efforts.
- Supporting innovative procurement mechanisms The Federal government could
  provide direct support (training, benchmarking standards, conditional funding tied to
  better procurement practices) to provinces to accelerate already-identified and needed
  changes and coordinate existing procurement practices across provinces helping them
  move toward value-based procurement.

#### Research:

- Align incentives for innovation Canada needs to expand its efforts that encourage
  partnerships between companies and highly qualified academics. Of note, targeted
  research funding could be channeled through industry, rather than directly to
  researchers, to better align incentives for innovation and encourage aligned goals.
  Israel's stance or approach to industry-government relations was highlighted as a good
  example, deserving of further consideration.
- Show better leadership in science and technology The government requires better scientific leadership within its current science and technology portfolio including more direct access at the highest level of government decision-making. The federal government's current science and technology strategy was developed through Industry Canada and led by non-scientists.
- Promote linkage and information technology Realizing the full potential of commercial innovation requires real-world information. Federal health research funders can promote wider usage and interoperability standards in information and communication technology by making them a condition for funding.



### **Background**

Industry-led innovations in healthcare include medical devices and equipment, including laboratory equipment and diagnostics, as well as vaccines and drugs (pharmaceuticals and biologics). They also include high technology (i.e., information and communications technology) innovation that in turn allow for innovations in process and organization of care.

Due, in part, to spillover effects from commercialization, industry associations and their supporters have suggested commercialized product innovation is a key to healthcare sustainability<sup>4</sup>. This is also reflected in Canada's 10-year plan to strengthen health care, where "health innovation" from science and technology research is identified as a key activity. The recommendations cite productivity and cost-effective health care as a result of strategic investment in "health innovation":

"Investments in health system innovation through science, technology and research help to strengthen health care as well as our competitiveness and productivity. Investments in science, technology and research are necessary to develop new, more cost-effective approaches and to facilitate and accelerate the adoption and evaluation of new models of health protection and chronic disease management."

Innovation is critical to ensuring a modern, efficient, patient-focused, quality directed healthcare system. The provincial/territorial governments may be primarily responsible for the administration and delivery of healthcare services, but the federal government has many levers that could facilitate an environment conducive to innovation development, implementation and utilization, including through various legislative and other relevant policy levers such as intellectual property law, taxation, and regulation. The federal government is also both responsible for and the predominant funder of research and development across Canada.

The Advisory Panel on Healthcare Innovation (the 'Panel') was created on June 24<sup>th</sup>, 2014 by the Federal Minister of Health, the Honourable Rona Ambrose, and tasked to examine innovative health care ideas and approaches that exist in Canada and internationally.

The Panel's mandate is to:

1. Identify the five most promising areas of innovation in Canada and internationally that have the potential to sustainably reduce growth in health spending while leading to improvements in the quality and accessibility of care.

<sup>&</sup>lt;sup>4</sup> Gabriela Prada, Kelly Grimes, and Ioulia Sklokin, "Defining Health and Health Care Sustainability" (The Conference Board of Canada, 2014), http://www.conferenceboard.ca/e-library/abstract.aspx?did=6269; Brett J Skinner, "Drugs and the Public Cost of Healthcare in Canada, 1974-1975 to 2011-2012" (Canadian Health Policy Institute, November 2012), http://www.canadianhealthpolicy.com/research/full-text/drugs-and-the-public-cost-of-healthcare-in-canada.html; Larry Arshoff, "Transforming Innovation Procurement: A Call to Action to Ensure Sustainability of the Healthcare System" (Canadian Healthcare Network, Autumn 2013), http://www.medec.org/webfm\_send/2200.

<sup>&</sup>lt;sup>5</sup> Health Canada Government of Canada, "A 10-Year Plan to Strengthen Health Care - 2004 First Ministers' Meeting on the Future of Health Care - Main Page," agreement, (May 9, 2006), http://www.hcsc.gc.ca/hcs-sss/delivery-prestation/fptcollab/2004-fmm-rpm/index-eng.php.



2. Recommend the five ways the federal government could support innovation in the areas identified above.

For more information about the Panel, its terms of reference and its mandate please see *Appendix A*.

## IHE Industry/Government Collaboration in Health Innovation – Roundtable

The "Industry/Government Collaboration in Health Innovation – Roundtable" was established as an opportunity for private sector leaders in Canada to voice the biggest challenges and opportunities with commercialized innovation in Canada and to provide concrete recommendations to the Panel, to ultimately inform its deliberations and work.

In advance of the roundtable, IHE asked participants to answer a brief survey questionnaire about their experience with healthcare innovation in Canada, including the key barriers faced by their organization and what governments can do to address these barriers. This survey was used to help develop the following background document, to help inform and enrich "Industry/Government Collaboration in Health Innovation – Roundtable" discussions on February 17th.

Several key themes emerged from survey responses:

- Federal leadership: (coordinating and setting national standards and/or guideline, better coordinated process of innovation development and implementation, etc.)
- Relationship building: (greater communications and collaboration between sectors, federal facilitations in linking private/public partnerships, etc.)
- More incentives: (access to venture capital, innovation awards, innovation centres, etc.)
- Concerns with the procurement processes: (greater alignment opportunities to replace incumbents, etc.)
- System Reform: (hospital outsourcing, undertaking pilot projects, regulation reform, etc.)
- Clarification of Legislation: (Personal Health Information Protection Act)

Survey respondents also provided several examples of successful collaboration between industry and government. For a copy of the backgrounder that was provided to participants, please see *Appendix B*.

The roundtable was held in Toronto, Ontario on February 17<sup>th</sup>, 2015. The meeting was held under the Chatham House rule, which encouraged a free exchange of ideas by allowing information from the meeting to be used, while the identities and affiliation of participants are not revealed. This document represents a summary reflection of issues raised by participants and



does not necessarily represent a consensus view of the participants or of the organizations involved.

### **Purpose of this Report**

This report is a synthesis of the meeting discussion. It follows the structure of the meeting and outlines the key issues and recommendations that emerged as Roundtable participants reflected on the following key questions:

- 1. How can governments and industry work better together to address key healthcare challenges?
- 2. What are the key barriers, in your experience, to the uptake of commercialized innovation in the Canadian market?
- 3. What recommendations would like to see reflected in the panel's report?



## **Findings**

#### **General Themes**

The Roundtable recognized that the Federal government plays a limited direct role in the actual delivery of healthcare and the direct purchasing and acquisition of commercial innovation. With the vast majority of healthcare under the jurisdiction of the provinces, the Federal government has, in recent years, taken a less active role and is widely perceived as a means to financing health via the Canada Health Transfer program.

Despite this, the Roundtable recognized that there are clear opportunities for the Federal government to take leadership when it comes to industry-led innovation. Unlike the provinces, the Federal government has a unique "bird's-eye view" across Canadian and international health systems. It can also influence provincial innovation policy through the Canada Health Act, medical product regulation, trade agreements, funding of research, creation of new programs, and strategic funding of existing programs and organizations.

## Q1: How can governments and industry work better together to address key healthcare challenges?

Many participants noted that industry must already work at multiple levels of government as well as with providers of healthcare delivery at regional and local levels. The unique federated structure of the Canadian healthcare system means that for innovation to better address healthcare needs, it is not sufficient that industry work better with government but that different levels of government and the silos within them also work better together. This recognizes the need for any successful program to foster innovation to work across jurisdictions, rather than in isolation.

A starting place for the federal government would be to create a stronger culture of science and technology leadership. Roundtable participants noted that compared to other jurisdictions internationally, there is more limited knowledge of science and technology issues at higher levels in federal government. For example, the Government Chief Scientific Adviser in the UK (currently, Sir Mark Walport) plays an active role in crafting innovation and other policies related to innovation<sup>6</sup>. In stark contrast, Canada's National Science Advisor position was eliminated several years ago, with advice to government now provided by the Council of Canadian Academies<sup>7</sup>.

The federal government also has an opportunity to work more closely with industry on defining clear goals for innovation in healthcare including guidelines and roadmaps for what needs to be

<sup>&</sup>lt;sup>6</sup> "Professor Sir Mark Walport - GOV.UK," accessed March 24, 2015, https://www.gov.uk/government/people/mark-walport.

<sup>&</sup>lt;sup>7</sup> "Council of Canadian Academies | CCA | Independent Scientific Advice, Assessments & Publications," accessed March 24, 2015, http://www.scienceadvice.ca/en.aspx.



achieved. The unique system-wide view of the government also means it is better placed to directly work with small-to-medium enterprise innovators to navigate through the Canadian health system (or systems). Although some of this work is currently done through Industry Canada, more could be done.

## Q2: What are the key barriers, in your experience, to the uptake of commercialized innovation in the Canadian market?

Workshop participants identified several barriers to commercial innovation within Canada. Many participants identified general and specific issues related to medical product regulation. Firstly, participants noted that it is often much faster and less costly to obtain licenses to market medical device in other large markets, particularly the US and the EU. For example, the US 510(k) provision more greatly facilitates prototyping and leads to a greater proportion of devices reaching the US market and seeing faster approval<sup>8</sup>. The EU CE-marking process allows even faster uptake.

A more specific regulatory barrier noted was the absence of legislation similar to the US Genetic Information Nondiscrimination Act (GINA) of 2008<sup>9</sup> that is seen as a barrier to the development and uptake of personalized medicine innovations within Canada. This Act was developed to protect individuals from discrimination based on revealing genetic information through testing. Discrimination can take the form of insurers denying people coverage, or employers denying healthy individuals work, firing current employees, or denying workers compensation benefits on the basis of genetic information. Individuals may also face discrimination from clinical professionals, blood banks, and other public institutions. These protections make it easier for genetic information-based innovators, including commercialized product innovators of personalized therapeutics, to offer protection to patients while developing products within Canada. It also provides a better ability to partner with insurers, claims managers and information technology companies.

Other aspects of federal government device regulation were also discussed. This included (1) reluctance on part of the Federal government to accept regulatory standards from other international jurisdictions and (2) the significantly extra time taken by Health Canada to approve a new device compared to other similar jurisdictions, such as the US. As one participant noted, "in very few cases does Health Canada approval come ahead of the U.S. adoption." Although the Federal government's commitment to the Canada–United States Regulatory Cooperation Council and the integration of safety standards across jurisdictions was viewed as a positive development, implementation of its work plan is still ongoing and much needed.

<sup>8 &</sup>quot;510(k) Clearances," accessed March 24, 2015, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510 kClearances/.

<sup>&</sup>lt;sup>9</sup> "Public Law 110 - 233 - Genetic Information Nondiscrimination Act of 2008," accessed March 24, 2015, http://www.gpo.gov/fdsys/pkg/PLAW-110publ233/content-detail.html.



Much of the discussion focusing on barriers is centered on challenges with changing the health workforce model. Roundtable participants note that some innovation, such as *ehealth* or innovations that replace the need for healthcare labour are difficult to introduce as provinces and local care delivery organizations may require changes to legislation or service agreements before being able to effectively implement. Roundtable participants noted that small changes continue to happen but large system-wide changes to healthcare service roles is politically challenging and difficult as it disrupts the *status quo*.

"We are not having those conversations. It is the key barrier. There is not the economic or the business case conversation. These one-offs of virtual care and fee schedules that are all new, small, changes are not enough. It really warrants, I think, a workforce conversation. And we do not want to have those conversations because it could be a complete change-up of the economics of who is employed now in the system."

Roundtable Participant

Similar challenges were noted in current models of health research. One participant noted that pressures on research budgets has independent research funders such as the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council (SSHRC) more clearly defining their territories. This makes it very difficult to support things that cross the boundaries of engineering and medicine and even more difficult if it crosses SSHRC territory outside the formal medical

structure." Other Roundtable participants noted that the current process and structure of research funding also makes it very difficult to translate "an idea to something tangible. Specifically prototyping is very, very difficult to get funded in Canada."

The lack of alignment of provincial evaluation and procurement processes was also seen as a

potential barrier. Despite some alignment of procurement principles (such as the Agreement on Internal Trade and New West Partnership Trade Agreement), provinces still host unique processes that mean companies must go province by province (and in some cases hospital by hospital) to see uptake. Alignment of health technology assessment and procurement processes might reduce barriers to entry.

"We are not a single payer. We have more payers than anywhere else I go to."

- Roundtable Participant

# Q3: What recommendations would like to see reflected in the panel's report?

Given the opportunities for industry and government to collaborate and some of the potential barriers to innovation identified, the Roundtable participants focused on concrete recommendations that could be considered by the Federal Panel. The recommendations focus on key areas where the Federal government has levers for change:



#### Regulation:

Although there was some focus on medical device regulation at the meeting, including the need for better harmonization across jurisdictions and faster approval times, many participants quickly shifted to other aspects of regulation, including a highly variable reimbursement (called 'regulatory') environment across provinces and the need to protect consumers from discrimination when revealing genetic information.

- **Provisions for prototyping** A starting point would be to introduce more provisions to accelerate certain types of innovation in current Medical Devices Regulations through making amendments and additions. The introduction of a 510(k)-like provision, for example, could reduce barriers to prototyping and in-health-system testing.
- Remove barriers to personalized medicine Despite considerable investment in genome-based innovation and translational research through Genome Canada and the Canadian Foundation For Innovation, Canada has not created legislation like the US Genetic Information Nondiscrimination Act (GINA) of 2008, that would assist in removing barriers for innovators for the development and uptake of personalized medicine.
- Incent value-based healthcare The federal government is in a position to create
  nationwide value-based standards including interoperability and data capture standards
  for information and communication technology care pathways, outcomes from and prices
  for new services. This can further support provinces in making decisions regarding what
  and how services are reimbursed. The implementation of value-based standards can be
  attached to conditions within the Canada Health Transfer.

#### **Coordination and Support for SMEs:**

Participants agreed that market approaches, to what extent possible, were best for driving the development of commercialized innovation in Canada. Rather than government investment directly in industry-led product development, participants highlighted the need for education, coordination, and innovative procurement approaches. As one participant noted, "Governments and industry are not working together at all." All participants emphasized mechanisms for aligning incentives for innovation, rather than direct investments.

- Monitoring and navigational support for industry The Federal government should extend its efforts to help industry, including small and medium-sized enterprises understand how healthcare is delivered across Canada and how innovation can be adopted and scaled within them (e.g., Concierge program). This program should be tied to existing programs like those in Industry Canada and the Business Development Bank of Canada (BDC)
- Coordinating regional efforts to accelerate innovation The Federal government can
  provide support to the provinces to create innovation councils and programs similar to
  what is seen in Ontario and Alberta, while also creating standards, additional
  coordination or other types of needed support for these councils.



 Supporting innovative procurement mechanisms - The Federal government could provide support to provinces to accelerate already-identified and needed changes and coordinate existing procurement practices across provinces— helping them move toward value-based procurement.

#### Research:

Research bodies were seen as a legitimate role for the Federal government. Many participants noted that the current model of research funding is not well-enough aligned with the needs of business. A fundamental shift is needed by way of providing funding that recognizes the goals of commercial innovators.

- Align incentives for innovation Canada needs to expand its efforts that encourage
  partnerships between companies and highly qualified academics. Importantly, research
  funding should be channeled through industry rather than to researchers to better align
  incentives for innovation.
- Show better leadership in science and technology The government requires better scientific leadership within its current science and technology portfolio. Its current science and technology strategy was developed through Industry Canada and led by non-scientists.
- Promote linkage and information technology Realizing the full potential of commercial innovation requires real-world information. Federal health research funders can promote wider usage and interoperability standards in information and communication technology by making them a condition for funding.

### **Concluding remarks**

The Roundtable participants recognize that commercialized innovation is only one part of a larger body of innovation that may be needed by Canada's federated healthcare system now and in the future. However, better efforts to align health and industry policy will have a significant and positive impact on the health and wealth of Canadians now and in the future.

For more information about this summary report, please contact Jasmine Brown, Senior Policy Associate, The Institute of Health Economics at <a href="mailto:jbrown@ihe.ca">jbrown@ihe.ca</a>.



# Appendix A: Advisory Panel on Healthcare Innovation – Terms of Reference

Advisory panel on healthcare innovation - Terms of reference

#### Context

Canadians benefit from a healthcare system that provides access to high quality care, supports good health outcomes, and contributes to a healthy and productive workforce. But it needs to adapt to remain sustainable in the face of changing economic, demographic and technological pressures [Footnote1].

Canada's total spending on healthcare (public and private) currently stands at 11.2% of GDP, the fifth highest among Organization of Economic Co-operation and Development (OECD) countries. At the same time, Canada continues to lag other leading industrialized countries on key health system performance metrics of access and quality. Footnote2

There is an emerging consensus that more money is not the solution. As noted in a 2013 article published by the Institute for Research on Public Policy, problems related to access, quality and equity of healthcare in Canada remain, despite the doubling of real healthcare spending between 1997 and 2011 [Footnotes]. And with most provinces and territories already devoting upwards of 40% of their budget to healthcare, there is little room to increase healthcare funding without compromising other important public services.

Innovation is critical if the healthcare system is to continue delivering the high quality care Canadians expect at a cost that is affordable to society. This means breaking down barriers, tapping into creative minds, and working collaboratively to make better use of existing resources to improve services and outcomes for patients.

All jurisdictions have taken action to slow the growth in health spending and have started to focus and align their innovation efforts. Provinces and territories are implementing innovations in healthcare both individually and collectively. For its part, the Government of Canada is providing significant support for healthcare innovation through the Canada Health Transfer, research funding and other targeted health initiatives (see Annex 1). Federal health transfers are now on a long-term growth track that is fiscally responsible and provides financial certainty for provinces and territories to plan around their health needs.

As jurisdictions accelerate their efforts to transform their healthcare systems to achieve the "triple aim" of improving patient care and health outcomes while reducing costs, it is time to take stock of where progress has been made in Canada and around the world. This is essential if we are to accelerate the pace of healthcare innovation and ensure the long-term sustainability of Canada's healthcare system.

#### **Key elements**

#### **Mandate**



- The Minister of Health will strike a time-limited Advisory Panel on Healthcare Innovation.
- The Panel will:
  - 1. Identify the five most promising areas of innovation in Canada and internationally that have the potential to sustainably reduce growth in health spending while leading to improvements in the quality and accessibility of care.
  - 2. Recommend the five ways the federal government could support innovation in the areas identified above.

#### 2. Guiding Principles

- In carrying out its mandate, the Panel will be guided by the following principles:
  - Respect for jurisdictional roles: The Panel will be mindful of and respect federal and provincial/territorial jurisdictions in health and will focus its recommendations on areas of federal responsibility.
  - Evidence-based: The Panel's work should be guided by the best evidence on what works.
  - Support for healthcare values: Innovation should not compromise core healthcare principles as set out in the Canada Health Act.
  - Avoiding duplication of effort: The Panel will not duplicate the work of other bodies in related fields of inquiry, such as the Council of the Federation's Health Care Innovation Working Group and the work of the *Independent Panel on* Federal Support to Research and Development (the "Jenkins Panel", 2010).
  - Fiscal responsibility: The Panel's recommendations must not imply either an
    increase or a decrease in the overall level of federal funding for current initiatives
    supporting innovation in healthcare. The recommendations must also not result
    in increasing spending pressure on provincial and territorial budgets.

#### 3. Panel Governance, Term and Composition

- The <u>Panel</u> is established as an ad-hoc Advisory Body, pursuant to *Health Canada's Policy on External Advisory Bodies*, 2011 with a limited term of one year.
- The Panel is headed by David Naylor as Chair, who is responsible for ensuring the Panel mandate is fulfilled and reporting back to the Minister throughout the Panel's review, as needed, and at its conclusion.
- The other members of the Panel are:
  - Cyril Frank
  - Neil Fraser
  - Francine Girard
  - Toby Jenkins
  - Jack Mintz
  - Chris Power
- The Panel Chair may select a Vice-Chair from the Panel members to help him with the Chair's duties.

#### 4. External engagement

• To ensure that the work of the Panel is informed by provincial and territorial perspectives, the Panel should meet as required and as requested with provincial and territorial representatives throughout the process, i.e., Ministers; Deputy Minister



- Steering Committee on Healthcare Innovation (Alberta, PEI, Yukon, Health Canada); Strategy for Patient-Oriented Research (SPOR) National Steering Committee.
- Given the importance of international perspectives in its work, the Panel may travel abroad to meet with international experts and learn from best practices in healthcare innovation. The Panel may also invite international experts to travel to Canada to engage in its deliberations.
- The Panel should also meet with representatives of healthcare professionals for their perspectives.
- Panel outreach and engagement should additionally draw upon a wide range of perspectives including:
  - Patients and consumers
  - Businesses and industry representatives
  - o Innovators and entrepreneurs
  - o Representatives of key health system stakeholders
  - First Nations leaders
  - o Experts across a range of relevant specialities
  - Other relevant federal advisory bodies (e.g. Jenkins Panel; Science, Technology and Innovation Council)

#### 5. Panel Process

#### Deliverables

• The Panel will provide an interim report in January 2015 and a final report at the Panel's conclusion, no later than by May 31, 2015.

#### Panel Activities

- In order to advance its work, the Panel could undertake a range of activities including:
  - In camera discussions to exchange perspectives, establish a shared understanding of issues, identify key themes, and develop advice
  - Meetings with the Minister at key milestones to receive direction and exchange views on key topics for further exploration (e.g. at launch, once outreach and information gathering is completed, and, upon completion of report)
  - Commission papers synthesising knowledge and providing analysis of selected themes and issues
  - Participate in site visits in Canada and internationally and host small group meetings to explore leading practices and facilitate dynamic engagement with a mix of experts
  - Invite guests with experience and expertise in key areas and issues to make presentations to, and engage in dialogue with, them
  - Prepare interim reports to the Minister on emerging findings and/or specific themes, as well as a final report with conclusions and advice in accordance with its mandate.

#### 6. Funding and Administrative Support

Funding and administrative support will be provided by Health Canada.



#### **Annex 1**

#### Federal Support for Healthcare Innovation

The Government of Canada's significant support for healthcare has laid a strong foundation for innovation upon which further efforts can build.

- 1. With the renewal of the Canada Health Transfer (CHT), the federal government has put funding for healthcare on a predictable and stable growth track. The CHT will continue to increase by 6% per year through 2016-17, and will grow at the rate of GDP growth (with a 3% floor) starting in 2017-18. The federal contribution through the CHT continues to rise annually, and by the end of the decade will surpass \$40 billion.
- 2. The Government of Canada also invests \$1 billion a year in research, which serves as an important catalyst for innovation. In particular, the Strategy for Patient-Oriented Research (SPOR) is helping to align research, innovation and health system needs through collaborations with provinces and territories. Other CIHR initiatives such as its Community-Based Primary Healthcare Initiative and Evidence-Informed Healthcare Renewal are also helping to provide evidence to support healthcare policy decision-making.
- 3. The federal government also provides other important support for healthcare innovation through organizations such as Canada Health Infoway, the Canadian Foundation for Healthcare Improvement (CFHI), the Canadian Agency for Drugs and Technologies in Health (CADTH), the Canadian Institute for Health Information (CIHI), and various Health Canada initiatives and programs. Healthcare innovation is also supported more widely through the Canada Foundation for Innovation, the National Research Council, Genome Canada, other granting councils and economic development agencies.
- 4. In addition, the Government of Canada provides important support for innovation in healthcare for First Nations communities. Budget 2013 provided predictable funding to maintain existing investments in connectivity and expand electronic health services in remote and isolated First Nations communities, as well as increasing the number of accredited health facilities.

#### **Footnotes**

#### Footnote 1

Dodge, David and Richard Dion, "Chronic Healthcare Spending Disease: A Macro Diagnosis and Prognosis", CD Howe Institute No. 327, April 2011

#### Return to footnote1referrer

#### Footnote 2

2013 Commonwealth Fund International Health Policy Survey; 2012 Commonwealth Fund International Survey of Primary Care Doctors

#### Return to footnote2referrer

#### Footnote 3

Lewis, Steven and Terrence Sullivan, " How to Bend the Cost Curve in Health Care", IRPP Insight, May 2013, No. 1



## **Appendix B: Roundtable Background Document:**

Industry/Government Collaboration in Health Innovation - Roundtable February 17<sup>th</sup>, 2015

**Background Document** 



#### Preface:

The federal Minister of Health, the Honourable Rona Ambrose, announced the creation of the Advisory Panel on Healthcare Innovation (Panel) on June 24, 2014, to examine innovative health care ideas and approaches that exist in Canada and internationally. The Panel's mandate is to identify promising innovations, here and internationally, which could help Canada reduce growth in health spending while improving the quality and accessibility of care. <sup>10</sup> It will also provide advice on ways in which the federal government can better align its initiatives to support those innovations.

The Institute of Health Economics (IHE), in partnership with Health Canada (HC), will hold a roundtable in Toronto on February 17<sup>th</sup>, 2015, to help inform the aforementioned Panel's recommendations. More specifically, the purpose of the roundtable is to gather key informants from industry and the public sector to engage in informative discourse around

"Access to high quality care is important to all Canadians. We need to work together across all sectors of society to harness the tremendous potential of innovation in healthcare and improve the responsiveness and sustainability of the healthcare system."

- Rona Ambrose, Minister of Health

the topic: *Industry/Government Collaboration in Health Innovation*, which will be summarized in a report to the Panel.

The background material following is presented to provide general informational support, upon which discourse for the roundtable can be built. Materials presented below are not all encompassing and discourse may go beyond the particular details or general themes highlighted in this brief.

<sup>&</sup>lt;sup>10</sup> For more information on the Advisory Panel on Healthcare Innovation, please see the following link: http://news.gc.ca/web/article-en.do?nid=860909



#### **Executive Summary:**

Innovation is a critical to ensuring a modern, efficient, patient-focused, quality directed healthcare system. Although the provincial/territorial governments are primarily responsible for the administration and delivery of healthcare services, the federal government has many levers that could facilitate an environment conducive to innovation development, implementation and utilization, including through legislative and policy levers such as intellectual property law, taxation, and regulation. The federal government is also both responsible for and the predominant funder of research and development across Canada.

The Advisory Panel on Healthcare Innovation was created on June 24<sup>th</sup>, 2014 by the federal Minister of Health, the Honourable Rona Ambrose, and tasked to examine innovative health care ideas and approaches that exist in Canada and internationally.

#### The Panel's mandate is to:

- 1. Identify the five most promising areas of innovation in Canada and internationally that have the potential to sustainably reduce growth in health spending while leading to improvements in the quality and accessibility of care.
- Recommend the five ways the federal government could support innovation in the areas identified above.

For more information about the Panel, its terms of reference and its mandate, please see *Appendix A*.

The "Industry/Government Collaboration in Health Innovation – Roundtable" provides an exciting opportunity for private sector leaders to voice their biggest challenges and opportunities in innovation to the Panel, which will ultimately inform its deliberations and work.

In advance of the roundtable, IHE asked participants to answer a brief survey questionnaire about their experience with healthcare innovation in Canada, including the key barriers faced by their organization and what governments can do to address these barriers. This survey was used to help develop the following background document, to help inform and enrich "Industry/Government Collaboration in Health Innovation – Roundtable" discussions on February 17<sup>th</sup>.

Several key themes emerged from survey responses:

- Federal leadership: (coordinating and setting national standards and/or guideline, better coordinated process of innovation development and implementation, etc.)
- Relationship building: (greater communications and collaboration between sectors, federal facilitations in linking private/public partnerships, etc.)
- More incentives: (access to venture capital, innovation awards, innovation centres, etc.)
- Concerns with the procurement processes: (greater alignment opportunities to replace incumbents, etc.)
- System Reform: (hospital outsourcing, undertaking pilot projects, regulation reform, etc.)
- Clarification of Legislation: (Personal Health Information Protection Act)



• Greater access to information and data: (global product registry, direct to patient education, etc.)

Survey respondents also provided several examples of successful collaboration between industry and government. These examples are listed on page 15.

In addition to the aforementioned survey, participants should be prepared to answer the following questions at the "Industry/Government Collaboration in Health Innovation – Roundtable" on February 17<sup>th</sup>:

- 1. Governments are increasingly concerned about the sustainability of the healthcare system, including how best to improve the quality of care while reducing costs. In this context, how can governments and industry work better together to address these key healthcare challenges?
  - E.g., what is the role of the private sector in supporting government disinvestment decisions regarding low-value products/tools, processes and services?
  - E.g., what is the role of industry in ensuring that governments have access to transparent evidence and evaluations that would support their decision-making process?
  - Are there other examples?
- 2. How can the economic opportunities provided by a strong healthcare system be strengthened through greater industry/government collaboration?
- 3. What do you see as the main barriers to enabling industry and government to work more collaboratively to ensure that the most appropriate innovations are adopted/diffused by the healthcare system in a timely manner?
- 4. What would be the top three recommendations that you would like reflected in the Panel's report and why?

The event will follow Chatham House rule and respondent's individual comments will be confidential but key issues raised will be summarized in a summary report.

The summary report will be submitted to the Federal Healthcare Innovation Advisory Panel once completed.



#### **Background Brief:**

Canadians have come to expect a high quality, high performing healthcare system that leads to strong health outcomes, and fosters a healthy and productive populous and workforce.

Canada spends 11.2% of GDP on public and private healthcare and is deemed the fifth highest in health care expenditure in the OECD, but lags in performance metrics for access and quality of care in comparison with other industrialized leaders. Restraining the growth of spending is imperative to ensure the sustainability of the system, while ensuring improvements are made on the quality of delivery of care.

Increased longevity is largely a sign of success of past efforts in innovation, but the Canadian population is younger than many other comparator countries and our spending levels for this demographic does not bode well for future management of costs with an aging population. Seniors are the largest user group of healthcare services and have the greatest per capita spending per hospital visit than any other demographic. There is also growing evidence of the need for increased early intervention and investment in children to create a 'healthy life trajectory'. Investments in this area will only be possible if we are able to more effectively manage the growth of overall health spending.

#### **Defining Healthcare Innovation:**

Healthcare innovation can be defined as "...the introduction of a new concept, idea, service, process, or product aimed at improving treatment, diagnosis, education, outreach, prevention and research, and with the long term goals of improving quality, safety, outcomes, efficiency, and costs." It should be thought of as a gradient measure, "...rather than a binary concept where something is or is not innovation," as there are many variations in defining or describing what innovation is.

As innovation is a critical component of business productivity and competitive survival, <a href="healthcare">healthcare</a> innovation can improve the way services are delivered, which in turn may increase quality, efficiency and the cost effectiveness of the health care system. Efficient and innovative healthcare systems, in turn, support a healthy populous, that not only increases productivity, but also stimulates economic growth and prosperity<sup>15</sup>.

<sup>&</sup>lt;sup>11</sup> Canadian Institute for Health Information, *Health Care Cost Drivers: The Facts. Ottawa: Canadian Institute for Health Information*, (2011), extracted from

https://secure.cihi.ca/free\_products/health\_care\_cost\_drivers\_the\_facts\_en.pdf.

<sup>&</sup>lt;sup>12</sup> Canadian Institute for Health Information, "National Health Expenditure Trends, 1975 to 2013," (2013), extracted from <a href="https://secure.cihi.ca/free\_products/NHEXTrendsReport\_EN.pdf">https://secure.cihi.ca/free\_products/NHEXTrendsReport\_EN.pdf</a>.

Omachonu, Vincent K., Einspruch, Norman G., "Innovation in Healthcare Delivery Systems: A Conceptual Framework," *The Innovation Journal: The Public Sector Innovation Journal*, Vol. 15(1), 2010.
 Http://www.htai.org/fileadmin/HTAi\_Files/Policy\_Forum\_Public/HTAi\_Policy\_Forum\_Background\_Paper 2013.pdf

<sup>&</sup>lt;sup>15</sup> Department of Health, NHS Improvement & Efficiency Directorate, Innovation and Service Improvement, "Innovation Health and Wealth: Accelerating Adoption and Diffusion in the NHS," *NHS Chief Executive Innovation Review: Call for Evidence and Ideas*, (Dec 2011).



#### **Patient-Centered Innovation:**

Provinces and territories are increasingly adopting "patient-centered" approaches to healthcare in their jurisdictions, including innovations in how we organize, fund and deliver services. The health system, however, can be criticized as being slow to adopt measures which would increase productivity through information technology or consumer/people/patient participation in their own health care and self-management.

It is estimated that about 5% of the population utilize 65% of resources and most of those would greatly benefit from completely new models to organize services to them. There are however, significant organizational barriers to implement best evidence, a lack of real-time point of service information supports and a lack of targeted market segmentation in the health system.

While more logical design of delivery models and incentives are important it must always be remembered that a key solution to sustainability

remembered that a key solution to sustainability
will be through the advancement of science and technology

will be through the advancement of science and technology. It is through such healthcare innovation that we may find methods for enhancing life expectancy, quality of life, and diagnostic and treatment options.

# "For patients, the most important determinant of value is improvement in the length and/or quality of their life.

Survival, freedom from pain, and the ability to undertake activities of daily living are therefore fundamental, but patients may also value choice; convenience; reduced financial and other burdens for them, their caregivers, family, or society; and increased certainty about diagnosis or outcomes."

#### Overview thoughts/issues for consideration:

#### **Regulatory Environment:**

The primary role for regulation for the federal government is in market authorization for medical technologies (safety and product claims), regulation of commercial business practices and in ensuring patent protection for innovators. Timeliness of such processes becomes a significant concern for innovative companies to capture return on investment in a short product life-cycle. Differences in evidentiary demands between regulators and health system managers is becoming an increasing point of interest and approaches are being looked at to harmonize and standardize such requirements globally, provide early advice to inform these evidentiary requirements for trial design and to promote early dialogue to ensure innovators are well aware of expectations of health system decision-makers. The provincial governments are responsible for the delivery of health care, establish standards/rules for payment and use and play a major role in the regulation of health professionals - defining scope of practice, and mechanisms to steer usage of new innovations. True innovation comes from wise application and appropriate system use.

Procurement and related issues (e.g., evaluation, pricing, reimbursement, etc.) .

For pharmaceuticals there are well-established processes in Canada for evaluation of drugs. Provinces and the federal government participate in supporting the Common Drug Review which provides a centralized approach for clinical and cost-effectiveness assessment. Provinces have established a Pan-Canadian Pricing Alliance to negotiate "Canadian public system" price deals on specific products. This has been mostly price-volume agreements but some work for



more innovative outcomes based agreements is underway nationally and in certain provinces to allow ongoing adaptation of usage or price based on real-world data gathering. Procurement is highly variable in terms of medical devices depending on the location of use (hospital or community/primary care setting) and the type of technology (drugs or devices). On a provincial level, Ministries provide health authorities and hospitals with funding and the individual organizations enter into purchasing agreements with innovative companies. Group purchasing arrangements occur between hospitals, regions or provinces to leverage negotiating power during purchasing activities. For example, Alberta, BC and New Brunswick have used Group Purchasing Organizations (GPOs) to conduct procurement. There are also Shared Service Organizations within hospital groups, which provided pooled services. As with pharmaceuticals, medical device companies are looking for more innovative agreements beyond price-volume where value and outcomes are more appropriately addressed.

#### **Existing funding/incentive models:**

Funding and incentive models are not seen by many in health care as being flexible enough to account for the full value of innovation across the full health care journey. A key issue is 'silo budgeting' - where investments in one part of the system produce value in another part of the system. Different funding models which cross silos of care or move to more outcomes-based funding approaches are in development. Another is the issue of 'uncertainty' – where either clinical outcomes, clinical use or budget impact are uncertain for payers and the return on investment is uncertain for innovators. We have primarily global budgets for hospitals which control expenditures through reducing capacity and fee-for-service systems in physicians' services which reward activity. In order to reward outcomes and value there needs to be investment in evidence generation and integrated data systems and development of pricing structures that appropriately recognize value. Given the closed budget within a publicly funded system – there is also great difficulty in extracting resources from outmoded technologies and cost structures. New mechanisms which would allow reassessment and removal of obsolete processes and technologies are needed.

#### Role of health professionals (e.g., clinicians, nurses, pharmacists, technicians etc.):

Health professionals in Canada have significant influence on the uptake of new innovations and practices in the health system. Clinical, and in particular physician, endorsement for new technologies and practices is essential for successful uptake. They can also present a barrier innovations significantly impact current standard of care and the business model for providers. In some cases new technologies require new professional roles to support use, can change existing workflow, or even eliminate positions. This is particularly true for therapeutic medical devices and diagnostics which rely heavily on appropriate and skilled use. An area of particular interest is in the area of precision or personalized medicine which combines a diagnostic with a therapeutic intervention – often made by different companies and having different pathways to reimbursement. The skills required to access this new genetic information may require new professional roles in the health system to support providers and patients in making choices.

#### **Existing government/industry partnership models:**



There are attempts underway across the country and internationally to establish new partnership models for how industry and governments collaborate across the life cycle of innovation. Past activities have been mainly focused on health system regulatory approval and assessment for adoption purposes (through HTA and other processes). Countries are realizing they have to move earlier in the life cycle to inform development through joint identification between public and private partners on what issues require innovation and further in the life cycle to support ongoing real world evidence generation that could inform obsolescence, adaptive pricing, adaptive restrictions on use. The MaRS EXCITE Program is an example of government/industry process collaboration that aims to accelerate pre-regulatory evidence generation, to help meet regulatory and reimbursement requirements, expedite market penetration and mitigate rejection risks. Another example is the UK Innovation, Health and Wealth program, which sought to identify in public/private partnership high impact innovations that addressed commonly agreed areas of need, and numerous examples of early dialogue, early access schemes and new procurement models. The Ontario Health Technology Advisory Committee (OHTAC), the Alberta Health Technology Decision Process and the activities of INESS in Quebec are examples of formal advisory structures with members from government, health professionals, association representatives and industry.

#### **Current Environment Overview:**

Unfortunately, the approval, adoption and protection processes for healthcare innovation in Canada can be slow, costly, and unpredictable, which means we may not be realizing its full potential. "Innovative technologies play a key role in improving health care, but the innovative process is too risky and expensive, so it is important that innovative technologies are properly valued and rewarded." The Canadian regulatory process is often deemed a substantial barrier to the adoption of innovation. 17

With respect to product innovation, there are some products that are real breakthroughs, with a dramatic improvement of survival or outcomes. There are other examples where improvement in outcomes relies on small, stepwise improvements, which add up to significant improvements overtime. This leads to controversy over the appropriate valuation of each of the incremental steps, largely reflected in difficult pricing negotiations and demonstrating the need for more innovative and nuanced approaches to reimbursements to address uncertainty of evidence at the time of launch.

Innovative technologies may also deliver value, through cost saving measures, and/or advances in safety or reliability to the healthcare system itself. Ensuring patients have access to new therapeutic developments is essential for such step-wise progress to occur. This need must be supported through appropriate investments to allow such advancements to take place.

<sup>&</sup>lt;sup>16</sup> Henshall and Schuller, "*Health Technology Assessment, Value-Based Decision Making, and Innovation*," International Journal of Technology Assessment in Health Care, 29:3 (2013) pg 3.

<sup>&</sup>lt;sup>17</sup> Hall, Linda, Bagchi-Sen, Sharmistha, "A study of R&D, innovation, and business performance in the Canadian biotechnology industry," Technovation 22 (2002) 231-244.

<sup>&</sup>lt;sup>18</sup> Example: breast and colon cancer are good examples of modest gains through incremental innovation over 10-15 years that resulted in significant improvement.



For informational diagrams on the decision making process for pharmaceuticals and medical devices and diagnostics, please see *Appendix B* and *Appendix C* attached.

#### Federal-Provincial Responsibility:

The roles and responsibilities for Canada's healthcare system are shared between the federal and provincial or territorial governments. The provincial and territorial governments have primary jurisdiction in the administration and delivery of health care services. This includes setting their own priorities, administering their health care budgets and managing their own resources. The federal government, under the *Canada Health Act*, sets out the criteria and conditions that must be satisfied by the provincial and territorial health insurance plans for provinces and territories to qualify for their full share of the cash contribution available to them under the federal Canada Health Transfer.

The Canada Health Transfer and the Canada Social Transfer: The federal government provides funding through cash and tax transfers to the provinces for healthcare services. The main transfers are the Canada Health Transfer (CHT) and the Canada Social Transfer (CST), made through block funding to support health, post-secondary education and social services. The provincial and territorial governments are entitled to use CHT and CST funding to meet their respective priorities, which differ throughout the country.

#### The Council of the Federation:

The Council of the Federation is composed of all provinces and they have established The Health Care Innovation Working Group (HCIWG) which is currently led by Prince Edward Island Premier Robert Ghiz, Ontario Premier Kathleen Wynne and Yukon Premier Darrell Pasloski. Members of the HCIWG include all provincial and territorial Ministers of Health. The HCIWG focuses on innovation to enhance provincial and territorial capacity in order to better meet existing and emerging challenges in our health care systems. First established in 2012, and initially led by Saskatchewan Premier Brad Wall and Prince Edward Island Premier Robert Ghiz, the mandate of the working group was extended for a further three years in July 2013.

The work of the HCIWG is focused on three priority areas:

- 1. **Pharmaceuticals** Over the past year, the working group has achieved a number of successes, including lowering the cost of pharmaceutical drugs and combined annual savings of over \$260 million.
  - a. <u>Brand Name Drug Products</u> <u>The pan-Canadian Pharmaceutical Alliance</u> (pCPA) conducts joint provincial/territorial negotiations for brand name drugs in Canada to achieve greater value for publicly funded drug programs and patients. As of August 2014, 43 joint negotiations have been completed through this process.
  - b. <u>Generic Drug Products</u> As of April 2014, 10 commonly-used generic drugs have been reduced in price.
- 2. Appropriateness of Care, including Team-based Health Care Delivery Models There is mounting evidence that some patients receive treatments that may not be best suited for their actual needs. The working group will look at appropriateness of care in several areas and will examine opportunities within the team-based model framework to increase the important role paramedics and pharmacists play in the provision of front line services.
- 3. **Seniors Care** The working group will look at successful efforts to prioritize homecare over long-term care institutionalization and identify two to three innovative models for



provinces and territories to consider adapting. In addition, the HCIWG will examine aging in place and issues related to dementia, including identifying best practices for early diagnosis.

For more information about the Health Care Innovation Working Group, please see the following link: <a href="http://www.councilofthefederation.ca/en/initiatives/128-health-care-innovation-working-group">http://www.councilofthefederation.ca/en/initiatives/128-health-care-innovation-working-group</a>.

#### **Health Policy Leaders and Influencers:**

The federal levers from which the public sector can draw from to support innovation are varied. In addition to numerous legislative and policy levers, such as intellectual property law, tax, and regulation, the federal government is both responsible for and the predominant funder of research and development. There are also several national agencies, including CIHI, CADTH, and CIHR, which support health innovation at a national level.

Some examples are the following:

- Health Canada: Health Canada is the federal department responsible for helping Canadians maintain and improve their health, while respecting individual choices and circumstances. It also regulates the introduction of new technology and administers the Canada Health Act. (www.hc-sc.qc.ca
- Other Federal Ministries involved in healthcare – Department of National Defense (Canadian Forces Health Services Group), Correctional Services Canada (Health Services), and Veterans Affairs Canada (Health Care Benefits).
- Setting and administering national principles for the health care system.

  Assisting in the financing of provincial/territorial health care services to specific groups (e.g., First Nations, veterans).

Based on text from Health Canada: www.hc-sc.gc.ca

- There are several national agencies. (e.g., CIHI, CADTH, CIHR, CFHI, CHI, PMPRB) and pieces of legislation which support and/or regulate health innovation.
  - O Canadian Institute for Health Information (CIHI): CIHI engages in the development of comprehensive and integrated health information that informs pulled and health system management. (www.cihi.ca).
  - Canadian Agency for Drugs and Technologies in Health (CADTH): CADTH provides health care decision-makers with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies. (<a href="https://www.cadth.ca">www.cadth.ca</a>).
    - Common Drug Review (CDR): CDR is a pan-Canadian process for conducting objective, rigorous reviews of the clinical effectiveness and cost-effectiveness, as well as reviews of patient input for drugs and providing formulary listing recommendations to Canada's publicly funded drug plans, excluding that of Quebec.



- The Canadian Drug Expert Committee (CDEC) is an advisory body to CADTH composed of individuals with expertise in drug therapy, drug evaluation and drug utilization, and public members to bring a lay perspective.
  - As part of CADTH's Common Drug Review (CDR) process, CDEC makes recommendations to each of the participating federal, provincial, and territorial publicly funded drug plans regarding the listings on their formularies. It also makes recommendations related to the identification, evaluation, and promotion of optimal drug prescribing and use in Canada.
- The pan-Canadian Oncology Drug Review (pCODR): pCODR is an evidence-based, cancer drug review process. The pCODR process is designed to bring consistency and clarity to the assessment of cancer drugs by reviewing clinical evidence, cost-effectiveness, and patient perspectives, and using this information to make recommendations to Canada's provinces and territories (except Quebec) in guiding their drug funding decisions.
- Canadian Institutes of Health Research (CIHR): CIHR is Canada's federal funding agency for health research. Composed of 13 Institutes, CIHR provides leadership and support to more than 13,200 health researchers and trainees across Canada. (www.cihr-irsc.gc.ca).
- Canadian Foundation for Healthcare Improvement (CFHI): CFHI supports healthcare leaders from different jurisdictions to work together on common improvement priorities, providing opportunities to share and implement evidence-informed solutions across regions, provinces and territories. (<u>www.cfhi-fcass.ca</u>).
- Canadian Health Infoway (CHI): CHI works with the health care community, Canadians, government, and the technology industry to improve access to health information for better care in Canada. Of note, there are concerns that progress to implement electronic health record infrastructure will be seriously jeopardized without renewal of funding for Canada Health Infoway. Provincial and Territorial Health Ministers have announced that they are united in calling for the federal government to renew funding for Canada Health Infoway.
- Patented Medicine Prices Review Board (PMPRB): PMPRB ensures that the prices of patented medicines sold in Canada are not excessive and reports on pharmaceutical trends. (www.pmprb-cepmb.gc.ca).
- The Patent Act: is one of the main pieces of Canadian legislation governing patent law in Canada. As such, it sets a framework for intellectual property protection in Canada. It sets out the criteria for patentability, what can and cannot be patented in Canada, the process for obtaining a Canadian patent, and provides for the enforcement of Canadian patent rights.
- The federal government's National Research Council's Industrial Research Assistance Program (IRAP) program provides early funding for research and development to small and mediumsized Canadian businesses.
- The Scientific Research and Experimental Development Tax Incentive Program (SR&ED) is a federal tax incentive program, administered by the Canada Revenue Agency (CRA), which



encourages Canadian businesses of all sizes, and in all sectors to conduct research and development (R&D) in Canada. The SR&ED Program gives claimants cash refunds and / or tax credits for their expenditures on eligible R&D work done in Canada.

- International trade can be used as a lever strengthening intellectual property protection legislation was recently highlighted in the Comprehensive Economic Trade Agreement (CETA) between the European Union and Canada.
- The federal government can increase capacity of Canada's regulatory agencies to help increase the speed of the regulatory approval system. Or they can also iron out inefficiencies in the approval process by ensuring that there are no duplication of services (e.g. the "one project, one review" approach to environmental regulations).
- National strategies can be created and outlined by the federal government, similar to the Science and Technology Strategy at Industry Canada, outlining federal priorities and intent, which can stimulate growth and investment.
- The Federal government has the power to commission surveys and reports through Statistics Canada. Information derived from those surveys could, in turn, inform policy that would lead to process innovation, etc.



#### **Pre-Roundtable Survey Responses:**

Pre-roundtable surveys were sent out to participants in advance of the Industry/Government Collaboration in Health Innovation – Roundtable, to gather a preliminary temperature on some of the overall issues that industry is currently facing on advancing healthcare innovation. The summary below is not all encompassing. Dialogue at the roundtable may build upon the considerations outlined below, or participants may choose to raise other thoughts or concerns altogether. If any details from survey responses were missed, please do not hesitate to raise or elaborate on your thoughts at the meeting on February 17, 2015.

#### A call for leadership:

A call for greater leadership from the federal government in healthcare innovation was reiterated throughout most of the survey responses provided by participants. Healthcare regulation, legislation and overall health policy largely exists in silos, divided by provincial boundaries. This approach is disjointed and proves to be burdensome and/or unmanageable for industry as they attempt to implement valuable innovation across the country. A call to action for federal leadership, to unite and harmonize policy and standards across provincial boundaries, was reiterated throughout many survey responses.

- There tends to be piecemeal adoption of new technologies/solutions, nationally and within provinces, rather than system wide implementation.
- There should be national standards and guidelines in certain areas of healthcare, including reimbursement and clinical guidelines.
- The process of innovation development and implementation in Canada is largely disjointed amongst provinces. Although there are many statements on using procurement as a tool for
  - innovation that circulate from various government committees federally and provincially, there seems to be no concerted effort for action that crosses provincial boundaries. There is a need for a system that flows through pre-market assessment, to acceptance of products into the healthcare systems, and onward to procurement. The federal government could provide leadership in this regard.

"The speed to the first order from the home market is one of the most important factors determining the survival and success of Canadian start-ups in health and medical technology."

- Roundtable Participant
- It was also recommended that Federal/Provincial/Territorial Ministers of Health and Science and Technology send a clear message to the technology assessment, reimbursement and procurement elements of their systems, that they must develop and implement a coordinated pathway quickly that benefits Canadian innovation. It is difficult to navigate individual systems, therefore, some sort of mechanism, such as a road-map or check-list to maneuver different Ministries or go-to organization to help champion or navigate the system for industry is also endorsed.
- The MaRS Excellence in Clinical Innovation Technology Evaluation (EXCITE) program in Ontario was highlighted as a helpful example that has had progress in starting to conduct pre-market evaluations with the intention of shortening the time for innovations to be accepted into the healthcare system.



## Relationships need to be better fostered between industry, government, and other leading policy makers in healthcare...

An open dialogue is essential to discuss methods and ways to evaluate new technology and its implementation in Canada. There is an apparent fissure between policy makers within different sectors that hinders the ability for all proponents to work together efficiently. This issue also spans the healthcare organizational chain, from the ground-up.

- Public, private and voluntary sectors need to communicate and work in collaboration with one another to build on each other's weaknesses and strengths. There needs to be openness from government officials to discuss new technologies and innovations.
- Federal and provincial governments should recognize that public organizations and systems cannot lead innovation. They need to partner with external players and industry, and value/leverage their complementary strengths.
- Government should help connect innovators with willing pilot partners, to help prove the efficacy of the innovation and collect data.
- The federal government should also help connect industry with distribution partners.

#### Greater incentives for innovation should be initiated...

The federal government should create incentives to fund new innovations, or provide greater access to funding generally.

- This could be done through greater access to venture capital, and venture loans, especially for early stage and early commercialization stage health technology and service companies.
- An incentive could be a "radical" innovation award or fund for deliverables that are dependent on new or non-linear solutions opposed to incremental improvements.
- Ministries should provide incentives for facilities to adopt new models of care and technological innovations.
- The federal government could create innovation centers/departments within major health and research institutions asked with identifying, piloting, and evaluating new health innovation.
- A claw back mechanism could be placed on publicly funded innovations that take too long to spread (incentive for greater efficiency in deployment).

## Anti-competitive, inefficient, and outdated approaches to procurement require amendment...

Procurement guidelines are structured in a way that, at times, cater to larger entities and may lead to an anti-competitive process. Where a desired contract is large enough to merit an Request for Proposal process, larger incumbent companies are allegedly more likely to win, even if their product is of lower quality. At times, hospitals will even lower pricing to avoid RFPs altogether.



- There is a lack of alignment across provinces for procurement (federal leadership).
   There should be national standards for procurement, and value-based procurement.
- In the last 3-5 years, the broad focus on provincially based procurement has increasingly limited the adoption of new technology and innovation. Once long term (5 to 8 year) contracts are established, there is little room to contemplate new technology.
- Multiple respondents requested that there be greater opportunity for new technologies to replace incumbents and for procurement guidelines be more flexible to support smaller companies.
- The system should look at total cost of ownership rather than acquisition cost. This approach should be embedded in future RFPs. Longevity of devices is critical especially when we consider the complexity of disease state management (not just demographics).
- Approaches to procurement tend to be price-based, rather than evidence- and valuebased.

#### Systematic reform is needed...

Survey responses indicated a need for greater collaboration between systems, and in system development or reform to foster an environment more conducive to innovation development and diffusion.

- Hospitals should begin to undertake pilot projects for the sake of optimizing outcomes/long-term adoption, and not only for the sake of research/publications.
- They should be outsourcing specialized projects and initiatives that are better suited to be performed by specialists. For example, technology vendors would be better suited to build robust technology solutions.
- The regulatory process is burdensome. It should be flexible and malleable to shifts in
  research methodology that incorporate lessons learned. There are also issues in
  efficiency, and regulatory duplication/overlap when seeking approvals, (e.g. ethics
  approvals, privacy assessments), which can be a lengthy process that delays progress.
  There should be a simplified, unified process where assessments are either done
  centrally, or at one hospital (equating to approval from all hospitals).
- There are challenges to implementing efficient, new processes such as virtual visits and communications into the healthcare system, as physicians and other proponents to the status quo tend to be adverse to changes that infringe on their practice. Also, this change should occur at the frontlines to embrace and champion the new spread of innovation (change through engagement, not change through management).

#### The Personal Health Information Protection Act requires clarification ...

The Personal Health Information Protection Act (PHIPA) requires clarification. This Act is deemed to be vague, outdated and does not account for advancements in technology. This leads to differences in interpretation at different hospitals and results in variations in the Act's ultimate implementation.

Industry needs greater access to information...



Other challenges include a reluctance to look at global product (registry) data, the industry's lack of strong health economic data, and restrictions on direct to patient education on new technology.

#### **Examples of successful collaboration:**

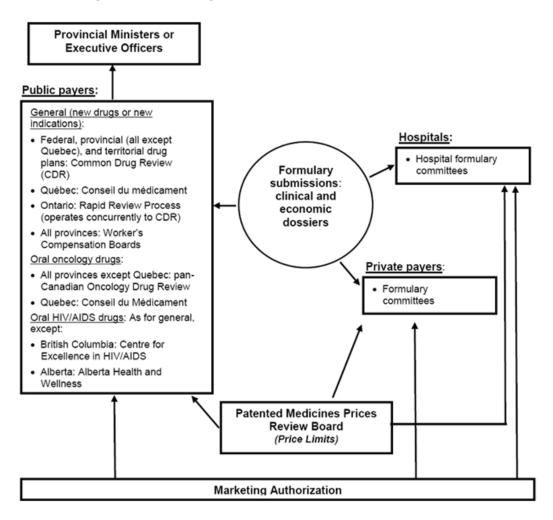
Several examples were highlighted for consideration in survey responses:

- In countries such as Australia, Sweden, and the UK, product registries are having a
  greater impact on the utilization of technology. The challenge here is that new
  technology requires time to determine its clinical efficacy but early results tend to be
  predictive of long term results.
- California Health Care Foundation: This body funds innovations that demonstrate a certain level of cost efficiencies/savings and level of engagement from end users.
- Denmark's Affordable Care Act: This legislation presumable encourages health systems
  to find better solutions (virtual visits are really a push right now (Boston's Mass General);
  more upstream solutions for conditions such as diabetes.
- The US's Affordable Care Act: The Act is undergoing a seismic shift in evaluating and introducing innovation to improve the state and cost of health care.
- Aetna Innovations: The model used with Aetna's innovation group was referenced as a particularly effective model that could be used and adapted for use in Canada.
- Use of impact bonds and other 'alternative' funding models that drive solutions/results vs focus on details of delivery was referenced.
- Alberta My Home Health pilot project deployed in the Edmonton region to 125 patients: The focus of the pilot was on heart failure patients. AHS was referenced in a survey response as being interested in expanding it to other regions and other chronic diseases.
- 15-year managed equipment services agreement with Humber River Regional Hospital covering over 1300 pieces of equipment: This technology and service agreement provides the hospital with a strategic approach to acquisition, replacement, and maintenance of equipment in surgery, cardiac care, and diagnostic imaging. The project will save the hospital between \$20MM and \$25MM over the fifteen year term.



**Appendix A: Advisory Panel on Healthcare Innovation – Terms of Reference** (Please note that Appendix A of this backgrounder has been removed to avoid repetition)

Appendix B: Pharmaceutical HTA and Reimbursement Processes – Decision Makers and Decision- Making Processes Diagram



#### Model description and Symbols:

The ultimate decision maker is listed at the top of the model

Boxes: Decision-making bodies

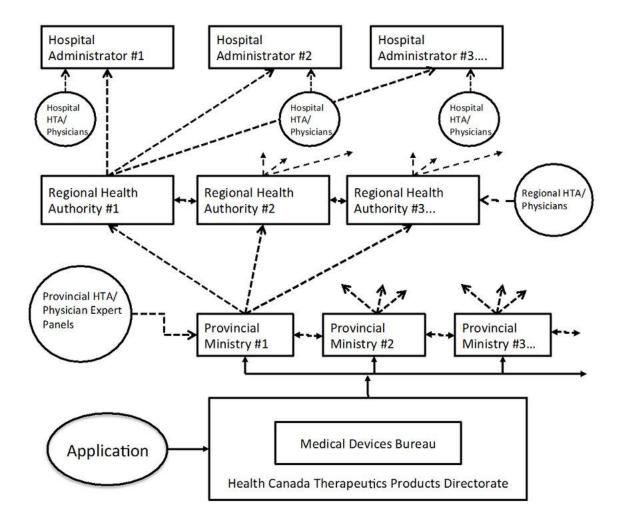
Solid Arrows: Required step in decision-making process

Broken Arrows: May or may not impact decision

This diagram was extracted from http://www.ispor.org/HTARoadMaps/CanadaPharm.asp

Appendix C: Canada Medical Devices and Diagnostics - Decision Makers and Decision-Making Processes Diagram





#### Model description and Symbols:

Boxes: Decision-making bodies.

Circles: Data requirements, tools, etc. which impact process.

Broken Arrows: May or may not impact decision.

Figure adapted from Arshoff L. Who Pays: Institutional Funding & Decision Models. Toronto,

ON; 2008 (4)

This diagram was extracted from http://www.ispor.org/HTARoadMaps/CanadaMDD.asp



### The Institute of Health Economics (IHE):

The Institute of Health Economics (IHE) is a non-profit Alberta-based research organization committed to producing, gathering, and dissemination evidence-based findings from health economics, health policy analyses, health technology assessment and comparative effectiveness research to support health policy and practice. Established in 1995, it is a unique collaborative arrangement among government, academia, and industry.

The IHE has a staff of 25 that includes health economists, health technology assessors, research associates and policy analysts, information specialists, and project and administrative personnel. The Institute is a member of the International Network of Agencies for Health Technology Assessment (INAHTA) and the World Health Organization's Health Evidence Network (WHO HEN) and is the secretariat for Health Technology Assessment International (HTAi) www.htai.org.

The IHE regularly designs and conducts consensus development conferences and policy dialogues for provincial and national public and private sector organizations on a wide range of issues. More detailed information on the IHE is available on our website. (www.ihe.ca).

#### **Health Canada:**

Health Canada is the Federal department responsible for helping Canadians maintain and improve their health, while respecting individual choices and circumstances.

According to our mission and vision, Health Canada's goal is for Canada to be among the countries with the healthiest people in the world.

To achieve this goal, Health Canada:

- Relies on high-quality scientific research as the basis for our work.
- Conducts ongoing consultations with Canadians to determine how to best meet their long-term health care needs.
- Communicates information about disease prevention to protect Canadians from avoidable risks.
- Encourages Canadians to take an active role in their health, such as increasing their level of physical activity and eating well.

For more information about Health Canada, please see the following link: <a href="http://www.hc-sc.gc.ca/ahc-asc/index-eng.php">http://www.hc-sc.gc.ca/ahc-asc/index-eng.php</a>.