

Special Fireside Chat on CADTH in a Post-Pandemic Landscape

7th Annual Forum on PATHWAYS TO ACCESS & REIMBURSEMENT

January 20 – 21, 2022 (EST) • Virtual Conference

Distinguished Co-Chairs:



Alexis Sciuk Canadian Health Care Solutions Lead



Farah Husein Director, Evidence Generation Scientific and Medical Affairs, Takeda Canada The Canadian pharmaceutical reimbursement landscape is on the cusp of significant change. Stakeholders are grappling with how to improve drug access and reimbursement for patients, in a sustainable way.

It's a critical time to work collaboratively, and think differently about drug-to-market processes.

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The 2022 Agenda features the latest insights on:

- The impact of the pandemic on **CADTH** reviews and **pCPA** negotiations, and how to mitigate time-to-market delays
- **Cell and Gene Therapy:** Securing public/private payer reimbursement for these potentially life-changing but high-cost therapies
- How to attract and retain top-notch talent to Canada's life sciences sector amid shifting public policy
- **Data Optimization:** How to obtain, analyze, and utilize health outcome data to empower decision-making from clinical trials to reimbursement and beyond

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he COVID-19 pandemic has exacerbated time and budgetary constraints leaving market access strategies in a precarious place. At the same time, the National Pharmacare program and PMPRB reforms continue to unfold slowly, with many questions yet to be answered about how these pieces will form a cohesive approach to improved access and affordability without sacrificing innovation.

The 7th Annual Pathways to Access & Reimbursement Forum will host critical conversations, examining the most vexing questions and challenges hovering over manufacturers, payers, and patient groups alike, while also exploring opportunities to empower decision-making so that the right treatment reaches patients at the right time. On January 20-21, Cl invites stakeholders to come together for constructive dialogue on:

- Adopting innovative approaches to contracting and drug pricing agreements within the Canadian context
- Optimizing Health Data: How to take a coordinated approach to harnessing data to improve patient outcomes
- Creating a National Pharmacare program that works collaboratively with industry stakeholders to fill gaps in drug access

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Distinguished Faculty

CO-CHAIR:



Alexis Sciuk Canadian Health Care Solutions Lead Pfize



Scientific and Medical Affairs, Takeda Canada

DISTINGUISHED SPEAKER:



Gail Attara President & Chief Executive Officer **Gastrointestinal Society**

Louise Binder Health Policy Consultant Save Your Śkin Foundation



Matthew Brougham President and CEO **Brougham Consulting Inc.**

Andrew Casey President & CEO **BIOTECanada**



BCCH CF Clinic Director, Medical Director **CF Care BC** Dr. Tijana Fazlagic Executive Director.

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Chad Jarema

Farah Jivrai Head, Market Access, Relations **Biogen Canada**

Professor, Department of Medicine, Division of Nephrology **University of Alberta**

Daphne Lainson Partner

Laurie Lambert CADTH

Sang Mi Lee Access Lead. Roche

Barbara A. Martinez National Practice Leader. Drug Solutions Canada Life

Andrea Masters Associate Director, Pricina



Smart & Biggar LLP

Lead. Real World Evidence

Personalized Healthcare



Wayne Critchley Senior Associate **Global Public Affairs**

2 #CIPathways TWITTER: @CI_Healthcare LINKEDIN: Healthcare, Pharmaceutical and Medical Device Network

Reviews CADTH Mathieu Gagné Partner

VP, Pharmaceutical

Fasken Martineau **DuMoulin LLP**

Brent Fraser

Brad Groves Associate Director. Managed Access

Director, Pricing Strategy, Contracting and Negotiation Merck

Policy and Stakeholder

Roche Suzanne McGurn







Partner Sidley Austin LLP Joan Weir Vice President of

Group Benefits **Canadian Life and Health Insurance** Association

Durhane Wong-Rieger President & CEO **Canadian Organization** for Rare Disorders









Daria O'Reilly

Lead Health Economist, Pharmacy Consulting,

Senior Strategic Advisor

PDCI Market Access Inc

Pediatric Neurosurgeon,

Canada Research Chair

in Human Cancer Stem

University Scholar Chair, McMaster College

of Health Inventors

Assistant Professor,

Leslie Dan Faculty of

University of Toronto

McMaster Children's

& President Emeritus

Dr. Sheila Singh

Hospital

Cell Biology,

Mina Tadrous

Pharmacv

Dominic Tan

pCPA Office

Trevor Wear

Senior Manager





Dr. Scott Klarenbach





Laboratory & Blood **BC Ministry of Health**

Life Sciences Ontario Pamela Fralick

President nnovative Medicines Canada

Services Division



Day One Thursday, Jan. 20, 2022 (EST)

8:45

Co-Chair Opening Remarks

9:00 OPENING KEYNOTE

Light at the End of the Tunnel—Yes or No? Examining What it Will Take to Build a More Resilient, Patient-Driven Health Care System in Canada

9:30

Forecasting Time-to-Listing Amid the Pandemic: What to Expect and How to Mitigate Delays in the CADTH Review and pCPA Negotiation Process

- Gain insights on how the pandemic has impacted CADTH and the pCPA and what to expect in 2022
- What manufacturers can do to reduce backlogs and expedite processes
- Examining the results of the new Targeted Negotiation Process (TNP) and implications for future negotiations
- Assess pricing and negotiation strategies, with guidance on what agencies are looking for and how they are conducting comparative analysis

10:30 Break

11:00

Innovative Contracting and Drug Pricing: How to Build a More Agile Reimbursement System in Canada

There have been successful innovative agreements and examples of agility in the Canadian pathway to access for innovations. However, there is a lack of sharing the learnings and no guidance for industry in terms of the characteristics or scenarios where innovative agreements are of value to payors and patients. More transparency, empathy and collaboration across all stakeholders is necessary to identify and achieve shared outcomes around building a more agile reimbursement pathway in Canada. This session will explore:

- How the current environment for new products and innovative medicines coming to market is not well served by the traditional negotiation approach that relies on setting prices or capping expenditure based on anticipated volumes or estimated cost-effectiveness
- An industry developed framework based on the key challenges in opportunities in Canada
- Examples of innovative agreements developed and used by public jurisdictions outside of Canada
- Examining high-level characteristics of these types of agreements (performance-based, amortization, subscription, package, portfolio)
- Working collaboratively: How public payors and manufacturers can develop a pan-Canadian process that includes different approaches beyond simple price first dollar discounts and volume agreements to achieve timely access to new treatments while providing increased value and improved fiscal sustainability for payors

12:00 CASE STUDY

How Stakeholders Collaborated to Achieve Timely Patient Access and Reimbursement for an Innovative Cystic Fibrosis Treatment

Expediting patient access for new, innovative treatments for rare diseases continues to be a challenge in Canada. The review and negotiation periods can be long and arduous for stakeholders who are working diligently to ensure safety and efficacy, while also grappling with the question of affordability. However, a newly developed cystic fibrosis treatment, lauded as life-sustaining for patients, secured a priority review by Health Canada, a recommendation from CADTH and successful pricing negotiations leading to PLAs for public reimbursement in several provinces. This session will examine:

- What contributed to market entry and reimbursement for Trikafta in Canada
- » Examining lessons learned for creating more timely access to other potentially life altering drugs for rare disease
- » Analyzing the details of CADTH's recommendation and the impact on reimbursement
- Identifying barriers to drugs for rare diseases and how to improve current pathways to access
 and reimbursement

12:45 1:1 Networking

1:00 Break

1:30

How to Optimize Data and Health Resources to Support Patient Centred Decision-Making on New and Innovative Therapies

- Identifying gaps in health data across Canada
 - » How to approach siloed data on apps, wearables, that could hold valuable insights and support reimbursement decisions
- Assessing the viability of a national health data registry
 - » What are the key steps towards building a robust database?
 - » How to build strong data governance practices that ensure patient privacy
- Explore practical examples of how RWD turned RWE can be used in reimbursement decisions

2:30

Key Industry Learnings and Good Practices Gleaned from Experienced pCPA Negotiators

- General principles and practices to optimize success
- Optimizing the negotiation flow for speed
- Initial meeting checklist to hit the ground running

3:15 Break

PMPRB Implications and Takeaways for Companies

4:15

How to Navigate Exceptions to the Co-Pay Ban under Bill 92 in Quebec

The Government of Quebec has published the final regulation restricting financial assistance to patients for drugs covered under Quebec's basic plan. To avoid running afoul of the regulation, manufacturers will need to reassess current activities within the context of the ban and gain clarity on where exceptions will apply. This session will cover:

- Examining what the prohibition under Bill 92 covers and the implications for manufacturers and PSPs
- Interpreting criteria set out for exceptions to the co-pay ban
- How to determine if payments are permissible on humanitarian grounds, and where a continuance applies

5:00 Conference Adjourns

Day Two Friday, Jan. 21, 2022 (EST)

8:50

Co-Chair Opening Remarks

9:00 FIRESIDE CHAT: THE VISION FOR CADTH 2022 AND BEYOND

How HTA & HTM is Evolving and the Implications for Canada's Health System and its Stakeholders

In July 2020, Ms. Suzanne McGurn stepped into the role of President and CEO of CADTH. This session will focus on lessons and insights from the first 18 months at the helm, amid immense change sparked by the pandemic. Learn how CADTH has responded and continued to be "Driven by the Evidence" during this turbulent time, the agency's top priorities for 2022 and how it will be engaging with industry.

- The importance of evidence and science has never been more visible and critical than during the pandemic, what may be the lasting impacts on decision-makers as they look forward to what a resilient and modern health care system will look like, while they continue to grapple with difficult decisions with finite resources?
- What role will organizations like CADTH play in a post-pandemic world and how is the organization reflecting and retooling to be ready to respond to the rapidly evolving needs of Canadian healthcare decision-makers?
- Building on the new relationships that have been forged amongst stakeholders old & new how do we maintain those relationships effectively in the future

9:30

Scaling up Canada's Life Sciences Sector: How to Attract Investment and Retain Talent

- Understanding how stakeholders can increase growth and investment in the life sciences and pharmaceutical sector
- How to attract top-level talent and retain it
- Identifying key obstacles to commercialization for innovative therapies and how to overcome them
 - » Sourcing funding for innovative research and the journey to market
 - » How to build industry partnerships
 - » Examining the influence of current domestic and international policies

10:30 Break

3:45

Journey Mapping: What the Patient Experience Reveals about Pathways to Access & Reimbursement for Rare Disease

In this session, Canadians living with a rare disorder will share their personal journey from the point of diagnosis through to drug access and reimbursement. A focus will put on:

- Identifying obstacles to innovative therapies
- How stakeholders within Canada's health system can improve the patient experience
- · How apply insights from the patient journey to decision-making on access and reimbursement
- Status of the National Strategy for Drugs for Rare Diseases

11:45 CASE STUDY

Analysis of Biosimilars in Canada: How have Switch Policies Impacted Drug Spending and Health Outcomes

Ontario, Quebec, and other provinces across Canada have announced that they will follow British Columbia's lead in pursuing their own non-medical switch policies for biosimilars. There has been extensive discussion about the impact on patients, who are already stable on a biologic as well as the opportunity for significant cost savings should biosimilars achieve similar therapeutic results. B.C. completed its phased approach to switching patients in October. This session will explore:

- What initial data indicates about the patient response to the switch to biosimilars
- How has this impacted the provincial budget?
 - » Is the program on track to achieve projected savings?
- Understanding how the province will approach biologics, and where medical exceptions will be made
- · How the switch to biosimilars could potentially support access to new innovation



12:15 1:1 Networking

12:30 Break

Perspectives on Creating Sustainable Pathways to Access and Reimbursement for Gene Therapies

Gene therapies present an exciting opportunity to significantly improve patient health outcomes but the road to access is fraught with challenges from a regulatory and reimbursement perspective. This session will examine how public payers and regulatory review bodies across Canada are developing strategies to:

- Evaluate the safety, efficacy and overall value of these specialized treatments
- Improve accessibility through collaboration with key stakeholders
- Manage the impact of high-cost therapies on the overall health budget

1:45

Top 3 Trends in the Private Payer Landscape that Could Impact your Market Access Strategy

- How are payers approaching reimbursement for gene therapies and high-cost drugs?
 - » Anticipating how this will impact drug plan design
 - » What happens when a patient moves to a new employer/plan?
- Examining drug utilization trends emerging from the COVID-19 pandemic, and anticipating what's coming
- Analyzing the current private payer market and how employers are approaching drug spending
- Identifying employer expectations and approaches to cost containment

2:30 Break

3:00

Where Patent Protection Intersects with Market Entry Decisions: How to Set Your Organization's Access Strategy Up for Success in 2022

- Assessing loss of exclusivity: managing multiple variables within the context of the global market
- Dealing with uncertainty: assessing legislative and judicial developments
- How to plan for 2022 and beyond

3:45

The Latest in U.S. Drug Pricing Reform and the Implications for Manufacturers

This session will examine the where proposals on drug pricing reform have landed and the implications for manufacturers.

- H.R. 3: Analyzing the steps being taken towards allowing government to negotiate drug prices
- » Projected impact on new drug development and generics
- Increasing drug importation, implications for Medicaid

4:30 Conference Adjourns



WHO SHOULD ATTEND

Practitioners at every level with experience in:

- Pricing
- Reimbursement
- Market access
- Patient access
- Government and regulatory affairs
- Health economics
- Research and development

From brand generic and manufacturing companies involved in:

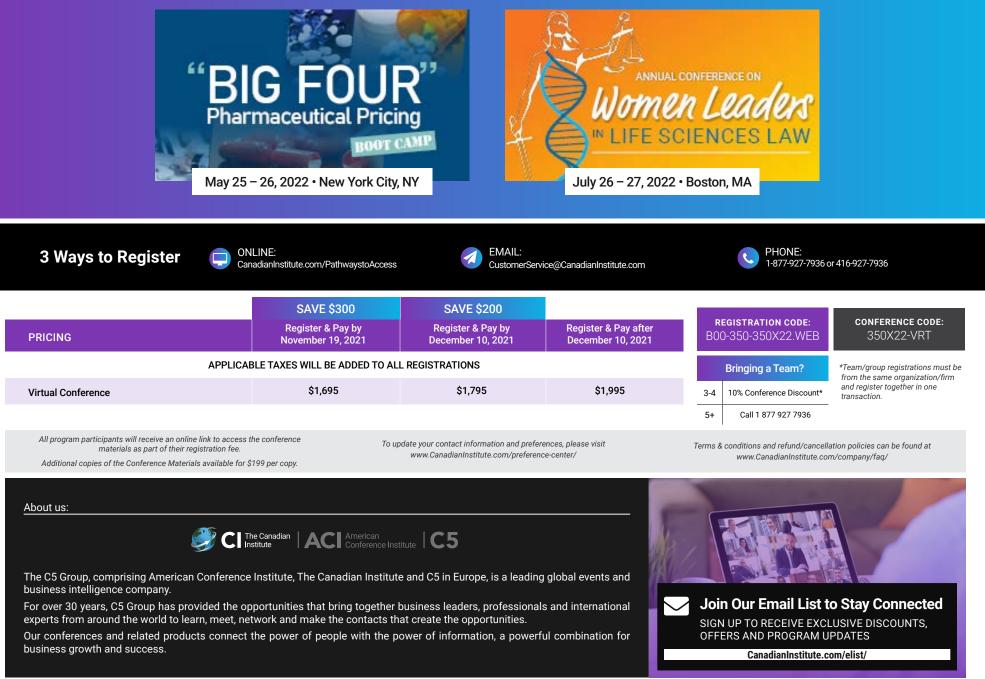
- Product development
- Public drug programs
- Pharmaceutical benefits
- Pharmaceutical strategy
- Drug submissions

And representatives from:

Associations

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- Marketing
- National trade
- Formularies
- Business development
- Sales
- Formulary management
- Policy and economic analysis
- Provider services and relations
- Pharmacy
- Patient Advocacy Groups

UPCOMING EVENTS



Join Us Virtually this January!

As the current global situation continues to unfold, we understand that it may not be possible to attend our events in person.

At the same time, we also understand that collaboration is more vital than ever and for that, you can still rely on C5 and ACI to bring the industry together but in a different way. We are transforming quickly to ensure you can now connect virtually and continue to gain unparalleled access to market leading intelligence and to the facilitation of a global exchange of expertise.

Our new virtual events continue to be guided by our unifying philosophy: we believe that growth and success occurs when the power of people and the power of information come together. We may not be able to gather in person, but nothing stops connection and innovation.



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