



PATHWAYS TO SUSTAINABLE ACCESS TO INNOVATIVE MEDICINES FOR CANADIANS

BALANCING INNOVATION, AFFORDABILITY AND OUTCOMES

APRIL 2018





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- Conducting research on critical issues
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Our approach – called Inclusion to Conclusion – brings emerging and established voices to policy conversations, which inform conclusions that identify obstacles to success and pathways forward. PPF is an independent, non-partisan charity whose members are a diverse group of private, public and non-profit organizations.

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Public Policy Forum

1400 - 130, rue Albert Street
Ottawa, ON, Canada, K1P 5G4
Tel/Tél: 613.238.7858

www.ppforum.ca

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EXECUTIVE SUMMARY

New pharmaceuticals pose challenges and opportunities for Canada's healthcare system. They stretch the ability of government to manage incremental costs, to ensure Canadians have access to products that deliver significantly better patient outcomes, and to position Canada as a centre of global investment and innovation. Innovative medicines — defined in Canada as “... a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient ...”¹ — require a new way forward in policy and practice.

Many innovative medicines represent clinical “breakthroughs,” offering previously unthought-of benefits for patients (e.g. immune-oncology medicines that provide non-tumour-specific treatments for multiple cancers; new curative treatments for Hepatitis C; new medicines to treat rare diseases). Yet the prices of such medicines have skyrocketed — sometimes without any demonstrated link to better outcomes for patients and health systems.²

Provincial drug spending is increasingly directed toward these expensive new therapies, raising questions about system sustainability. Spending on pharmaceuticals, which already makes up 16 percent of total healthcare spending and is the fastest rising health cost per person, is expected to accelerate.³ Prescription drug expenditures in Canada jumped 9.9 percent in 2015-16.⁴ The use of medicines exceeding \$10,000 per patient in annual treatment costs increased by 60 percent in 2015-16 and accounted for 27 percent of total drug costs.⁵ New higher-cost medicines are a bigger contributor to pushing up public costs than the gradual rise in population size.

Other countries have partially confronted these realities. They have implemented a variety of innovative solutions, ranging from pay-for-performance models for medicines to new framework agreements with industry, seeking to balance the price paid for medicines and timely access to the latest innovations.

This report is the culmination of a project that engaged Canadians in roundtable discussions about access barriers, the role of real-world evidence in system improvement, and how to move the healthcare system forward. Participants' recommendations on reducing barriers to access, strengthening data and evidence and finding balance in our healthcare system will be of interest to policymakers, industry, healthcare

¹ Health Canada. 2017. [Guidance Document: Data Protection under C.08.004.1 of the Food and Drug Regulations](#). Health Canada, Health Products and Food Branch.

² OECD. 2017. [New Health Technologies: Managing Access, Value and Sustainability](#). OECD Publishing, Paris.

³ Canadian Institute for Health Information. 2017. [National Health Expenditure Trends, 1975 to 2017](#). Ottawa, ON: CIHI; 2017.

⁴ Patented Medicine Prices Review Board. 2017. [CompassRx, 3rd edition: Annual Public Drug Plan Expenditure Report, 2015/16](#). Ottawa, ON: PMPRB; 2017.

⁵ Ibid.

providers and patient groups alike. Government has an essential role in ensuring that the ideals of our healthcare system extend to pharmaceuticals, but we all have a part to play in ensuring effective and sustainable healthcare delivery. Roundtable participants provided the following recommendations:

Reduce barriers to access

1. **Implement payment models that link approval and price to strength of evidence.**
2. **Conduct more clinical trials in real-world settings.**
3. **Collaborate with and draw on evidence from other countries.**

Strengthen data and evidence

4. **Build and integrate system data infrastructure.**
5. **Standardize terminology and develop shared national outcomes.**
6. **Enable the sharing of health data.**
7. **Educate patients on the risks and opportunities associated with real-world trials.**

Find a balance

8. **Deepen the commitment to patient engagement.**
9. **Develop the necessary legal and regulatory framework.**
10. **Empower an independent convenor to advance national solutions.**
11. **Define a new funding model for pharmaceuticals.**

Developing a new health framework that determines how Canadians access innovative medicines will take courage, commitment and compromise from all stakeholders. The literature already contains frameworks for change that lay out objectives and actions related to access and value.⁶ What we need now is dedicated leadership and a renewed commitment in government to join patients, healthcare providers and industry to take action. Aligned public policy will be the most important enabler to a transformed health system.

Courage starts with patients and their allies in government, industry and healthcare. We saw firsthand the tenacity of Canadians at roundtables across the country, with participants who engaged in an open and, at times, charged conversation. There is ample will for change, but Canada needs a leadership call to action to take the first big step.

⁶ Morgan, S. G., Gagnon, M. A., Mintzes, B., & Lexchin, J. 2016. A better prescription: advice for a national strategy on pharmaceutical policy in Canada. p. 18. *Healthcare Policy*, 12(1).

INTRODUCTION

Healthcare around the world is undergoing dramatic changes as new therapies and technologies are developed and brought into general practice. In Canada, this is occurring in a healthcare system facing an aging population, an increased prevalence of chronic diseases, and the need for timely access to care within a fiscally constrained environment.

As Canadians, we generally believe in the quality of our public healthcare system and support the values that underpin it. But we also recognize it is challenged to deliver services that provide maximum patient benefits while ensuring cost-effectiveness. We need a healthcare model that ensures the right medicines are available at the right prices, with good patient outcomes and appropriate compensation for industry. Innovative medicines — defined in Canada as “...a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient...”⁷ — are a case in point.

There are four major policy objectives with respect to pharmaceuticals in health systems: widely available medicines, equitable access, appropriate and safe use, and affordability for both individual consumers and the system itself.⁸ In 2014, the Government of Canada launched the Advisory Panel on Healthcare Innovation, which identified five areas of innovation with significant potential to improve the quality and accessibility of Canadian healthcare⁹:

1. Patient engagement and empowerment;
2. Health systems integration with workforce modernization;
3. Technological transformation via digital health and precision medicine;
4. Better value from procurement, reimbursement and regulation; and
5. Industry as an economic driver and innovation catalyst.

Innovation in these areas continues to play an important role in improving our health system. But Canada also needs policy innovation to respond to the cost and access pressures related to innovative medicines.

⁷ Health Canada. 2017. [Guidance Document: Data Protection under C.08.004.1 of the Food and Drug Regulations](#).

⁸ Bigdeli, M., Peters, D., and Wagner, A. 2014. [Medicines in Health Systems](#). World Health Organization. Geneva: World Health Organisation.

⁹ Advisory Panel on Healthcare Innovation. 2015. [Unleashing Innovation: Excellent Healthcare for Canada: Report of the Advisory Panel on Healthcare Innovation](#). Health Canada.

THE RISING COSTS OF NEW PHARMACEUTICALS

Spending on pharmaceuticals makes up roughly 16 percent of total healthcare spending, compared to hospitals at 28 percent and physicians at 15 percent, but it is the fastest rising cost per person. Spending on pharmaceuticals has an annual growth rate of 4.2 percent, compared to 1.9 percent for hospitals and 3.4 percent for physicians, and it is expected to accelerate.¹⁰ In 2015-16, prescription drug expenditures in Canada jumped 9.9 percent.¹¹ While spending temporarily slowed beginning in 2010 thanks to a wave of generics and policies to limit their price, this price slowdown is now being more than offset by the nature of innovative medicines.

Innovative medicines have the potential to save lives or enhance a patient's quality of life, with possible cost savings to payers elsewhere in the healthcare system.¹² For example, a study of six classes of innovative medicines in Ontario found that the cost of the new medicines were offset by reductions in the use of other healthcare resources such as physicians and hospitals, and reduced productivity losses.¹³ Some innovative medicines are true breakthroughs and bring huge benefits to patients, such as new treatments for Hepatitis C. On the other hand, as prices of new medicines have leapt upward, there hasn't always been a clearly demonstrated link to improved health outcomes.¹⁴

New medicines, particularly biologics and antivirals, tend to be expensive. The use of medicines exceeding \$10,000 per patient in annual treatment costs increased by 60 percent in 2015-16. While being used by less than one percent of public drug plan beneficiaries, they accounted for 27 percent of total drug costs.¹⁵ The number of beneficiaries using high-cost medicines has remained fairly stable, but the effect of higher-cost medicines is increasing total public drug costs. This trend is unlikely to slow down.

Of the new medicines brought to market in Canada in 2015, 43 percent were for rare diseases.¹⁶ Orphan medicines, developed specifically to treat rare conditions, are increasingly important in policy considerations related to pharmaceutical access and coverage. They are expensive but are necessary to reduce the morbidity and mortality of rare diseases.¹⁷ Countries with regulations and incentives to stimulate the development of orphan medicines (such as market exclusivity, accelerated market-approval reviews,

¹⁰ Canadian Institute for Health Information. 2017. [National Health Expenditure Trends, 1975 to 2017](#).

¹¹ Patented Medicine Prices Review Board. 2017. [CompassRx, 3rd edition: Annual Public Drug Plan Expenditure Report, 2015/16](#).

¹² Chambers, James D., et al. 2014. "Despite high costs, specialty medicines may offer value for money comparable to that of traditional medicines." Pp. 1751-1760. *Health Affairs* 33(10).

¹³ Hermus, G., Stonebridge, C., Dinh, T., Didic, S., and Thériault, L. 2014. [Reducing the Health Care and Societal Costs of Disease: The Role of Pharmaceuticals](#). Conference Board of Canada.

¹⁴ OECD. 2017. [New Health Technologies: Managing Access, Value and Sustainability](#).

¹⁵ Patented Medicine Prices Review Board. 2017. [CompassRx, 3rd edition: Annual Public Drug Plan Expenditure Report, 2015/16](#).

¹⁶ Patented Medicine Prices Review Board. 2015. [Meds Entry Watch, 2015](#).

¹⁷ Gammie, Todd, Christine Y. Lu, and Zaheer Ud-Din Babar. 2015. "Access to orphan medicines: a comprehensive review of legislations, regulations and policies in 35 countries." *PLoS one* 10(10).

regulatory fee reductions and tax incentives) are seeing rapid increases in new drug designations and market approvals.¹⁸ But the lack of robust clinical and patient outcome evidence often makes reimbursement decisions challenging.

As healthcare and drug prices rise, health systems need to participate in research that creates value for patients and society. The innovative medicines industry in Canada contributes over 30,000 jobs (direct and indirect) across the country and generates \$19.2 billion per year in annual revenue. It claims to invest 9.97 percent of annual total revenue, or \$1.2 billion, into research and development, making it the third largest R&D investor in Canada.¹⁹ However, estimates of R&D investments differ between the federal government and the innovative medicines industry. While Innovative Medicines Canada includes pharmaceutical company funding of hospital and university research in its calculation, the federal government does not, reducing the calculation of R&D investment to \$918.2 million in 2016, which is a 4.4 percent R&D-to-sales ratio.

The federally reported R&D-to-sales ratio has been declining for the past two decades. Despite a 1989 agreement between the federal government and the innovative medicines industry that the industry would invest 10 percent of sales into R&D, the R&D-to-sales ratio has been below that benchmark since 2000. Industry links the price of medicines to investment in R&D, but even with prices on the rise, R&D investment continues to drop. There is limited data to suggest that drug prices are linked to the R&D investment needed to bring them to market, though the high cost of R&D is often used to justify rising costs in medicines.

The changing nature of pharmaceuticals today is relevant to public payers and individual citizens alike. While 70 percent of total health expenditure in Canada comes from public sector funding,²⁰ 57 percent of pharmaceutical costs are covered privately, either by private insurance or out of pocket.²¹ The inconsistency in prescription drug coverage leads to inequitable access to medicines as well as fiscal strain on public payers.^{22,23} The health system invests in pharmaceuticals with an anticipated return on that investment; fewer surgeries, disease prevention from vaccines and more effective chronic disease management provide cost-savings. Employers provide employees with pharmaceutical coverage both as a means of attracting employees and to protect their productivity. These benefits will not be achieved if the system itself is not sustainable. Medicine prices are part of that equation.

¹⁸ Ibid.

¹⁹ Innovative Medicines Canada. 2017. [Annual Report 2017](#).

²⁰ Canadian Institute for Health Information. 2017. [National Health Expenditure Trends, 1975 to 2017](#).

²¹ Canadian Institute for Health Information. 2016. [Prescribed Drug Spending in Canada, 2016: A Focus on Public Drug Programs](#). Ottawa, ON: CIHI; 2016.

²² Morgan, Steven G., et al. 2015. "Pharmacare 2020: the future of drug coverage in Canada." University of British Columbia, Pharmaceutical Policy Research Collaboration.

THE PATCHWORK OF PUBLIC AND PRIVATE INSURANCE PLANS

New health technologies provide opportunities and raise challenges for policymakers, payers, patients, physicians and the authorities that regulate these technologies. The Canada Health Act²⁴ requires that medically necessary services be universally accessible and free of charge, but the requirement does not extend to prescription medicines used outside of the hospital setting. Provincial governments are responsible for ensuring universal access to necessary services, but are not required to insure prescription medicines. The result has been a patchwork of public and private insurance schemes, with variation in who is covered, what is covered, and how it is financed. This is one key underpinning of the ongoing national debate about the need for a national pharmacare plan.

Provincial medication insurance plans differ in age eligibility, premium and copayment, first-payer coverage, and how many programs are actually offered.²⁵ For example, each province with the exception of Quebec has more than one insurance plan, ranging from five (Manitoba, Nova Scotia, Newfoundland and Labrador) to 27 (Prince Edward Island). Each province has social assistance programs that result in patients paying no or low (i.e. \$2 to \$5) out-of-pocket amounts. Quebec is alone in requiring that all residents have medication insurance. The overall picture is one of a balkanized system with questionable implications for equal access and affordability across the country.

While debates on equitable access to medicines have continued for decades, recent provincial and territorial health ministers' meetings have signaled political will for collaboration on public coverage of medicines. Federal and provincial governments have collectively formed the pan-Canadian Pharmaceutical Alliance (pCPA) to reach coordinated pricing agreements for selected medicines going through the Common Drug Review or pan-Canadian Oncology Drug Review.²⁶ Although this has resulted in significant savings for public drug programs, the savings are being offset in the short term by increased spending on innovative medicines such as biologics and medicines for rare diseases.²⁷ In addition, while the pCPA sets the parameters, agreements are finalized in each province.

How then can Canada balance the equally important objectives of pharmaceutical innovation, affordability for public payers and good patient outcomes? Striking this balance is essential in order to work within the

²⁴ Canada. 1985. [Canada Health Act](#). Department of Justice.

²⁵ Campbell, David JT, et al. 2017. "Comparison of Canadian public medication insurance plans and the impact on out-of-pocket costs." *CMAJ* open 5(4).

²⁶ Canada's Premiers. n.d. [The Pan-Canadian Pharmaceutical Alliance](#).

²⁷ Canadian Institute for Health Information. 2015. [Prescribed Drug Spending in Canada, 2013: A Focus on Public Drug Programs](#). Ottawa, ON: CIHI; 2015.

available public healthcare budget, support continuing excellence in Canadian industry and, most importantly, ensure the best health outcomes for Canadians.

METHODS

This report summarizes the recommendations from six roundtables across Canada. The conversations have been supplemented by a summary of relevant recent literature on innovative medicines and pharmaceutical policy. The search was selective and non-systematic, drawing on open-source literature and grey literature²⁸ pertaining to the issues raised in the discussion guide that was developed to inform the roundtable discussions. There was no specific examination of pharmacare — often described as a single, publicly funded national drug program in lieu of, or in addition to, existing public drug programs — although access to innovative medicines is part of the broader debate around the potential for a national pharmacare program.

We conducted roundtables in Edmonton, Toronto, Montreal, Ottawa, Vancouver and Halifax. Ninety-one unique participants (see Annex 1) attended these roundtables, including patient group representatives, government policymakers, academics, healthcare providers, and representatives of industry and the business community. Invitations to participate were extended to organizations and individuals with an established stake in pharmaceutical policy.

An individual with expertise in health and innovation policy moderated each session. Sessions lasted for 90-120 minutes. Notes were taken by Public Policy Forum staff, and common concepts, opinions and values were extracted by thematic analysis. Transcripts were not produced. Participants were sent a summary report of each session to provide the opportunity to validate the identified themes. These reports are available upon request.

Participants at the roundtables were asked to respond to the following questions:

1. **Barriers to access:** What characteristics of the Canadian healthcare system create barriers to accessing new medicines?
 - What barriers do physicians and patients face in accessing new medicines?
 - How does the pathway to commercialization in Canada affect the ability to bring new therapies to the health system?
 - Could changes to the way payers reimburse new medicines provide earlier and better access?

²⁸ Grey literature: materials and research produced by organizations outside of traditional commercial and academic publishing channels.

2. Evidence and innovation: What is needed in order to make better use of data, analytics and real-world evidence (RWE) to improve how new medicines are used in the healthcare system?

- What barriers do patients, healthcare providers and Canadian payers experience in using RWE to inform decisions?
- What infrastructure and processes do we need in order to improve the use of RWE in the current model of Canadian pricing and reimbursement process?
- What is needed so that existing RWE in Canada is better coordinated and used in system-level decisions?

3. Finding a balance: How do we move toward a healthcare model that optimizes a balance of innovation, affordability and good patient outcomes?

- What processes and pan-Canadian approaches could be adapted or built upon?
- Do we need an entirely new public coverage framework?
- Who must be involved? Who could provide the leadership that is needed to bring people together?

BARRIERS TO ACCESS

Medicines are a valuable part of the healthcare system and can improve patient outcomes. But patients, industry and government alike face difficulties in ensuring appropriate access and system improvements. Government is slow in changing processes, patients experience barriers to accessing medicines, pharmaceutical developers find it takes a long time to access to the Canadian market, universities have structures that impede commercialization of innovations, and industry holds data that doesn't always reach decision-makers to inform policy. In short, all stakeholders have their challenges, and some of those challenges conflict with the priorities of others.

APPROPRIATE ACCESS TO PHARMACEUTICALS

Patient access to medications depends on a variety of factors including therapeutic benefit, cost effectiveness, affordability in the context of public drug plans and health spending overall, price, care decisions and patient location. Cost is the most prevalent barrier reported by patients. In a recent national survey, Twenty three percent of Canadians reported that they or their relatives have faced financial barriers to pharmaceutical access, an issue that is especially prevalent in British Columbia and Atlantic Canada.²⁹ While eligibility for public drug plans is often based on age, income, or specific medical needs, remaining coverage gaps are not necessarily filled by private plans, which are voluntary outside of Quebec. For instance, a third of the employed workforce in Ontario lacks employer health benefits.³⁰ Even those who qualify for public coverage experience cost barriers because of cost-sharing approaches like co-insurance and deductibles.³¹ Increased deductibles and copayments have been associated with reduced use of medications and increased hospitalizations – shifting the cost elsewhere in the system.

Those without access to private or public prescription drug coverage will either pay out of pocket or be unable to receive medically necessary medicines. This is a major source of medical inequity.³² Only an estimated 1.8 percent of Canadians are uninsured, but on average, Canadians still paid \$1,824 in direct healthcare costs per household in 2016³³.

In Edmonton, we heard that patients experience a two-tiered insurance landscape, where those with good private drug coverage experience one system and those without good coverage another. Canadians who fall just above low-income thresholds are especially vulnerable to gaps in the system, with individuals in the

²⁹ Angus Reid Institute. 2015. [Prescription drug access and affordability an issue for nearly a quarter of all Canadian households.](#)

³⁰ Barnes, S., Abban, V., & Weiss, A. 2015. [Low wages, no benefits: Expanding access to health benefits for low income Ontarians.](#) Wellesley Institute.

³¹ Morgan, Steven G., & Boothe, Katherine. 2016. "Universal prescription drug coverage in Canada: Long-promised yet undelivered." *Healthcare management forum*. 29(6). Sage CA: Los Angeles, CA: SAGE Publications, 2016.

³² Wellesley Institute. 2015. [Access to Prescription Medicines. Federal Election 2015. Health Equity Impact Assessment.](#)

³³ <http://www5.statcan.gc.ca/cansim/a47>

second-lowest income quintile spending the most out-of-pocket on healthcare. The lowest income Canadians spend over 5 percent of their incomes on prescription medicines³⁴, highlighting the hidden cost barriers to prescription medicines. People fall through the cracks even where public coverage exists, for instance by not being able to access medicines that aren't on approved lists. Access isn't necessarily about getting the newest medicines — it's about access to whatever will work, at an affordable price.

Across Canada, the fragmented nature of pharmaceutical coverage means there isn't a healthcare system per se. Rather, there are at least 13 distinct systems. Participants in Vancouver pointed out that Indigenous people are further forced to navigate a system within a system. The fragmented nature of public programs raises barriers to quick access to the right medications, and the barriers are particularly difficult for already marginalized and under-resourced groups.

Patients, healthcare providers and industry each face challenges because pharmaceutical coverage policy is set by so many jurisdictions. For example:

- Participants in Nova Scotia reported that some patients move to other jurisdictions to get access to particular medicines. Access to orphan medicines is particularly problematic because coverage differs so much among the provinces.
- In Toronto, participants reported that as young people leave their parents' employer-provided insurance, they no longer can afford essential medications for conditions like arthritis. The new OHIP+ coverage is helping to fill this gap, but deductibles and copayments, even for those with private insurance, remain a barrier to affordability.
- In Edmonton, participants said the drug-funding model shouldn't be looked at in isolation. The broader health system isn't working as well as it could be, and government needs a better understanding of the effect that patient access to medicines has on other aspects of the system and on overall costs or savings.
- Participants in Vancouver reported that while patients experience barriers to accessing new medicines, industry experiences challenges in bringing innovative medicines to the market in Canada. The cost of bringing a new drug to market is relatively high because companies need to seek approval of multiple public payers across the country.
- Physicians in several cities said that it's difficult to even know which new medicines are proven to be effective and worth prescribing in place of existing medicines. They said the data shows that some new medications are not therapeutically innovative and many medicines are not clinically effective in real-world settings.

³⁴ Statistics Canada. 2016. [Average household out-of-pocket expenditures on health care as percentage of after-tax income, by household income quintile, Canada excluding territories, 1997 to 2009.](#)

Clinical trials were discussed in Toronto and Vancouver. Trials are one way for patients to have early access to promising therapies and must be a part of the access discussion. In Canada, once a drug trial closes, the participants become involved in a waiting game between the clinical trial and the health technology assessment process. While trials are an access pathway for a lot of patients, care is not continuous and access to trials is not equitable across Canada.

Participants in Halifax and Montreal validated this, saying that while Health Canada has improved its review process and the health technology assessment process is good compared to other countries, public plans are still comparatively slow to cover new medicines. Canadian public payers can take as long as 2.5 years after the Notice of Compliance before putting a drug on the public plan. A side effect for private insurers is that they take on an increasing share of high-cost treatments.

In Ottawa, participants affirmed that time is a particularly salient issue for those living with rare diseases. Some medicines take years to become available to patients in Canada, even while they can be accessed in other countries. Policymakers recognize the issue; Canada is working toward having medicines in this country become available as soon as they are approved and available in the U.S. and Europe, and companies are encouraged to file for market review in Canada at the same time that they file in other countries.

One structural barrier to nationwide systemic improvement is what is and isn't legislated. In Ottawa, participants pointed out that not all of the existing structures that influence pharmaceutical policy in Canada have a legally constituted framework. Without legislation, there is limited accountability or public recourse. Legislation is required to develop a more cohesive and accountable system.

Participants in Montreal discussed capacity issues within government to develop new processes and public policies that lead to a better innovative medicines review process. Current processes for integrating innovations into the healthcare system were described as segmented and difficult to navigate, with obstacles at the provincial and federal level.

Participants in Vancouver were enthusiastic that Canada excels at certain types of innovation, with great scientists and strong investment in the scientific engines that yield discoveries. But Canadian companies have a hard time accessing capital, keeping talented managers and leaders, and reaching large distribution channels. For firms in Canada to become global leaders they need an innovation framework that is more systematic and has a longer time horizon. As the Patented Medicine Prices Review Board currently reviews

its policies, guidelines and procedures, industry is uncertain of the implications of this review even as it works to encourage a Canadian market that supports the entry of new medicines.³⁵

We heard repeatedly that the national patchwork of public pharmaceutical coverage is inefficient for payers, leads to uncertainty for patients and physicians, and challenges innovators that are developing and bringing new therapies to market. The pCPA is an added layer in the Canadian listing process, although it doesn't appear to have lengthened the process.³⁶ Still, we heard that government struggles to keep up with the pace of change and determine what is and isn't clinically and cost effective. Patient groups and industry urgently await policymakers to act on market access issues. How can we do a better job of uniting these disparate conversations and making the link between the different topics, such as innovation, health outcomes and policy goals?

Government, industry, patients and clinicians all have a role in remaking the healthcare system so that patients can access the medications they need. While all stakeholders agree with this principle, it quickly breaks down because of disagreements over evidence-based decision-making and a lack of trust. Requiring companies to deal with 13 jurisdictions hinders the commercialization of innovative medicines, and thus impedes patient access to new therapies. We need clear criteria, consistent across jurisdictions, to inform decisions about what is and isn't publicly covered.

BALANCING INNOVATION AND ACCESS

Participants offered different opinions on the appropriate balance between investing in new and existing medicines. Some participants discussed the need to de-invest in medicines that can be replaced by new and innovative ones, creating an ongoing cycle where obsolete innovations are discarded to make room for new ones. What was innovative in the past may no longer be so today. On the other hand, patients and clinicians aren't only interested in the newest medicines — access should be given to those with evidence of real-world effectiveness and therapeutic value, whether new or existing.

It's challenging for physicians to know which medicines are actually innovative, since medicines are not always as effective in the real world as clinical trials data would suggest. While informational tools such as those provided by the Mayo Clinic can help people consider whether new medicines are right for them, lobbying and inconsistent literature cloud the picture for physicians and policymakers alike. We heard

³⁵ Innovative Medicines Canada. 2017. [Consultation Document, Protecting Canadians from Excessive Drug Prices. Patented Medicine Prices Review Board \(PMPRB\) and the Patented Medicines Regulations.](#)

³⁶ Robertson, C., Zhang, Y., & Bosnic, N. 2014. Impact of the pan Canadian pricing alliance on time to listing in Canada. *Value in Health*, 17(3).

concerns from government and clinicians that sometimes the literature doesn't completely bear out claims of effectiveness.

There was a vigorous discussion about how innovation is more than new medicines. For example, new clinical uses for existing medicines create opportunities for businesses and patients. It was felt that industry and government need to find ways to combine or organize efforts so inventions or re-inventions don't get in the way of making good use of existing, effective technology. Research funding could be directed to doing more with existing research.

Processes put in place decades ago, such as the Scientific Research and Experimental Development Tax Incentive Program, don't suit how industry innovates today. Similarly, provincial and federal review requirements are difficult to navigate. There aren't incentives in the system to create value for patients, and without aligned incentives drug developers and payers aren't being reimbursed properly for desired health outcomes. Governmental processes must be modernized to remain relevant, which requires strong leadership within large governmental institutions and healthcare centres.

With questions about what makes a drug truly innovative, participants suggested that one way to improve access for patients and industry alike would be to introduce new risk-sharing arrangements between industry and government. Adaptive licensing and alternative reimbursement mechanisms whereby prices fluctuate depending on emerging evidence could help work through uncertainty. Such flexibility in the assessment process could provide a new balance between value and effectiveness.

Industry has also expressed willingness to explore new payment schemes that cover high-cost but curative medicines, taking on the cost of treatments until real-world patient effectiveness is demonstrated. This could help government accommodate incomplete evidence when making approval and de-listing decisions, assuming appropriate safety standards are in place.

EVIDENCE AND INNOVATION

Innovation in the pharmaceutical policy space applies to more than new medicines. The system itself needs significant change in how it designs and provides care for patients so that outcomes are optimized.

There are four major policy objectives with respect to pharmaceuticals in health systems: widely available medicines, equitable access, appropriate and safe use, and affordability for both individual consumers and the system itself.³⁷ While these priorities need to align for Canadians to experience the full value of pharmaceuticals in the form of better outcomes, participants noted the priorities often compete with each other. For example, cost containment measures may lead to some medicines being unavailable, whereas public subsidization of costs can put greater pressure on the overall health system. The right data can guide policymaking and clinical decisions.

VALUE-BASED DECISION-MAKING

Participants voiced an impression that the current healthcare system makes decisions that are largely based on cost rather than the long-term value of medicines. Innovative medicines, such as Hepatitis C treatments, may be considerably expensive up-front but represent high value in terms of overall health system savings and better patient health outcomes. Current provincial and territorial systems are not developed enough to assess the long-term value of such investments. Analyses can miss quality of life indicators, and outcomes such as reduced work absenteeism don't capture the full value of a drug.

Value-based healthcare has received a great deal of attention. It promises a transition to a patient-centred way of designing and managing health systems, and could deliver improved health outcomes at lower costs.³⁸ It requires systematically evaluating the health outcomes that patients say matter, as well as measuring costs and developing interventions to improve value. It would be transformative, but requires the right data, infrastructure and expertise.

Even if Canada doesn't quickly move to value-based care, it is important to enable the collection and use of good health system and clinical outcome data. RWE will increasingly be a part of the use of data in the health system. Shifting metrics further to focus on outcomes rather than volume and outputs is important for sustainable and efficient health systems anchored in value for patients.

³⁷ Bigdeli, Maryam, D. Peters, and A. Wagner. 2014. [Medicines in Health Systems](#).

³⁸ Value in Healthcare: Laying the Foundation for Health System Transformation. April 2017. World Economic Forum. REF 220317

INVESTING IN REAL-WORLD EVIDENCE

We did not provide a specific definition of RWE at the roundtables, giving latitude for participants to address it from their own perspective. For the purposes of this report, we adopted the overview of the Institute of Health Economics to mean evidence derived from real-world data sources (i.e. not exclusively from randomized clinical trials) such as electronic health records, claims databases and observational studies.³⁹

Each roundtable extensively discussed the role of evidence in decision-making. We heard that Canada needs to move to a multi-stakeholder understanding of value, and the way we collect and analyze data will be critical to decision-making processes for research-based companies, public payers and other important stakeholders. Measurement can provide a baseline understanding of system issues, and data can inform innovation at the system level.

There was consensus that evidence on drug effectiveness and appropriateness could guide investment away from the prescription of and payment for obsolete or ineffective medications. Physicians and payers need good evidence to make these determinations, and policymakers need good data to decide to de-list a drug that is already covered. Resources such as the [Choosing Wisely](#) initiative and [Deprescribing.org](#) were mentioned as two examples of steps in the right direction for clinical decision-making. Moving toward value-based decisions, however, requires investment in evidence infrastructure, including data collection and analysis, development of centralized registries, and enhanced capacity of information systems to support clinical decision-making.

To make good use of RWE, decision-makers need advice from people with research and analysis skills. While Canada has a wealth of excellent researchers, parts of the country have skills shortages. Atlantic Canada, for instance, doesn't have enough health economists to meet its needs for health system data analysis and policymaking. Data repositories are also siloed, presenting another obstacle to comprehensively looking at data. While government would like different sectors to have reasonable access to anonymized patient data for research and evaluation, there isn't strong direction or strategic deliberation for this.

Some provinces are improving data access and use through electronic medical records. Alberta, for instance, has strong data capacity and has had secondary use data available for years. In one current initiative, government staff, industry staff and drug plan managers are collectively mining data. Through this project they have learned the importance of asking the same questions from the outset and then reviewing the same datasets. Researchers in B.C. have been using RWE in health systems research for more than 10 years.

³⁹ Husereau D. 2017. [Real-world evidence: What role can it play in real-world decision-making? Summary report of the IHE Roundtable](#). Institute of Health Economics. Edmonton (AB):

And Nova Scotia's *One Patient – One Record* system is an electronic health record that provides foundational health data.

There are multiple real-world datasets in use and Canada has enormous troves of data, but they aren't organized systematically. Claims data aren't linked to outcomes and there are questions about security and data ownership. Nova Scotia's platform could be the kind of RWE infrastructure that government needs, and the Toronto roundtable suggested strengthening the ability of the Institute for Clinical Evaluative Sciences and the Canadian Institute for Health Information to emphasize outcomes data collection and analysis. The Canadian Agency for Medicines and Technology in Health could contribute to making processes more flexible by integrating regulatory procedures with treatment.

RWE opens many opportunities, but its promise can't be achieved without multi-stakeholder commitment to pursue and share actionable health information. The pCPA has made progress for the provinces to collectively negotiate fair prices, and developing a national RWE infrastructure is a next step.

REAL-WORLD EFFECTIVENESS

RWE isn't just about pharmaceuticals; it's also about practical decision-making. Patients and clinicians are interested in more than just the newest medicines. They want a system that uses RWE to understand the clinical utility of existing medicines and determines the effectiveness of innovative medicines in real-world settings after medicines have been through the health technology assessment process. Clinical studies of drug effects do not always translate to improved patient outcomes,⁴⁰ a challenge that is exacerbated in drug development for rare diseases. But RWE can do more for practical decision-making.

Australia's National Prescribing Service is an example of a national hub for best available evidence. In Canada, a fulsome decision support service for physicians and patients, informed by re-analysis of clinical trials data, real-world outcomes and quality of life data, would help guide decisions for starting and stopping use of medicines and make the promise of personalized medicine based on biomarkers more realistic.

Well-conducted randomized control trials (RCTs) are the historical gold standard for evaluating the intended effects of new medicines, but RCTs for rare disease medicines are difficult to carry out in Canada because there are few patients spread out over a wide geographical area.⁴¹ Evaluating the effectiveness of new medicines will increasingly require drawing on multiple sources of health outcome data, emphasizing clinical utility and outcomes that are meaningful to patients. Federal funding of outcome evaluation, such as

⁴⁰ Naci, Huseyin, and John PA Ioannidis. 2015. "How good is "evidence" from clinical studies of drug effects and why might such evidence fail in the prediction of the clinical utility of medicines?." pp. 169-189. *Annual review of pharmacology and toxicology*, 55.

⁴¹ Nony, Patrice, et al. 2014. "A methodological framework for drug development in rare diseases." p. 164. *Orphanet journal of rare diseases* 9(1).

in large research hospitals where healthcare is tied to data collection and mobilization, is one way to collect and share post-approval effectiveness data.

Using RWE to support decisions is becoming a reality. Alberta has compared primary care data to prescription data to find gaps in physician diagnosis of chronic disease. Saskatchewan can already merge different data sources on some medicines. However, there aren't yet enough resources being dedicated to building the required data infrastructure, and legislative requirements concerning privacy can impede sharing and accessing data. Privacy and intellectual property are essential and have to be addressed in appropriate regulation and legislation. But they don't need to be a barrier to RWE. National legislation is necessary for data-sharing agreements to be widely implemented and consistent across Canadian jurisdictions.

FINDING A BALANCE

Innovation, affordability and patient outcomes aren't mutually exclusive: Together, these three components support the entire healthcare system. They are the legs of the Canadian healthcare stool, providing balance for the entire system. To best support the healthcare system, stakeholders need a shared understanding of innovation, the ongoing pressure of affordability must be considered, and the system must be designed around good patient outcomes.

PATIENT-CENTRED CHANGE

The roundtables were united in seeing patient-centred care as the cornerstone of decisions on innovative medicines. Putting patients first is a shared value, but it is talked about more than it is practiced. Drug discontinuation is one example of system decisions that don't adequately include patient perspectives. Old products are discontinued as new ones arrive on the market, even though patients were doing well on the existing medicines. This happens because public servants cannot always represent patient perspectives. Yet patients can be more than just consultation participants; they can be active partners in defining issues and identifying solutions.

We were told that patients should be at the centre of a shared leadership approach involving representatives of government, industry, healthcare providers, academia and patient groups. Such a coalition needs political authority to make systemic change happen. Many solutions and good practices already exist, but there is not yet the will to implement them or scale them up.

We have seen strong citizen engagement from previous exercises such as the Citizens' Reference Panel on Pharmacare in Canada. This panel developed a vision for a healthcare system in which necessary coverage is universal, there is a selective list of essential medicines, rigorous evaluation ensures that medicines are the most effective treatment at the price, and supplementary insurance can be purchased for medications that

are not publicly covered.⁴² These recommendations haven't been acted on. Without a clear vision and logical planning and commitment from federal and provincial governments, change can be incremental at best.

BUILDING ON WHAT WE KNOW

There are many good examples from which to learn and scale up towards transformational change. As a country of provinces, Canada is a natural laboratory for policy experiments. We know a lot about what works. And we can look to other countries for solutions that have been implemented or that are being tested.

Roundtable participants noted that the U.K., Belgium, Italy and France have already done a good job of moving care toward a patient-centred model. The quality of procedural management is much higher in Germany. Spain and some health management organizations in the U.S. have made progress on whole system data. New Zealand has managed to keep drug prices very low (although the number of medicines available through the public formulary is relatively limited). While none has a perfect system, all have elements from which we can learn.

Canada has a wealth of best and promising practices among the provinces, especially regarding datasets that are being increasingly used as RWE inputs. There are bright spots in most provinces that could be examined more closely, such as Alberta's secondary data capacity, researcher use of large public datasets in B.C. and Saskatchewan's analysis of multiple drug datasets.

The pCPA stands out as a bright spot. It is benefiting the provinces while streamlining negotiations for industry. Roundtable participants said that pCPA working with different levels of government is one way forward, and the pCPA could take on a stronger federally oriented role. As the provinces move forward on new pricing models for innovative medicines, there is opportunity to translate the existing good practices to a nationwide, made-in-Canada approach. Similarly, the pan-Canadian Oncology Drug Review has made cancer drug reviews more consistent and clearer for multiple participating jurisdictions, and it considers clinical evidence as well as cost-effectiveness.

A TRANSFORMATIONAL COALITION

Improving public coverage of new and innovative medicines can only be done with a broad coalition of government, industry, healthcare providers and patient groups coming together and being willing to compromise on issues of pricing and coverage. Industry in particular indicated a willingness to work with

⁴² Citizens' Reference Panel on Pharmacare in Canada. 2016. [Necessary Medicines: Recommendations of the Citizens' Reference Panel on Pharmacare in Canada](#). University of British Columbia, Pharmaceutical Policy Research Collaboration.

government to explore new payment models, shared-risk approaches and ways of facilitating patient access to new medicines.

All actors within the healthcare system must work together better. Institutions such as research centres and industry must become closer so that innovations can be tested in real-world settings to generate useful data. Institutional cultures need to change to become more innovative and flexible. Innovative medicines cannot be developed and evolve within a system that struggles to adapt to new technologies and the rhythms of change in our healthcare system.

Changing the way Canada ensures access to affordable therapeutic medicines will take the courage and commitment to let go of certain vested interests. Governments are trying hard to change things for the better, but have to move deliberately. More than ever before, there is better communication between ministries and better government engagement with patient groups. But these changes are incremental, and patients want a transformed system.

Healthcare in Canada is a complex adaptive system with many components working in tension with each other. Some participants felt that while the needs of each province and community are unique and require local solutions, the decision-making process could be spread and applied across Canada. Such a distributed leadership model would require meaningful engagement of patients, payers including private insurers, industry and government from all across Canada.

Transparency implies accountability, but not all the existing structures that influence pharmaceutical policy in Canada have a legal framework. Without legally mandated roles, there is limited accountability or public recourse. Developing the system to become less of a patchwork will likely require new legislation. The federal and provincial governments need to be at the table and willing to lead. Pharmacare is easily politicized, with lobbying pushing certain interests. Local and national conversations would need to be honestly brokered and have participants who can objectively consider the data.

Patient engagement should be a meaningful component of true system improvement, reducing the influence of industry and opening the space for a process that leads to real balance between the needs of patients, limitations of government and interests of business.

WHERE NEXT? PARTICIPANT RECOMMENDATIONS

Roundtable participants offered the following recommendations on how Canada adapts our healthcare system to the nature of innovative medicines. Some of the recommendations follow a common theme and provide additional insight into different issues on a general topic.

REDUCE BARRIERS TO ACCESS

1. Adopt adaptive licensing models and/or coverage with evidence development. Public health plans face pressure from patients, physicians and industry to cover expensive new medicines even when effectiveness has not been fully proven. But they are understandably reluctant to pay high prices in these situations. For high-priced medicines, including for rare diseases, government could implement payment models that link approval and price to strength of evidence. These approaches are commonly referred to as adaptive licensing in the case of approval and coverage with evidence development as applied to reimbursement. Provinces with strong data systems could serve as testing grounds for innovative payment models.

2. Conduct more trials in real-world settings. Clinical trials are an important access pathway for patients in Canada. This landscape could be improved by conducting more trials in real-world settings, with industry working closely with healthcare providers and patients to define outcomes and develop the required data infrastructure.

3. Draw on evidence from other countries. Health Canada has peers in the United States, Europe, New Zealand, the United Kingdom and other important pharmaceutical markets. Other countries have tested and implemented innovative adaptive access pathways, providing a wealth of examples from which Canada can learn. Government and industry should look for collaborations where robust evidence can inform Canadian decision-making.

STRENGTHEN DATA AND EVIDENCE

1. Build data infrastructure to integrate data systems. There is widespread support for more use of real-world evidence (RWE) but it will take political, bureaucratic and clinical will to integrate data systems to generate the relevant data required for high-quality evidence. Government can facilitate the transition by repurposing existing innovation and skills program funding toward building the required data infrastructure and health system workforce. For data integration to be successful, payers will need to be to act uniformly in the application of this evidence to decision-making.

2. Standardize care terminology and develop shared outcomes. Health outcomes need to be systematically tracked as a data input for RWE use, but there isn't a shared set of definitions or outcomes. Government can accelerate the use of RWE by bringing stakeholders together to establish RWE and value-based care terminology, develop a shared outcomes framework that emphasizes outcomes that matter to patients, and facilitate the tracking of health outcomes.

3. Enable sharing of health data. For a pan-Canadian approach to RWE to become a reality, government, industry and healthcare providers need to find a balance between patient privacy and data sharing. The government needs to implement national guidelines and legislation that enable the sharing and use of anonymized health care data while respecting privacy legislation.

4. Explain the risks associated with real-world trials. Shifting the approval pathway to enable quicker access to promising medicines could compromise patient safety if clinical trials are incomplete and RWE is needed to further demonstrate effectiveness. Patient groups and physicians have an important role in educating patients and explaining the risks associated with participating in real-world trials.

FIND A BALANCE

1. Deepen commitment to patient engagement. All stakeholders should deepen their commitment to meaningful patient engagement as a core principle of health system planning and development.

2. Develop a legal and regulatory framework. Although all stakeholders aspire to an improved healthcare system and patient access to innovative medicines, the current incentives and barriers built into the system prevent any single group from making significant progress. Government can lay the cooperative groundwork by developing a legal and regulatory framework that moves us toward value-based healthcare and harmonization of pharmaceutical access.

3. Create an independent convener. Conversations about pharmaceutical access are happening across Canada, with people talking about pricing, user fees, health technology assessment, provincial vs. federal roles, pharmacare and other topics of special interest. Stakeholders need to empower an independent entity to act as a convener and network hub to draw on ongoing work, broker connections and unite recommendations for government.

4. Define a new funding model for pharmaceuticals. For long-term system sustainability, federal and provincial policymakers need to come together to define a new funding model for pharmaceuticals. The costs and benefits of innovative medicines should be discussed within the context of the role of pharmaceuticals in the healthcare system as a whole, emphasizing value for patients and payers while ensuring an innovative industry ecosystem.

CONCLUSION

Developing a new health framework that determines how Canadians access publicly covered innovative medicines will take courage, commitment and compromise from all stakeholders. Governments are trying hard to change things for the better and need to work with patients, clinicians and industry to design a modern system that ensures access to the right mix of proven and innovative medicines.

Since 2010, the provinces have voluntarily worked through the pCPA. Some provinces, Ontario most recently, have called for a breakthrough in federal-provincial collaboration to make medicines more accessible to all Canadians.⁴³ There is better communication than ever before between ministries, and better government engagement with patients, physicians and innovators. But pharmaceutical innovation leaps ahead while policy change is incremental, and patients want policy transformation.

The literature already contains a variety of frameworks for change that lay out objectives and actions related to access and value.⁴⁴ What we need now is dedicated leadership and a renewed commitment in government to join patients, healthcare providers and industry to take action. Canada's health system is large and complex. Aligned public policy will be the most important enabler to a transformed health system.

Courage starts with patients and their allies in government, industry and healthcare. It's being seen at the highest levels, with former federal Minister of Health Jane Philpott's call in 2017 for healthcare integration and a better healthcare system and the 2018 federal budget commitment to an Advisory Council on the Implementation of National Pharmacare. Ontario's OHIP+ program is evidence of provincial political will. We saw firsthand the tenacity of Canadians at roundtables across the country, with participants who engaged in an open and, at times, charged conversation. There is ample will for change, but Canada needs a leadership call to action to take the first big step.

⁴³ Morgan, S. G., Gagnon, M. A., Mintzes, B., & Lexchin, J. 2016. A better prescription: advice for a national strategy on pharmaceutical policy in Canada. p. 18. *Healthcare Policy*, 12(1).

⁴⁴ Ibid.

ANNEX 1: PARTICIPANTS

TORONTO ROUNDTABLE

Allison Barr

Ontario Ministry of Health and Long-Term Care

Pamela Fralick

Innovative Medicines Canada

Paul Grootendorst

University of Toronto

Fred Horne

Fred Horne and Associates

Ella Korets-Smith

TO Health! Initiative

Fiona Legere

McCarthy Tétrault LLP

Joel Lexchin

York University

Susan Marlin

Clinical Trials Ontario

Suzanne McGurn

Ontario Ministry of Health and Long-Term Care

Sang Mi Lee

Pan-Canadian Pharmaceutical Alliance

Glenn Monteith

Innovative Medicines Canada

James Pan

Centre for Commercialization of Antibodies and
Biologics

Nav Persaud

St. Michael's Hospital

Rocco Rossi

Prostate Cancer Canada

Hugh Scott

Innovative Medicines Canada

Naomi Shuman

Science Policy Researcher

Brad Wouters

University Health Network

Janet Yale

The Arthritis Society

Moderator

John T. Wright

University of Regina

EDMONTON ROUNDTABLE

Anne Babineau

Innovative Medicines Canada

Alex Boudreau

Alberta Health Services

Hubert Eng

Government of Alberta

Michael Flood

BioAlberta

Farid Foroud

Government of Alberta

Beth Kidd

Health Coalition of Alberta

Sohaib Khalid

Government of Alberta

Christie Lutsiak

Government of Alberta

Rob MacDonald

Government of Alberta

Tatiana Makhinova

University of Alberta

Greg Metzger

Government of Alberta

Ronnie Miller

Roche Canada

Ruth Mitchell

Government of Alberta

Glenn Monteith

Innovative Medicines Canada

John Sproule

Institute of Health Economics

Moderator

John T. Wright

University of Regina

Observing:

Hugh Scott

MONTREAL ROUNDTABLE

Frédéric Alberro

Innovative Medicines Canada

Luc Boileau

Institut national d'excellence en santé et en services
sociaux

Micheline Boucher

Retired doctor, representing Conseil de la
protection des malades

Marie-Kym Brisson

Génome Québec

Frédéric Fasano

Servier Canada

Pamela Fralick

Innovative Medicines Canada

Michel Gagné

McCarthy Tétrault LLP

Carole Jabet

CRCHUM

Glenn Monteith

Innovative Medicines Canada

Nathalie Ouimet

Montréal InVivo

Hugh Scott

Innovative Medicines Canada

Moderator:

Paul L'Archevêque

CapCOGITO

OTTAWA ROUNDTABLE

Amir Attaran

University of Ottawa

Louise Binder

Save Your Skin Foundation

John-Peter Bradford

Life Saving Therapies Network

Niya Chari

Canadian Breast Cancer Network

Douglas Clark

Patented Medicine Prices Review Board

Connie Côté

Health Charities Coalition of Canada

Wayne Critchley

Global Public Affairs

Perry Eisenschmid

Canadian Pharmacists Association

Nancy Farady-Smith

Innovation, Science and Economic Development
Canada

Pamela Fralick

Innovative Medicines Canada

Gerry Jeffcott

3Sixty Public Affairs

Jennifer Kitts

Health Care CAN

Stéphanie Michaud

BioCanRx

Glenn Monteith

Innovative Medicines Canada

Susan Murray

Canadian Life and Health Insurance Association

Renata Osika

National Alliance of Provincial Health Research
Organizations

Cathy Parker

Health Canada

Karen Reynolds

Health Canada

Jill Skinner

Canadian Medical Association

Maureen Smith

Canadian Organization for Rare Disorders

Joan Weir

Canadian Life and Health Insurance Association

Moderator

Rob Annan

Public Policy Forum

Observers:

Hugh Scott

Innovative Medicines Canada

Gemma Legresley

Innovation, Science and Economic Development
Canada

VANCOUVER ROUNDTABLE

Carl Anderson

B.C. Innovation Council

Gail Attara

Gastrointestinal Society

Brian Carter

Ayogo Health Inc.

Lisa Carver

Michael Smith Foundation for Health Research

Jennifer Cudlipp

Life Labs

Karimah Es Sabar

Quark Venture

Diane Finegood

Simon Fraser University

Pamela Fralick

Innovative Medicines Canada

David Frost

McCarthy Tétrault LLP

Paul Gudaitis

Innovative Medicines Canada

Malcolm King

Simon Fraser University

Richard Klasa

Canadian Doctors for Medicare

Cheryl Koehn

Arthritis Consumer Experts

Eric Lun

Ministry of Health

Larry Lynd

University of British Columbia

John Mah

First Nations Health Authority

Marlee McGuire

University of British Columbia

Darren McKnight

First Nations Health Authority

Glenn Monteith

Innovative Medicines Canada

Susan Ogilvie

LifeSciences BC

Dean Regier

University of British Columbia

Hugh Scott

Innovative Medicines Canada

Caroline Wang

Family Physician

Moderator:

Fred Horne

Horne & Associates

HALIFAX ROUNDTABLE

Bruno Battistini

New Brunswick Health Research Foundation

Sara Colburne

NATIONAL Public Relations

Benjamin Davis

MS Society of Canada

Pamela Fralick

Innovative Medicines Canada

Tim Gillis

STI Technologies Inc.

Doris Grant

Dalhousie ILI Department

Eleanor Hubbard

Elevate Strategies Inc.

Robert MacDonald

Lung Association of Nova Scotia

Marli MacNeil

Nova Scotia Health Research Foundation

Pat McGrath

Nova Scotia Health Authority and Dalhousie University

Scott Moffitt

BioNova

Glenn Monteith

Innovative Medicines Canada

Tracey Preeper

Nova Scotia Department of Health and Wellness

Angela Purcell

Nova Scotia Department of Health and Wellness

Hugh Scott

Innovative Medicines Canada

Ingrid Sketris

Dalhousie University

Peter Vaughan

Canada Health Infoway

Moderator

Fred Horne

Fred Horne and Associates

