# Interview: Brian O’Rourke – President and CEO, Canadian Agency for Drugs and Technologies in Health (CADTH)



***"Our engagement with industry is equally proactive, collaborative, and transparent."***

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*Dr. Brian O’Rourke, president and CEO of CADTH, presents the organization’s main programs and the strategies it has put in place in order to ensure excellence in the future as they face reforms in the country’s healthcare system. Adaptation to stakeholder needs, including those of the pharmaceutical industry, and to new drug forms will be required to maintain CADTH’s reputation and ensure successful outcomes.*

**Can you please introduce CADTH’s mandate to our international readers?**

CADTH is an independent, non-for-profit organization that provides Canada’s healthcare decision makers with evidence-informed advice and recommendations on the optimal use of drugs and medical devices in our healthcare system. We were originally established almost 30 years ago as a small organization, with the mandate to help coordinate the health technology assessment (HTA) that was happening, primarily for medical devices, across Canada. Over time CADTH grew and added the assessment of prescription drugs to our portfolio. In 2003, in an effort to standardize input into public drug plan listing decisions, the Ministers of Health established the CADTH Common Drug Review (CDR). Previously, each public drug plan conducted its own drug reviews and decided independently which drugs it would pay for. The consolidation of drug reviews under CADTH established a much-needed pan-Canadian approach that was more efficient, consistent, and

transparent.

Today, CADTH continues to grow, evolve, and innovate, but we remain a vital and trusted resource for the Canadian healthcare system. We're well known for the quality of our science, decision makers depend on us for both our advice and recommendations, but also to help them keep pace with the emerging trends and health technologies they need to be thinking about now. We employ approximately 200 people today, are funded by Canada's federal, provincial, and territorial governments, with the exception of Quebec, We organize our work across two main portfolios – one being pharmaceuticals and the other medical devices , which includes medical, dental, and surgical devices, as well as procedures, programs, and diagnostics.

Our goal at CADTH is to shift our activities more and more towards implementation, by helping jurisdictions in the concrete implementation of our recommendations.

**What have been some of the services you developed within your portfolio in the past years?**

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As I mentioned, the CADTH Common Drug Review is a flagship program that we've operated for over a decade. Through the program, we review new drugs and existing drugs for new indications, and provide evidence-informed reimbursement recommendations to the public drug plans (except Quebec). In April 2014, the pan-Canadian Oncology Drug Review (pCODR) program was transferred to CADTH to help consolidate policy direction across Canada's drug review programs. The pCODR program assesses cancer drugs and makes reimbursement recommendations to the public drug plans and cancer agencies. There are many similarities in terms of how the programs approach pharmaceutical reviews, but they operate as separate and distinct programs.

Over and above the single technology reviews we deliver through CDR and pCODR, we also do therapeutic (or "class" reviews) when the drug plans need help positioning all the drugs available for a particular disease. Over the past few years we've done therapeutic reviews on drugs for multiple sclerosis, rheumatoid arthritis, hepatitis C and diabetes. We also produce Optimal Use Reports and Recommendations that inform policy makers, but also help clinicians and patients understand how to appropriately use drugs available within a particular class.

Horizon scanning is another critical service we've been providing for many years, where we identify emerging therapies and other health technologies that could have a significant impact on Canadian healthcare. We summarize the best available evidence and include considerations like regulatory

status, cost, and considerations around implementation. We also leverage our pan-Canadian networks to conduct Environmental Scans that can help inform decision makers understand how health technologies are used across Canada, or in some case globally, with insight into practice variations and policy gaps.

In 2015, we introduced one of our newest products, the Scientific Advice Program. Typically, our customers are governments and other healthcare decision makers, but this new offering is intended for the pharmaceutical industry. Through this program, companies can turn to us, typically during their pre-phase three clinical trials, and request advice from us from the HTA perspective rather than a regulatory perspective. Based on a short dossier the company submits, we provide a series of recommendations on the design of their clinical trial, the outcomes and the various economic considerations involved. Our advice is non-binding and confidential, but it can help companies determine if adjustments should be made to their drug development plans. We've had excellent feedback on the program and even had requests for later stage reviews during phase three trials.

In the medical devices space, our best known program is the Rapid Response Program. It's a popular service that allows anybody in the public system — clinicians, policy makers, or administrators — to put forward a policy or practice research question and we provide an answer within a specified timeframe, whether that is a few weeks up to six months. Reports are delivered to the requestor, but they're also posted on our website for anyone to access. This program has been quite successful in supporting more evidence-informed policy and practice decisions

**The Canadian healthcare regulatory landscape is undergoing some reforms, involving Health Canada, CADTH as well as other bodies like PMPRB (Patented Medicines Prices Review Board). What is CADTH's involvement here?**

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We were asked by the federal government to submit a proposal describing how CADTH could expand what we do and offer greater support to Canadian jurisdictions, particularly around implementing our recommendations and advice. We submitted a Health Technology Management Strategy that outlines our vision to move beyond health technology assessment, towards a more comprehensive and holistic technology management approach. In the 2017 federal budget we received significant new funding to begin this evolution and grow our organization. Much of this work will involve other organizations, including Health Canada and PMPRB.

One of the first issues we're tackling with Health Canada is looking at how we can better align the regulatory and reimbursement systems and consider how we do more to work in parallel. Right now there is a pilot project underway with Health Canada's Bureau of Metabolism, Oncology, and Reproductive Science and our pCODR program to identify opportunities to share information, better align our work and identify gaps in the current processes.

I think that throughout 2018 we'll reach some milestones in terms of greater alignment, but it won't be without some disruption to the industry. Right now we operate on a "first in, first out" approach, where drugs are reviewed according to the order in which they were submitted. But if we want to get promising new therapies to patients faster, it means those drugs that really do show some promise are the ones we should be assessing first and perhaps working towards delivering regulatory approval, our reimbursement recommendation, and maybe even the price negotiation in a similar window of time.

**Some of the major trends and "game-changers" within the healthcare and life sciences industry include the rise of "niche-busters", biosimilars, companion diagnostics, cell therapies, etc. What do you see as some of the gamechangers affecting the Canadian market?**

I generally prefer the term "promising therapies". I believe the changing landscape is best illustrated by comparing the list of the top ten drugs by global sales in 2010 to one from 2016. In 2010, most drugs on the list were the traditional blockbusters, chemically synthesized drugs with a modest cost but targeting the masses. Today, the list has evolved and most of the products on it are biologics, with several for cancer indications, as well as orphan drugs for rare diseases. Although these "niche-buster" drugs generate over USD one billion in global sales per year, their targeted patient groups are much smaller and their costs per patient are extremely high.

These circumstances have really altered the HTA and payer landscape — the biologics certainly changed the market in that they are significantly improving patient outcomes, and they are creating budgetary challenges for public and private payers. Other trends we are observing are a growing pipeline of cancer drugs and drugs for rare diseases, and now with the introduction of gene therapies. Regulators, HTA bodies, payers, and clinicians will all need to adapt to meet these challenges.

**Given the fast-paced environment of healthcare, how does CADTH adapt to keep up with the ever-changing demands placed on the organization?**

Adapting will go hand in hand with CADTH gaining a greater awareness of upcoming trends, changes in methodologies, policy implications etc. CADTH needs to go further up-stream and to help us stay ahead of the game, we've done things like expand our Horizon Scanning service and Scientific Advice program to gain more insights into what's in the pipeline.

**In particular, a growing trend is the use of outcomes-based pricing models and the industry has been advocating for it in Canada. How ready is the Canadian health system for such models?**

That's a challenging question. In my experience, very few countries have true outcomes-based performance agreements — most are financial-based agreements, and we have those in Canada as well. Every province or territory has financial-based agreements of some kind in place, whether it's through spending caps, discounts, or rebates. The payers that I've spoken to see many challenges with outcomes-based agreements — how do you develop it, who monitors and reports on the outcomes, and who determines whether outcomes have been reached?

I think that in the future, we may see reassessments going forward to supplement financial agreements. For example, drugs that received a positive listing recommendation a few years ago may be reassessed based on new evidence that becomes available. Whenever an agency like CADTH delivers a recommendation, or when the regulator has given approval, there is still some uncertainty with that product — in some cases, a lot of uncertainty remains. So we could move to reassess a drug when new evidence becomes available, whether that's real-world data, new observational studies or new RCTs. We could bring that product back to our expert committees and the outcome could be a new recommendation that could then stimulate new price negotiations with the manufacturers, or could even lead to de-listing or disinvestment.

**In order to ensure the most effective products reach the patient in the end, it is essential for HTAs to collaborate with the industry. How does CADTH work with industry to ensure best outcomes for Canadian patients?**

CADTH is convinced of the importance of stakeholder engagement. In addition to engaging with the public programs that fund us, we frequently engage with key groups including hospitals and health authorities, the pharmaceutical and medical device industries, clinicians (physicians, nurses, pharmacists using and prescribing the technologies) and, most importantly, patients. For each of these four groups we have been taking specific actions to better address their needs.

I've said before that if you're not engaging with patients, you're not doing HTA, so we strive to put that philosophy into practice and find ways for patients to contribute to almost everything we do.

There are patient input opportunities for all our reviews of drugs and medical devices. We established a Patient Community Liaison Forum to share information and collaborate broadly on a variety of issues. In terms of our processes, we consult broadly on any proposed changes through a public call for stakeholder feedback.

Our engagement with industry is equally proactive, collaborative, and transparent. We established our Industry Liaison Forum, where the CEOs of Innovative Medicines Canada and BIOTECanada and a few of their member companies meet twice a year with me and my leadership team for high level discussions. We create opportunities for interaction with companies when we are reviewing one of their products. We host an annual CADTH drug information session for patients, clinicians, and industry representatives where we provide advice and clarification on existing or new programs and practices. We invite companies to respond to program changes through an online consultation. And we hold a number of educational events that are open to all stakeholders.

We've also identified engagement with clinicians as an area of focus going forward. We'd like to do more to reach out and understand the distinct needs of healthcare providers and how we can better inform the appropriate use of health technologies across the country.

**How do you collaborate with international HTA agencies, through the International Network of Agencies for Health Technology Assessment (INAHTA) for instance?**

I'm a big believer in co-creating and learning from other countries — there are important things that Canada can learn from countries like Germany, France, Australia, and the United Kingdom, for example — and the best way to do that is to be part of international networks.

INAHTA is indeed one big part of our international cooperation, but we work with many international agencies and networks. Health Technology Assessment International is a great society for individuals – anyone can become a member, whether you are a patient, an academic, on staff at an HTA agency, or work with industry. Their annual conference is an important meeting place to bring everyone together to share and learn from one another.

INAHTA is a network of 50 HTA agencies from over 30 countries and I'm proud to serve as the current Chair of the INAHTA Board of Directors. We recently approved a new strategic plan for the network that outlines how we can take a stronger leadership role and foster more collaboration between members. The field of HTA is continually evolving and it's through networking and collaboration that we can connect with colleagues who likely face similar issues and challenges, and have come up with novel solutions we can learn from.

**What can HTA agencies from other countries learn from CADTH?**

CATH is one of the larger HTA agencies around the world and over the past 28 years we've developed a very strong reputation in many aspects of HTA. I'm very proud of our efforts to expand patient engagement in all aspects of our work and I think we're well recognized in that area. And we make a concerted effort to continue evolving in this area, but also to share our learnings with our national and international colleagues. I also think our diverse portfolio of products, spanning pharmaceuticals and medical devices, is an excellent example that other countries can take inspiration from.

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