



INNOVATIVE  
MEDICINES  
CANADA

## 2016 ANNUAL REPORT

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Our industry is uniquely positioned to offer health system solutions to improve Canadians' lives as well as opportunities to build Canada's innovative economy.

## MESSAGE FROM THE INTERIM PRESIDENT

Innovative Medicines Canada is the national voice for the research-based pharmaceutical industry in Canada. Our members are a key component to the success of our healthcare system – it is through their research and expertise that new medicines are able to come to market and make a difference in the lives of Canadians.

I began my tenure as Interim President of Innovative Medicines Canada a few short months ago after having previously served on the association's Board of Directors as the former President and CEO of AstraZeneca Canada Inc. In the 28 years I have spent in this sector, I have witnessed the changing landscape of policy discussions and decision making and the accelerating rate of change in the past decade.

Health ministers and drug plan managers are facing significant pressures brought on by demographic shifts and economic challenges which are posing difficulties to healthcare sustainability. Conversations on healthcare models are increasingly focused on national initiatives such as the renewal of the Health Accord, a national formulary for prescription medicines and the increasing role of the pan-Canadian Pharmaceutical Alliance (pCPA).

Our industry is uniquely positioned to offer health system solutions to improve Canadians' lives as well as opportunities to build Canada's innovative economy. We are coming to the close of the second year of our strategic plan and our objectives to:

- Become an authentic, solution-driven partner through effective alliances, policy and leadership.
- Improve the access and regulatory environment in Canada.
- Advocate for a globally competitive Intellectual Property (IP) regime.

Beginning in 2015, Innovative Medicines Canada (then Rx&D), had initiated comprehensive consultations with all members of our healthcare ecosystem to better understand their needs and align ourselves on how best to serve Canadians.

We are listening, and changing, and we need to do more of both. On January 4 2016, the association became Innovative Medicines Canada and the spark of innovation our guiding light. It is much more than just a new name. It's a fundamental shift in the way we look at the challenges facing the industry and the healthcare system. We are seeking to build new partnerships and innovative solutions with governments, the life sciences sector and patient advocates to create fair, equitable and sustainable access to new innovative therapies.





As our environment changes, we must adapt our way of thinking and working, and align ourselves with the objectives of all the players in the healthcare ecosystem.

We are also continuing to put ethics and compliance front and center in these discussions. The association has been recognized internationally for our role in the development of the Canadian Consensus Framework for Ethical Collaboration which brings together leading health organizations that are committed to ensuring the relationships between patients, healthcare professionals and the pharmaceutical sector are based on ethical and responsible decisions.

As our environment changes, we must adapt our way of thinking and working, and align ourselves with the objectives of all the players in the healthcare ecosystem. The only way we will be successful is to become active participants in the discussion on sustainability, access and innovation. We have the skills and resources in our membership and our relationships with other stakeholders to offer real solutions to real systemic problems, and we have been actively pursuing these initiatives – from value demonstrating initiatives in Atlantic Canada to funding patient outcome research in the Prairies.

None of this work is feasible without the dedication of our Board, governance team members and staff. I have seen the commitment and hard work by our staff and membership as we tackle the issues of tomorrow and I can say with utmost certainty that the association and our members are poised to make a difference.

Sincerely,

Elaine Campbell  
Interim President

## MESSAGE FROM THE CHAIR

As I enter into my second year as Chair of the association's Board of Directors, I am pleased to see the progress we have made as an industry and within the association itself. Change is never easy, but it is often necessary.

What began as a reflection on the association's centennial in 2014 has culminated in a new vision for the future. After 40 years of working in the industry I am proud to see these changes come to pass during my first year as Chair.

I believe the association's new approach as Innovative Medicines Canada is more reflective of the industry in Canada and has allowed us to re-envision how we want to approach the next 100 years. The industry is a fundamental part of the healthcare system and our new brand and narrative now reflect the role we play.

Innovation is not only what we do – It's how we do it.

Along with the rebrand of the association, changes were made to our governance model resulting in a representative Board of Directors and the introduction of a two-year term for the Chair. These changes are key pieces in the evolution of the industry and allow us to better effect change as we work towards our strategic priorities.

From coast to coast we have seen great strides in the areas of access to medicines, regulatory improvements and authentic alliances. Some of these advances include:

- The creation of a clinical trials investment case which was piloted at a panel session at the Bio International Conference 2016, entitled "[Clinical Trials – The Canadian Advantage](#)";
- The funding of a new access model project in PEI through the Health Research Foundation to evaluate the impact of early access of three truly innovative medicines to patients, the health system and society;
- The acceleration of evaluation by *Institut national d'excellence en santé et en services sociaux (INESSS)* of breakthrough medicines to facilitate faster access; and
- Working with Health Canada to reduce compliance burden and reduce time to submission associated with plain language requirements for drug submissions.

These are just a few examples of the ways in which our association is actively pursuing our objectives and ensuring that access to innovative therapies remains a priority throughout the ever changing healthcare landscape.



We need to be collaborators, conveners and, most importantly, innovators as we navigate a new system that will serve the next generations of Canadians.

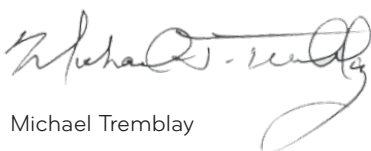
With a new federal government in place, and a renewed brand and vision for our future, we have the ability to shape the years to come in a way that has not been done for decades. We can no longer operate in silos and think of our industry as a standalone player in the healthcare ecosystem. We need to be collaborators, conveners and, most importantly, innovators as we navigate a new system that will serve the next generations of Canadians.

We are well on our way to achieving this goal but there is still work to be done. Assessments and understanding of common goals continue to be a priority, modernizations of the regulatory environment need to be evaluated and measured, and value demonstrating initiatives will continue to play a vital role.

I would be remiss if I did not recognize the hard work and dedication of the staff at Innovative Medicines Canada and the members of the Core and Advisory Teams that make up our new governance structure. It is because of the dedication of these individuals that I am able to report on the success of our strategies and renewed focus. This focus will be needed as we head into a new year with new ideas on how we will build solutions for Canadians.

If we are to be successful with the goals we set for our industry, we must be prepared to work together both as individual companies and as an industry within the healthcare ecosystem. We have the ability to offer real solutions to the issues facing our industry and the healthcare system and we are ready and willing to be a strategic partner to governments, payers and the life sciences sector to make those solutions a reality.

The future will be bright so long as we continue to come together and spark innovative ideas on achieving our common goals. The future of our healthcare system depends on it.



Michael Tremblay  
Chair of the Board of Directors

## THE INNOVATIVE MEDICINES CANADA BRAND

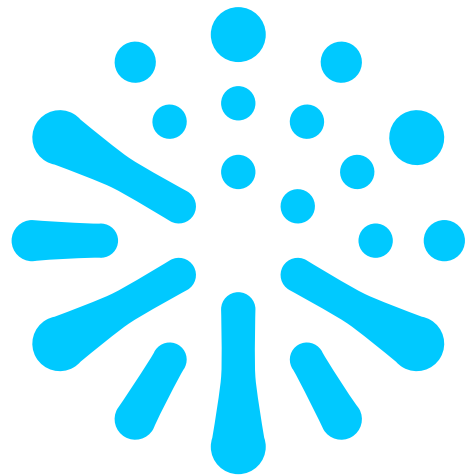
Innovation is about bringing together disparate ideas, people or processes. When the dots are connected, the resulting spark of discovery brings something completely new into the world.

The “spark” symbol for Innovative Medicines Canada evokes this spirit of innovation. The idea of innovating by drawing connections is central to the purpose of Innovative Medicines Canada. By bringing together patients, partners, processes, research and new treatments, Innovative Medicines Canada enables its members to discover, develop and deliver innovative medicines and vaccines to Canadians.

Innovation transcends research facilities and underlines all that we do.

We are innovative when we:

- Change the way we engage with and listen to our stakeholders
- Partner in research
- Demonstrate the value of our medicines and vaccines, and the value of our industry to Canada
- Lead the way in setting high ethical standards for our behaviour
- Push the envelope to make Canada more competitive internationally





A young woman with dark hair and glasses is smiling at the camera. She is wearing a light-colored, textured sweater and a thin necklace. She is holding a stack of books in her hands. The background is a library with many bookshelves filled with books. The entire image has a blue tint.

By working collectively on our strategic priorities we are contributing to a broader dialogue on the sustainability of our healthcare system and collaborating to create programs and solutions to meet the challenges of tomorrow.

## EXECUTIVE SUMMARY

Innovative Medicines Canada and our members believe all Canadians can and should have access to the best healthcare system and the innovative therapies that are a part of it. By working collectively on our strategic priorities we are contributing to a broader dialogue on the sustainability of our healthcare system and collaborating to create programs and solutions to meet the challenges of tomorrow.

2016 was the second year of Innovative Medicines Canada's three year plan to address the following strategic objectives:

- Become an authentic, solution-driven partner through effective alliances, policy and leadership.
- Improve the access and regulatory environment in Canada.
- Advocate for a globally competitive Intellectual Property (IP) regime.

We began the year with the exciting launch of our new name and brand *Innovative Medicines Canada* – a name which now truly reflects our values and the innovation of not only what we do, but how we do it. This new visual representation also came with a reaffirmed commitment to build partnerships that help spark innovation and better access to health solutions.

These partnerships are founded on trust, mutual understanding and the highest ethical standards. Along with our Code of Ethical Practices, the newly launched Canadian Consensus Framework for Ethical Collaboration reaffirmed our commitment, along with those of leading Canadian health organizations, that collaboration is needed between patients, researchers, industry and healthcare providers to drive healthcare innovation and generate improved healthcare outcomes.

These authentic alliances have been formed across our country with governments and patient groups, health research organizations and life science centres. They broaden our collective knowledge and measure the positive effects of innovative medicines on Canadian patients, healthcare sustainability and Canada's knowledge-based economy.





Innovative Medicines Canada also continues to play an integral role in providing advice, guidance and support to the Canadian Clinical Trials Coordinating Centre (CCTCC) to create a more visible and navigable environment in Canada.

#### FROM COAST TO COAST, WE HAVE BUILT MANY PARTNERSHIPS:

In British Columbia, we are working with LifeSciences BC and the Centre for Drug Research and Development to demonstrate how the industry can address the province's healthcare sustainability concerns through innovative and holistic approaches to policy development.

Funded by the Health Research Foundation of Innovative Medicines Canada, the Saskatchewan Adherence Project is underway in two communities to support adherence to chronic disease medications.

We partnered with Alberta Innovates Health Solutions on a collaborative solution-building seminar with key Alberta strategic clinical networks and worked directly with the Ontario government on Drug Submission Guidelines and the Exceptional Access Program.

A partnership between industry, Montreal InVivo and university research hospitals in Quebec will improve the clinical research environment and increase clinical trials in Montreal and our work with INESSS has resulted in the province accepting pre-NOC submissions and a more rapid evaluation process.

In Atlantic Canada, we are paving the way for future collaborations between industry and government health plan providers to create solutions that will benefit Atlantic Canadians. Innovative Medicines Canada and BioNova signed a Memorandum of Understanding (MOU) that will help develop partnerships that will lead to the discovery of the next generation of life-saving therapies.

Innovative Medicines Canada also continues to play an integral role in providing advice, guidance and support to the Canadian Clinical Trials Coordinating Centre (CCTCC) to create a more visible and navigable environment in Canada to enable the attraction of more clinical trials investment, jobs and options for patients.

At the federal level, Innovative Medicines Canada provided significant government relations outreach support and intellectual property expertise during the Comprehensive Economic and Trade Agreement (CETA) negotiations between Canada and the European Union and we will continue to leverage our collective strengths as we work towards the government's innovation strategy and health system goals.

Our members continue to research, develop and introduce new medicines, and vaccines to Canada. Our *Access to New Medicines in Public Drug Plans Annual Report for 2016* shows that 121 new medicines were introduced to Canada between 2010 and 2014. A review of this period shows the increasing importance of biologics and targeted therapies and the shift to the era of personalized medicine that has begun. These new medicines will not only save lives and improve the quality of lives for millions of Canadians but continue reduce demand for hospital services while improving workplace productivity.


The global pipeline continues to grow, with over 7,000 new medicines in development to help address cancer, cardiovascular disorders, diabetes, mental health, neurological disorders, infectious disease and immune disorders. By working collaboratively with governments, the private insurance industry and all other healthcare system stakeholders, we can ensure these new treatments options are accessible quickly and fairly for all Canadians who may need them.

We have the skills, knowledge, resources and understanding to leverage assets that have been built over many years in partnership with the Canadian healthcare system. Whether it is the programs our members deliver, the medicines they develop or the investment we bring that supports the life sciences sector, we have shown that we are committed to both sustainability and improved outcomes.

The work done over the past two years to meet our priorities has laid a foundation for exceptional years ahead. The future will see the industry become an active and more visible participant in the pharmaceutical policy environment and a key driver in the development of sustainable solutions for our healthcare systems.

We have the skills, knowledge, resources and understanding to leverage assets that have been built over many years in partnership with the Canadian healthcare system.



A full-page background image with a blue tint. It depicts a woman and a young child playing in shallow water. The woman is leaning over the child, holding them, and both are laughing and splashing. Water droplets are frozen in the air around them. The scene is joyful and captures a moment of connection.

Authentic alliances cannot occur without mutual respect and an understanding of the perspectives of others. Canadians also expect their institutions to adhere to the highest ethical standards.



## REPORT ON PRIORITY 1

### BECOMING AN AUTHENTIC, SOLUTION-DRIVEN PARTNER THROUGH EFFECTIVE ALLIANCES, POLICY AND LEADERSHIP.

Innovative Medicines Canada and our members are key pillars to the success of Canada's healthcare system and innovative economy. Over the years, we have developed effective alliances that focus on creating sustainable solutions for Canada's healthcare ecosystem.

Governments face a growing challenge to modernize and sustain Canada's healthcare challenges while managing an aging population during an era of slower economic growth. They are seeking solutions to address the many challenges they face including how to leverage the value of innovative products and processes while addressing provincial inequities in access to healthcare. Collaboration between healthcare professionals and patient organizations is essential and increasingly important to healthcare delivery and research. Authentic alliances cannot occur without mutual respect and an understanding of the perspectives of others. Canadians also expect their institutions to adhere to the highest ethical standards.

That is why Innovative Medicines Canada was proud to join Canada's leading health organizations to create a framework that will help ensure that the relationships between patients, healthcare professionals and the pharmaceutical sector are based on ethical and responsible decisions. [The Canadian Consensus Framework for Ethical Collaboration](#) provides guidance on activities like clinical trials, continuing health education, conferences, accountability and funding.

The Consensus Framework was recently cited as a global best practice by Asia Pacific Economic Cooperation (APEC) and is a collaborative work between the Best Medicines Coalition, Health Charities Coalition of Canada, the Canadian Medical Association, the Canadian Nurses Association, the Canadian Pharmacists Association and Innovative Medicines Canada. It will help generate more initiatives that connect the best and brightest across the country to create funding initiatives, develop value demonstrating initiatives and bring together key opinion leaders on health policy issues.

Across the Prairies, similar alliances are taking shape with a focus on ethical collaboration. The University of Manitoba is reviewing its industry relations policy to ensure a fair and consistent policy implementation that provides an opportunity for ethical industry interactions. Alberta Innovates Health Solutions is partnering with Innovative Medicines Canada for a collaborative solution-building seminar with key Alberta strategic clinical networks. Funded by the Health Research Foundation (HRF) of Innovative Medicines Canada, the Saskatchewan Adherence Project is underway in two communities to support adherence to chronic disease medications.





The Innovative Medicines Canada team is working diligently to create strong connections with key decision makers and influencers among the 338 elected Members of Parliament.

The HRF has focused on funding collaborative applied health research projects that improves patient outcomes and health system sustainability. Communication tools including a video and region-specific data sheets on HRF investments and its impact were developed to highlight the Foundation's leadership in health system sustainability research.

For the second year, we have created a national health advisory panel that allows us to engage with thought leaders on issues of critical importance to the future of the healthcare system, its sustainability and maintaining a vibrant life sciences sector across the country. We are also engaging with governments to look at these same issues and bring together key stakeholders to bridge gaps and focus on solutions. With the association newly rebranded, and a newly formed federal Liberal government, there was a need and opportunity to educate stakeholders, including almost 200 first time elected officials about our shared values and collective goals.

The Innovative Medicines Canada team is working diligently to create strong connections with key decision makers and influencers among the 338 elected Members of Parliament. Combining Innovative Medicines Canada meetings and individual company outreach efforts we connected with well over 200 MPs and Senators. Over 1,000 registered lobbying activities occurred with key government decision makers providing an opportunity for dialogue about our collective efforts to strengthen Canada's healthcare system and innovative ecosystem. An innovation fair on the drug discovery process connected industry representatives and researchers with over 40 Members of Parliament, to showcase Canada's life science expertise.

At the Committee level, we have engaged with the House of Commons Health Committee to speak about the importance of access to medicines for all Canadians. We have also worked closely with Finance, Innovation, Science & Technology and International Trade committees to build relationships with key government and opposition elected officials.

We have held several meetings with the Minister of Innovation, Science and Economic Development, his staff and the department about the role that life sciences must continue play in the Canada's innovation agenda.

In British Columbia, relationships with the health and life sciences community such as LifeSciences BC and the Centre for Drug Research and Development continue to demonstrate how the industry can address the province's healthcare sustainability concerns through innovative and holistic approaches to policy development.

We have worked with the Ontario government on Drug Submission Guidelines and the Exceptional Access Program and recently released a report to align the life sciences voices and commit to growing the sector in Ontario. Innovative Medicines Canada is also working with INESSS to organize a workshop about global best practices in innovative drug evaluations in order to improve the Quebec regulatory environment to identify duplication and synchronization issues and harmonization between INESSS and other Health Technology Assessment organizations. A partnership between industry, Montreal InVivo and university research hospitals in Quebec will improve the clinical research environment and increase clinical trials in Montreal.

In Quebec, work by the Quebec Core Team and association staff led to the Quebec government agreeing to the creation of a government and life sciences working group that will bring together key ministers and stakeholders.

In Atlantic Canada, we are paving the way for future collaborations between industry and government health plan providers to create solutions that will benefit Atlantic Canadians.

To strengthen our relationships with our local bio/life science associations, Innovative Medicines Canada and BioNova signed a Memorandum of Understanding (MOU). The MOU will allow BioNova and Innovative Medicines Canada to offer a joint membership to life science companies and associated stakeholders in Nova Scotia in an effort to enhance networking opportunities and develop partnerships that will lead to the discovery of the next generation of life-saving therapies.

Our work also includes forging a stronger collaboration with private drug markets. Meetings with all major national and regional insurers, plan benefit managers and advisors discussed Innovative Medicines Canada's possible collaboration and position on the sustainability of the private market. We are also working with the Canadian Life and Health Insurance Association to establish a working relationship and initiate collaborative initiatives including a pan-Canadian study on insurance benefit gaps. We participated in the Conference Board of Canada's [\*The Value of Specialty Medications: An Employer Perspective Report\*](#) and partnered with Telus to develop several major new analytics projects that will help our community better understand private market trends.

These alliances not only demonstrate our achievements in reaching our strategic priority but also set the foundation for future collaboration, creating new and exciting possibilities for 2017 and many years to come.

A man with short dark hair, wearing a dark t-shirt, is sitting in a wheelchair outdoors. He is looking off to the side with a slight smile. The background is a grassy field with trees in the distance. The entire image has a blue tint. A semi-transparent dark blue rectangle is overlaid on the lower left portion of the image, containing white text.

We work to ensure that our regulatory systems are internationally competitive and incorporate the latest evidence-based best practices that are developed with clinician collaboration and patient input.

## REPORT ON PRIORITY 2

### ACCESS AND REGULATORY: IMPROVING THE ACCESS AND REGULATORY ENVIRONMENT IN CANADA.

Canadians believe they should have high quality access when it comes to healthcare, and that includes innovative medicines and vaccines. We must continually improve the timeliness and quality of access to innovative medicines in both the public and private reimbursement sectors. We work to ensure that our regulatory systems are internationally competitive and incorporate the latest evidence-based best practices that are developed with clinician collaboration and patient input. It also means leveraging Canada's many benefits as a globally competitive environment to host and participate in clinical trials.

Innovative Medicines Canada staff and members have engaged with key government officials to discuss priority regulatory and market access issues and the variety of forms in which these issues arise. This includes the Patented Medicine Prices Review Board (PMPRB) reform, the pan-Canadian Pharmaceutical Alliance (pCPA), Health Technology Assessment (HTA) policy as well as better methods for evaluating the value of medicines in Canada, and access to medicine.

Innovative Medicines Canada's regulatory affairs team has focused on developing ways to reduce the time from first global regulatory submission to approval in Canada. Phases one and two of a study designed to quantify the true access gap in Canada are well underway and looking at time from first global filing and approval, to time to approval in Canada to identify factors associated with delayed access in Canada by comparing individual submissions with different outcomes in Canada versus the US and the EU. A separate survey has also been completed by members to measure industry experience and perceptions of Health Canada's performance.

Innovative Medicines Canada held a roundtable in 2016, with industry and patient stakeholders, to review and prioritize the changes that will have the greatest impact on Health Canada's performance and for Canadian patients. This initiative led to Health Canada modifying requirements and expectations associated with new Plain Language Labelling requirements for drug submissions. This greater flexibility reduced compliance burden and reduced the time to submission.





A newly revised model Clinical Trial Agreement is planned for launch in 2017 to help reduce contract negotiation times in Canada.

We have also participated in the PMPRB Guidelines Modernization Consultation and conducted a study examining how the prices of *market exclusive* medicines in Canada rank internationally compared to medicines with generic competition. Generally speaking, Canadian launch prices are consistent with the mandate that was developed almost 30 years ago, ranking mid-range of the PMPRB comparator markets' price.

For the private markets, Innovative Medicines Canada has partnered with Benefits Canada magazine to sponsor six events held across Canada. We have also developed a microsite on private markets in Canada to assist benefit advisors, plan sponsors and employers to navigate and better understand their drug plan benefits. A new private market core presentation kit includes new analytic data and updated pharma 101 training modules are being leveraged when meeting with drug benefits managers and brokers.

The Innovative Medicines Canada Medical Advisory Team has played an integral role in providing advice, guidance and support to the Canadian Clinical Trials Coordinating Centre to create a better environment in Canada to attract more clinical trials investment. This culminated in a clinical trials investment case that was piloted at a panel session at the BIO International Conference 2016, titled "Clinical Trials – The Canadian Advantage."

A comprehensive model Clinical Trial Agreement (mCTA) consultation process with our membership has taken place to ensure awareness and alignment to the CLEAR language initiative being managed by TransCelerate. A newly revised mCTA is planned for launch in 2017 to help reduce contract negotiation times in Canada.

Innovative Medicines Canada continues to support Canadian Clinical Trials Asset Map (CCTAM) and conducted a metrics gap analysis in order to provide insight into the development of a sustainable clinical trials metrics platform for Canada.

Along with the improvement in the clinical trials environment, the Association and the Health Research Foundation (HRF) are funding initiatives to improve access to new innovative medicines. A new access model project in PEI in partnership with Innovative Medicines Canada, Health PEI and the REAL Evaluation Services unit of the Nova Scotia Health Research Foundation will evaluate the impact of early access of three truly innovative medicines to patients, the health system and society.

The HRF funded a research project with the Conference Board of Canada on innovative procurement models implemented around the world with key learnings disseminated to key healthcare decision makers in Canada.

Despite these advances in some provinces, others have continued to implement cost containment initiatives that reduce access. In 2016 the British Columbia Ministry of Health moved forward with an expansion of their access limiting Reference Drug Program (RDP). Efforts continue with senior healthcare executives and leadership across various government ministries to address and improve upon BC's current restrictive and limited access environment.

In Alberta, Innovative Medicines Canada focused its efforts in monitoring and outreach activities on times to listing. Alberta has included an industry representative on a special review of its "expert drug review committee" to ensure that this group reflects the evolving environment in Canada and to ensure a streamlined approach to meeting local needs.

Saskatchewan continues to improve its processes to create streamlined and efficient access to medicines. Industry was consulted on the "Master Listing Agreement" template which is expected to be implemented by the end of 2016.

In Manitoba, two initiatives to leverage the province's rich data resources and capacity for "real world effectiveness" were initiated. Innovative Medicines Canada sponsored a forum with leading industry and data experts to explore the benefits and opportunities in Manitoba and a partnership project to demonstrate the data capabilities in Manitoba received HRF funding.

The HRF funded a research project with the Conference Board of Canada on innovative procurement models implemented around the world with key learnings disseminated to key healthcare decision makers in Canada.





2016 has been an active time for our industry with the Ontario Government engaging in a number of consultations relating to issues such as Drug Submission Guidelines and the Exceptional Access Program (EAP). Through the Ontario Network and the Ontario Core Team a number of our members played a significant role in these consultations.

In Quebec, Innovative Medicines Canada has advocated for a Quebec life sciences strategy which the Quebec government confirmed will be implemented before the end of 2016. The association's work with INESSS has also resulted in the province accepting pre-NOC submissions and a more rapid evaluation process. In its 2016 Budget, Quebec announced:


*"The acceleration of the evaluation by INESSS is to ensure that the results of its recommendations coincide as much as possible with the Health Canada NOC to facilitate faster access to certain drugs."*

Innovative Medicines Canada is now working with INESSS to organize a workshop about global best practices in innovative drug evaluations in order to improve the Quebec regulatory environment to identify duplication and synchronization issues, and harmonization between INESSS and other HTA organizations.

Similarly, successful Atlantic Canada stakeholder meetings focussed on best practices and discussions with the Government of New Brunswick at BIO 2016 in San Francisco, California and revolved around value-based procurement, value demonstrating initiatives, Atlantic Common Drug Review process changes, regional strategic procurement, international trade (CETA, TPP) and drug shortages.

Innovative Medicines Canada has continued its collaboration on the Prince Edward Island Value-Based Patient Health Outcomes Management Access Study and secured funding for the evaluation of the PEI Hepatitis C Virus (HCV) program.

Nationally, the HCV disease area treatment program was the first value-based procurement contract in Canada. The evaluation program for the first year of the program demonstrated 93 treatment starts in the first year, compared to four in the prior two years. Through this collaboration, the Government of Prince Edward Island became the first province to implement a comprehensive HCV treatment strategy. The program model demonstrates a streamlined system for HCV treatment that can serve as an example for other publicly funded systems. This program was the basis for the current chronic disease program for the next phase of the project. The goal is to commence the project on the first medication by January 2017. This work will lead to an enhanced relationship between industry and government to collaborate on other therapeutic areas in the future.

A photograph of three business professionals in a modern office setting, overlaid with a blue gradient. In the foreground, a man with a shaved head and a slight smile is looking towards the camera. Behind him, a man with dark hair and glasses is looking forward. To the right, a woman with blonde hair is smiling. A semi-transparent blue oval contains white text at the bottom left.

We will continue to offer our support towards to the implementation of CETA which will enable Canada to become a stronger competitor for attracting international life sciences investment.



## REPORT ON PRIORITY 3

### INTELLECTUAL PROPERTY: ADVOCATE FOR A GLOBALLY COMPETITIVE INTELLECTUAL PROPERTY REGIME.

In March 2016, the Competition Bureau of Canada released the final version of its revised Intellectual Property Enforcement Guidelines (IPEGs). The IPEGs guide the Bureau's enforcement activities with respect to intellectual property (IP) issues. Their release marked the end of over two years of consultations with Innovative Medicines Canada and many other stakeholders. While the final version did not address all of our concerns, consistent and effective representations by Innovative Medicines Canada staff and company representatives resulted in significant risk mitigation and several important improvements from the Bureau's original 2014 draft version.

Innovative Medicines Canada provided significant government relations outreach support and guidance on IP, including staffing both domestic and European Union outreach efforts to key International Trade and Innovation, Science and Economic Development Canada (ISED) elected officials and staff. This includes direct meetings with the Ministers for International Trade, ISED and Science as well as with their Parliamentary Secretaries. We were pleased to see the finalization and signing of the Comprehensive and Economic Trade Agreement (CETA) between Canada and the European Union on October 30th, 2016. We will continue to offer our support towards the implementation of CETA which will enable Canada to become a stronger competitor for attracting international life sciences investment.

In August 2016, Innovative Medicines Canada and BIOTECCanada were granted leave by the Supreme Court of Canada (SCC) in the upcoming case of AstraZeneca Canada v. Apotex Inc., which was heard by the SCC on November 8th, 2016. The intervention application aims to support AstraZeneca and to assist the SCC with respect to patent utility and the promise doctrine. Since the promise doctrine increasingly began to be applied by the courts in 2005, there have been 28 decisions invalidating pharmaceutical patents, either solely or in part, for lack of utility. Innovative Medicines Canada and BIOTECCanada's members are parties and/or patentees in all but one of these cases. The outcome of the SCC case is unknown at present, but it will likely have a major impact on the Canadian IP environment for innovators for many years to come.

## THE ASSOCIATION'S BOARD OF DIRECTORS FOR 2016

Innovative Medicines Canada has an effective and engaged Board of Directors that enables member companies to achieve common objectives.

<b>Chair</b>	Tremblay, Michael	President, Astellas Pharma Canada, Inc.
<b>Vice-Chair</b>	Fasano, Frédéric	Chief Executive Officer, Servier Canada Inc.
<b>Past-Chair</b>	Helou, John	President, Pfizer Canada Inc.
<b>Treasurer</b>	Lirette, Paul	President, Canada Pharmaceuticals, GlaxoSmithKline Inc.
<b>Interim President</b>	Campbell, Elaine	Interim President, Innovative Medicines Canada
<b>Members</b>	Gudaitis, Ed	General Manager, Gilead Sciences Canada, Inc.
	Halyk, Chris	President, Janssen Inc.
	Lassignardie, Stéphane	General Manager, AbbVie Corporation
	Maloney, Tim	President, Novartis Pharmaceuticals Canada Inc.
	Matar, Lisa	President & General Manager, Eli Lilly Canada Inc.
	Miller, Ronnie	President & CEO, Hoffmann-La Roche Limited
	Dr. Peacock, Nawal	President & General Manager, Bristol-Myers Squibb Canada
	Rosenthal, Allison	General Manager, Otsuka Canada Pharmaceutical Inc. (OCPI)



## INNOVATIVE MEDICINES CANADA MEMBER COMPANIES

A thriving innovative industry is important to Canada.

The innovative pharmaceutical industry in Canada supports 34,000 high-quality, well-paying jobs in Canada. Our industry creates an overall economic impact of more than \$3 billion a year on Canada's economy.

Our members create jobs and contribute to the sustainability of our healthcare system. New medicines represent some of the most scientifically advanced, safest and effective treatments to help Canadians live longer, better and more productive lives. Guided by our Code of Ethical Practices, we work with governments, private payers, healthcare professionals and stakeholders in a highly ethical manner.

AbbVie Corporation	JSS Medical Research
Actelion Pharmaceutiques Canada	Janssen Inc.
Amgen Canada Inc.	KalGene Pharmaceuticals Inc.
Astellas Pharma Canada, Inc.	LEO Pharma Inc.
AstraZeneca Canada Inc.	Medicago
Bayer Inc.	Merck Canada Inc.
BioVectra Inc.	Novartis Pharmaceuticals Canada Inc.
Boehringer Ingelheim (Canada) Ltd.	Novo Nordisk Canada Inc.
Bristol-Myers Squibb Canada	Nucro-Technics
Brunel Canada Ltd.	Otsuka Canada Pharmaceutical Inc. (OCPI)
Ceapro Inc.	Paladin Labs Inc.
Charles River Laboratories	Pediapharm Inc.
Conundrum Solutions	Pfizer Canada Inc.
Council for Continuing Pharmaceutical Education (CCPE)	Proteocyte Diagnostics Inc.
Eisai Limited	ProMetic Life Sciences Inc.
Eli Lilly Canada Inc.	Purdue Pharma
EMD Serono, A division of EMD Inc.	Ropack Inc.
Endoceutics Inc.	Sanofi Canada
Ferring Pharmaceuticals	Sanofi Pasteur Limited
Génome Canada	Servier Canada Inc.
Gilead Sciences Canada, Inc.	Shire Canada Inc.
GlaxoSmithKline Inc.	Sunovion Pharmaceuticals Canada Inc.
GLyPharma Therapeutic Inc.	Takeda Canada, Inc.
Hoffmann-La Roche Limited	Therapure Biopharma Inc.
Horizon Therapeutics Canada	Theratechnologies Inc.
Innoviva Inc.	Vantage BioTrials Inc.



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