



ANNUAL REPORT 2017



INNOVATIVE
MEDICINES
CANADA



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LETTER FROM THE PRESIDENT



Innovative Medicines Canada represents Canada's innovative pharmaceutical industry. Our members make significant contributions to the country's economy through its R&D investments, the creation of high value jobs and support for homegrown startups, while providing funding for patient support programs, medical education, as well as local community organizations.

I joined Innovative Medicines Canada at the start of the year following many years working with patients and leading health systems and patient-oriented organizations. Throughout my career – this year included – my colleagues and I have faced many different challenges and problems in our healthcare system. But I have also been proud and excited to bear witness to many advances that have been the result of efforts of the Canadian and international research community working together to address previously intractable problems.

Today, our industry has never been better equipped to harness the potential of science, technology and data to improve Canadians' quality of life and, at the same time, generate wealth for the country through a vibrant, innovative life sciences industry. I do not exaggerate when I say that no other industry can have such a sweeping, transformational effect on a country's economy and its people than Canada's medical research community.

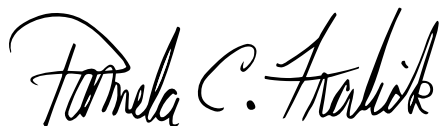
In March of this year, the Hon. Bill Morneau used his budget speech to identify the health and life sciences sector as pivotal to positioning Canada as global centre for innovation. Around the same time, I was given the mandate from our members to start a new conversation with government and decision makers about doing things differently. Our members share the same goals as the government and we believe that by working together, we can find win-win solutions that benefit patients, strengthen the healthcare system, address budget sustainability, foster innovation and drive economic growth.

There is no denying we have some complicated challenges ahead of us. Healthcare is undergoing dramatic change, with aging populations and game-changing but expensive scientific breakthroughs putting pressure on governments to lower costs and achieve sustainability. At the same time, global competition to attract coveted pharmaceutical investment is heating up as countries look to leverage the dual benefits of enhanced healthcare and economic growth and position themselves as global life science leaders.

We are an industry of innovators, employers, investors, mentors, partners and catalysts. On behalf of all Canadians, the time is now to seize the moment and build a better, more innovative and sustainable system for the future. Our collective knowledge and passion serve as a powerful platform for us to forge a new future; one that will benefit everyone, but especially patients and families in Canada.

I want to thank our Board of Directors, governance team members and staff for their unwavering dedication, guidance and hard work. From my first day, their commitment to making a difference has been a beacon for me, for all of us, as we strive to make a meaningful difference.

Thank you.



Pamela Fralick
President

LETTER FROM THE CHAIR



As the end of my two-year term as Chair of Innovative Medicines Canada's Board of Directors approaches, I would like to take this opportunity to reflect on what has truly been a transitional period for the industry and for the association itself.

You may remember that changes made to our governance model in 2015 saw the introduction of a two-year term for the Chair. Consequently, I became the first person to have had the opportunity to sit as Chair of the board for longer than twelve months. The decision to implement this change was made to help us all think more long-term, with the benefit of sustainable leadership, to bring about real change for the industry. While real change takes time to evolve, I think we can all be extremely proud of what we have accomplished to date.

Our focus has always been on delivering innovative solutions to improve the health and well-being of Canadians. However, last year I challenged us all to think differently as "collaborators, conveners and, most importantly, innovators," in order to secure a broader role for the industry within the healthcare ecosystem for the future.

To that end, over the past twelve months, we have actively pursued engagement with the provinces and the territories, as well as the federal government and other stakeholders, to create a more integrated and predictable Canadian governance and regulatory framework for both the industry and patients. In doing this, important initial progress has been made, but there is still a lot of work to be done. We know there remain groups and individuals that may be somewhat circumspect about a new partnership - although hopefully this number is smaller than it was at the start of the year.

We hope they can acknowledge that the 30-year-old government-industry agreement, established to provide a framework for pharmaceutical price stability, R&D investment and patent protection, needs to be modernized.

This federal government has identified health and life sciences as pivotal to positioning Canada as a global centre for innovation. We share the government's goal, and this year engaged EY, a leading professional services firm, to undertake a comprehensive, data-driven analysis that quantifies the industry's true economic footprint and investment contribution in Canada. The findings were astonishing.

Some key points include:

- The overall economic footprint of the innovative pharmaceutical industry is estimated at \$19.2 billion
- The activities of the industry support just over 30,000 jobs (12,836 direct, 10,287 indirect and 7,416 induced)
- The life sciences sector is the third largest funder of R&D in Canada after aerospace and software/computer services
- In 2016 alone, Innovative Medicines Canada members:
 - Invested \$1.2 billion in R&D to support innovation in Canada
 - Provided support for 673,000 Canadian patients through compassionate care programs, financial assistance and counselling

Statistics like these make me extremely proud to be a part of this industry and highlight the very real and tangible impact our industry has on healthcare, from providing critical patient support programs, to funding medical education, to investing in local communities. Ultimately, we all want to ensure that everybody, including the most vulnerable of Canadians, has access to the medicines they need.

I want to take this opportunity to thank all the staff at Innovative Medicines Canada, and my fellow board members, for their hard work and commitment over the last two years. I would also like to thank Pamela Fralick for her inspiring leadership and dedication as president of Innovative Medicines Canada. All of these individuals have taken ground-breaking steps forward this year, and their hard work behind the scenes should not be underestimated. I am proud to pass the baton to Frédéric Fasano, Chief Executive Officer of Servier Canada Inc. to be the incoming Chair of Innovative Medicines Canada.

I know the progress and achievements of this year are just the beginning. While I will no longer be at the helm of the association next year, our goals remain the same, and we must all continue to come together to build a stronger and more sustainable healthcare system that benefits all Canadians.

Thank you.



Michael Tremblay
Chair of the Board of Directors

OVERVIEW

2017 was the third year of our three-year plan to address the association's three 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

As the end of this three-year initiative approaches, we can report that while significant progress has been made, our continued focus is required to ensure the type of outcomes that Innovative Medicines Canada believes are necessary to improve patient care and to maximize the economic potential of the innovative medicine sector in Canada.

Just as importantly, we hope progress has been made in demonstrating to our key stakeholders, our contribution to patient outcomes and our commitment to ongoing collaboration. Thanks to the dedication of Association staff, the guidance of its Board of Directors, the hard work of the Core and Advisory Teams and the active engagement of its members, we feel Innovative Medicines Canada has begun to establish itself as a credible, ethical, innovative and trusted collaborator with governments and other stakeholders in the healthcare ecosystem. Looking ahead, these relationships and trust will be critical for the development and implementation of win-win solutions to the many and pressing healthcare challenges facing policy makers, the federal and provincial treasuries, healthcare providers, patients and innovative medicines companies.

The innovative medicines created by our members are a key contributor to a healthy community and to a sustainable, accessible healthcare system for all Canadians. Innovative medicines are one of the most cost-effective technologies available to healthcare professionals. Studies have found that every dollar spent on new medicines reduces non-medication healthcare costs by seven dollars.

A vibrant innovative medicines industry has the potential to make significant positive contributions to Canada's overall economic health.



Today, the innovative medicines industry is a major investor, innovator and employer in all regions of Canada. The industry's economic footprint is estimated to be \$19.2 billion and it supports over 30,000 jobs across the country (direct, indirect and induced). The industry invests 9.97 per cent of its total annual revenue, \$1.2 billion, in research and development, making it the third largest R&D investor in Canada.

The industry also finances patient support and community-based charitable initiatives across the country.

Though already a major economic player, the industry's potential is enormous. Canada currently attracts only 1 per cent of global pharmaceutical investment. We believe that Canada is well positioned to attract significant new investment by leveraging with the global industry and the unique advantages it enjoys relative to other competing jurisdictions. We are willing and ready to work with governments at all levels to develop the robust, comprehensive and integrated policy framework necessary to ensure that Canada realizes the full potential of the innovative medicines sector for the benefit of all Canadians.

As Innovative Medicines Canada has demonstrated in our dealings with Canadian governments in 2017, we share their objectives of a sustainable and accessible healthcare system and of fostering economic growth through innovation and research and development. Our association wants to work with governments to achieve these two objectives by developing and refining a policy environment that will enable Canada's innovative medicine companies to sustainably contribute, to their full potential, to an effective, accessible and affordable healthcare system and to Canadian economic growth.

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- **the country (direct, indirect and induced). The industry**
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REPORT ON PRIORITY 1

Become an authentic, solution-driven partner through effective alliances, policy and leadership

Effective and sustainable solutions to healthcare challenges will only be generated through the constructive and good-faith collaboration of multiple stakeholders involved in the sector. To help build those partnerships, Innovative Medicines Canada initiated a project in 2016 which resulted in the creation of the *Canadian Consensus Framework for Ethical Collaboration*. The framework has since become a model for collaboration around the world. Today, all Innovative Medicines Canada partnerships and collaborative relationships are based on the standards and principles of the framework and align with our Code of Ethical Practices.

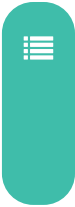


In 2017, our framework partners – Best Medicines Coalition, Health Charities Coalition of Canada, the Canadian Medical Association, the Canadian Nurses Association, and the Canadian Pharmacists Association – developed a long-term communication and engagement plan to continue to work together and to refine the framework in response to changes in the healthcare system.

Innovative Medicines Canada chaired the first Canadian Pharmaceutical Compliance Conference in Canada. Some 200 stakeholders attended the conference which was held in Toronto, June 6-7, 2017. The conference focused on the key elements of a compliance program including training, monitoring and transparency reporting. The conference was a success and a second one is planned for June 2018.

In 2017, we sustained our efforts to build alliances and strategic relationships across Canada.

In British Columbia, the relationships with LifeSciences BC, the University of British Columbia's Faculty of Pharmaceutical Sciences, the Faculty of Medicine and the Centre for Drug Research and Development were extended. We also participated in the inaugural round table meeting of BC life sciences influencers.

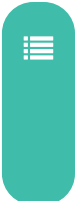



In Quebec, in addition to partnering with the Montreal Chamber of Commerce on a life sciences panel and media event in April, Innovative Medicines Canada partnered with Quebec International for an industry conference on value-based health systems and innovations integration; with Génome Québec on a research event; chaired a conference for patient groups on drug reimbursement; and led the creation of a life sciences coalition in the province.

In Atlantic Canada, we are working with the Pharmacy Association of Nova Scotia (PANS) to help improve the current medication and sharps disposal program. These improvements include the launch of a promotional program to encourage higher levels of responsible disposal to ensure patient safety and removal of products from provincial landfills. Using the PANS program as a model, Innovative Medicines Canada is also working with the New Brunswick Pharmacy Association and the Government of New Brunswick on the creation of a similar disposal program focused on patient and environmental safety.

Innovative Medicines Canada continues to assist with the Prince Edward Island Value-Based Patient Health Outcomes Management Access project with Health PEI, Government of Prince Edward Island and the Health Research Foundation (HRF) of Innovative Medicines Canada. As a direct result from this project, we are also working with the Government of Prince Edward Island on the creation of a Centre for Health Innovation in Chronic Disease Management. This centre will be a federally incorporated non-profit association with the overall mission of assessing healthcare innovation in terms of impact on patient outcomes and health system costs. It will also provide real world health data for pharmaceutical companies, governments, and other stakeholders seeking to understand how innovation in medications, models of care, technology and other new initiatives impact the health of patients relative to health system costs.

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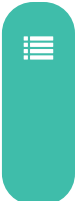


Another notable partnership is our direct involvement with the Canadian Clinical Trials Coordinating Centre (CCTCC). An unique collaboration, funded partly by industry - represented by Innovative Medicines Canada, government (represented by Canadian Institutes of Health Research) and healthcare institutions (represented by HealthCareCAN), was created in 2014 to improve the operational efficiencies of the Canadian clinical trial field (CT) and to promote Canada as a go-to destination for clinical trials. CCTCC has worked in a collaborative manner with several pan-Canadian partners such as Clinical Trials BC (British Columbia), New Brunswick Clinical Trials, Montreal InVivo, Clinical Trials Ontario, and Catalis (in Quebec) amongst others.

Past accomplishments include the creation of the Clinical Trials Asset Map (CCTAM) which is the first searchable, pan-Canadian, pan-therapeutic database showcasing the country's clinical trials capabilities and the creation of an investment case titled "Clinical Trials: The Canadian Advantage" which is an in-depth, concise narrative that communicates Canada's strengths in terms of speed, quality, and incentives. After several years of effort and collaboration, 2017 marks the launch of a model Clinical Trial Agreement (mCTA) which will greatly help to reduce start-up times for new clinical trials in Canada.

The Health Research Foundation (HRF) of Innovative Medicines Canada continued its work in 2017. Several projects produced reports this year including:

- An interim report on *A Multidisciplinary Approach for Improved Care in COPD* in Ontario
- A final report on *Increasing Adherence Rates through Collaborative Practice* in Saskatchewan
- Reported data on *Diabetes Clinical Order Sets* in Manitoba
- Five case studies from The Conference Board of Canada on successful access frameworks in foreign jurisdictions and Canada



These projects are examples of HRF partnerships that lend support to value-based discussions with federal, provincial and territorial governments.

With patient input becoming a more important factor in approval and access decisions, we continued our efforts to build ethical and meaningful relationships with patient groups and health charities. A key forum for the development of those relationships was the Innovative Medicines Canada 2017 meeting of the Stakeholder and Partnership Advisory Group which was held on June 27 in Toronto. More than 30 patient organizations and health charities attended the meeting and provided valuable insights and perspectives on the complexity of the issues and the impact on patients.

Through our interactions with government and healthcare partners, Innovative Medicines Canada has demonstrated our willingness to be a collaborative partner. Working on mutually beneficial solutions to healthcare challenges will lead to better programs and policies for Canadians while we continue to be an effective and forceful advocate for our membership.

- **After several years of effort and collaboration,**
- **2017 marks the launch of a model Clinical Trial**
- **Agreement (mCTA) which will greatly help to reduce**
- **start-up times for new clinical trials in Canada.**

REPORT ON PRIORITY 2

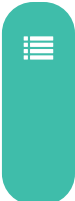

Improving the Access and Regulatory Environment in Canada

Canadians value and expect timely access to quality healthcare which include innovative medicines and vaccines.

In interacting with governments over the past year, we focused on the opportunity to work together towards a new pharmaceutical framework for Canada that would help tackle pressing challenges. The overall goal of this initiative is a more predictable and sustainable healthcare system - one which best serves the needs of all Canadians. We are committed to engaging in a new, collaborative way to build an innovative and sustainable environment for our health systems that allows for better access to medicines for Canadians. We created important public awareness and interest around our intention to engage with stakeholders in a patient-focused discussion on improving access to healthcare. We discussed it with a range of audiences - from all levels of government to patient groups and other stakeholders.

Our member companies not only develop life-changing and life-saving medicines for Canadians, they are also economic drivers in the life sciences ecosystem. This fact was not clearly understood. As a result, Innovative Medicines Canada engaged EY to measure the economic value of the innovative pharmaceutical industry in Canada. The Innovative Medicines Canada full-member data collected by EY includes revenue, R&D, other investments and operational and corporate datasets. The result of this first-of-its-kind study highlight the industry's significant contribution to Canada's economy and its healthcare system. The objective of this project was to inform future public policy responses using hard data, supported by an analytical model, and based on actual member data. Efforts will be made to maintain and build on the current dataset, to establish a longitudinal and robust set of information which can be analyzed over time.





At the federal level, various advocacy, issue management and legislative and regulatory efforts concentrated on:

- Sensitizing policy makers to industry concerns related to the upcoming consultations on the PMPRB regulations and executing an advocacy campaign to ensure access and investment is supported, not hindered in that process
- Beginning to research the potential implications for the industry arising from the NAFTA renegotiations
- Responding to the regulations implementing Bill C-17, *Protecting Canadians from Unsafe Drugs Act* by ensuring the regulations were in line with international norms and did not increase the compliance burden

Innovative Medicines Canada entered into a number of new collaborative relationships with governments in 2017.

In Alberta, a Memorandum of Understanding (MOU) was signed with Alberta Health and Alberta Economic Development and Trade to advance a collaborative approach to attract investment, expand research and improve patient access while supporting economic diversification. Innovative Medicines Canada also worked with the governments of Alberta and Manitoba on industry data projects.

In Ontario, we had face-to-face member consultations and provided detailed feedback to the province on its OHIP+: Children and Youth Pharmacare program, coming into effect January 1, 2018.

In Quebec, the association participated in the consultation process on a new framework for the *Institut national d'excellence en santé et en services sociaux* (INESSS) and for a provincial life sciences strategy with the Quebec Life Sciences Working Group.



A number of our recommendations were recognized in the life sciences strategy including:

- Faster and ongoing INESSS evaluation and increased pre-notice of compliance (NOC) evaluation
- A reduction in delay between NOC and drug plan reimbursement
- Establishment of a working group to identify a Quebec advantage in terms of drug access

At the BIO International Conference 2017 in San Diego, California, Innovative Medicines Canada hosted successful bilateral meetings with provincial delegates from Alberta, Ontario, Quebec, New Brunswick and Prince Edward Island. Discussions centred around government and industry collaboration to provide better access to medicines for Canadians while ensuring continued investment in research and innovation.

- **We are committed to engaging in a new, collaborative way to**
- **build an innovative and sustainable environment for our health**
- **systems that allows for better access to medicines for Canadians.**

REPORT ON PRIORITY 3

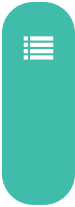
Advocate for a Globally Competitive Intellectual Property Regime

Innovative Medicines Canada sees 2017 as a watershed year for pharmaceutical intellectual property (IP) in Canada. Two major developments – the implementation of the Canada-EU Comprehensive and Economic Trade Agreement (CETA) and the Supreme Court of Canada (SCC) decision in the *AstraZeneca Canada Inc., et al. v. Apotex Inc., et al.* case – will influence the life sciences environment for years to come.

Innovative Medicines Canada was heavily involved in both developments.

We closely monitored the Canadian government's implementation of CETA's pharmaceutical IP provisions and participated in the pre-consultations and the consultations on the draft implementing legislation and regulations. Our objective throughout the process was to ensure the effective implementation of CETA commitments regarding Patent Term Restoration (PTR) and patent linkage. Innovative Medicines Canada made the industry case to both elected and bureaucratic officials in Ottawa and presented to both House of Commons and Senate Committees on CETA. The federal government released the final CETA implementation regulations in September 2017. The regulations establish a system for PTR for pharmaceuticals to compensate for delays in obtaining market approval. Canada was one of only three OECD countries that did not provide any form of PTR at the outset of CETA negotiations and CETA's implementation marked an improvement in this regard. However, the proposed regulations change Canada's patent linkage regulations in a manner not required under CETA. We are concerned that these changes will result in increased pharmaceutical patent litigation in Canada. Innovative Medicines Canada will monitor the impact of the newly amended patent linkage regulations and will tailor our advocacy accordingly.





Jointly with BIOTECCanada, we successfully intervened in the *AstraZeneca Canada Inc., et al. v. Apotex Inc., et al.* case, which resulted in a unanimous SCC decision to strike down the promise doctrine¹ on June 30, 2017. Previously, Canadian courts had interpreted the utility requirements of the *Patent Act* in a way that differs from other countries and which impacted the pharmaceutical industry specifically. This was an important Canadian life sciences patent case and the decision was welcomed by academics, intellectual property experts, business leaders and the innovation community both in Canada and internationally.

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- **Canada-EU Comprehensive and Economic Trade Agreement**
- **and the Supreme Court of Canada decision in the**
- ***AstraZeneca Canada Inc., et al. v. Apotex Inc., et al.* case –**
- **will influence the life sciences environment for years to come.**



¹ The promise doctrine referred to part of the *Patent Act* requiring an invention, such as a new pharmaceutical, to be "useful" to be patent-eligible. Pharmaceutical patents were susceptible to invalidation if the product didn't do what the patentee "promised."



INNOVATIVE MEDICINES CANADA MEMBER COMPANIES

AbbVie Corporation	Ipsen Biopharmaceuticals Canada Inc.
Actelion Pharmaceutiques Canada	JSS Medical Research
Akcea Therapeutics 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	Pfizer Canada Inc.
Council for Continuing Pharmaceutical Education (CCPE)	ProMetic Life Sciences Inc.
Eli Lilly Canada Inc.	Purdue Pharma (Canada)
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 Pharma Canada ULC
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.

ASSOCIATION BOARD OF DIRECTORS 2017

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

Chair	Tremblay, Michael J.	President	Astellas Pharma Canada, Inc.
Vice-Chair	Fasano, Frédéric	Chief Executive Officer	Servier Canada Inc.
Treasurer	Rosenthal, Allison	General Manager	Otsuka Canada Pharmaceutical Inc. (OCPI)
President	Fralick, Pamela	President	Innovative Medicines Canada
Members	Al-Khoury, Niven	President	Sanofi Canada
	Dybka, Ed	President	AstraZeneca Canada Inc.
	Halyk, Chris	President	Janssen Inc.
	Helou, John	President	Pfizer Canada Inc.
	Lassignardie, Stéphane	General Manager	AbbVie Corporation
	Lirette, Paul	President, Canada Pharmaceuticals	GlaxoSmithKline Inc.
	Matar, Lisa	President and General Manager	Eli Lilly Canada Inc.
	Miller, Ronnie	President and CEO	Hoffmann-La Roche Limited
	Peacock, Dr. Nawal	President and General Manager	Bristol-Myers Squibb Canada
Staff Support	Ouderkirk, Judy	Secretary to the Board of Directors	Innovative Medicines Canada

HEALTH RESEARCH FOUNDATION (HRF)

Chair	Cappe, Mel	University of Toronto
Vice-Chair	Kanti, Alok	Bayer Inc.
Treasurer	Fralick, Pamela	Innovative Medicines Canada
Member of the Board and Scientific Advisory Council	Koutsavlis, Tom	Shire Pharma Canada ULC
Executive Director	Scott, Hugh	Innovative Medicines Canada
Members	Campbell, Elaine	
	Desjardins, Dr. Clarissa	Clementia Pharmaceuticals Inc.
	Ellis, Shaun	Janssen Inc.
	Tyrrell, Dr. Lorne	Li Ka Shing Institute of Virology
Staff Support	Weedmark (Kehoe), Jessica	Innovative Medicines Canada



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