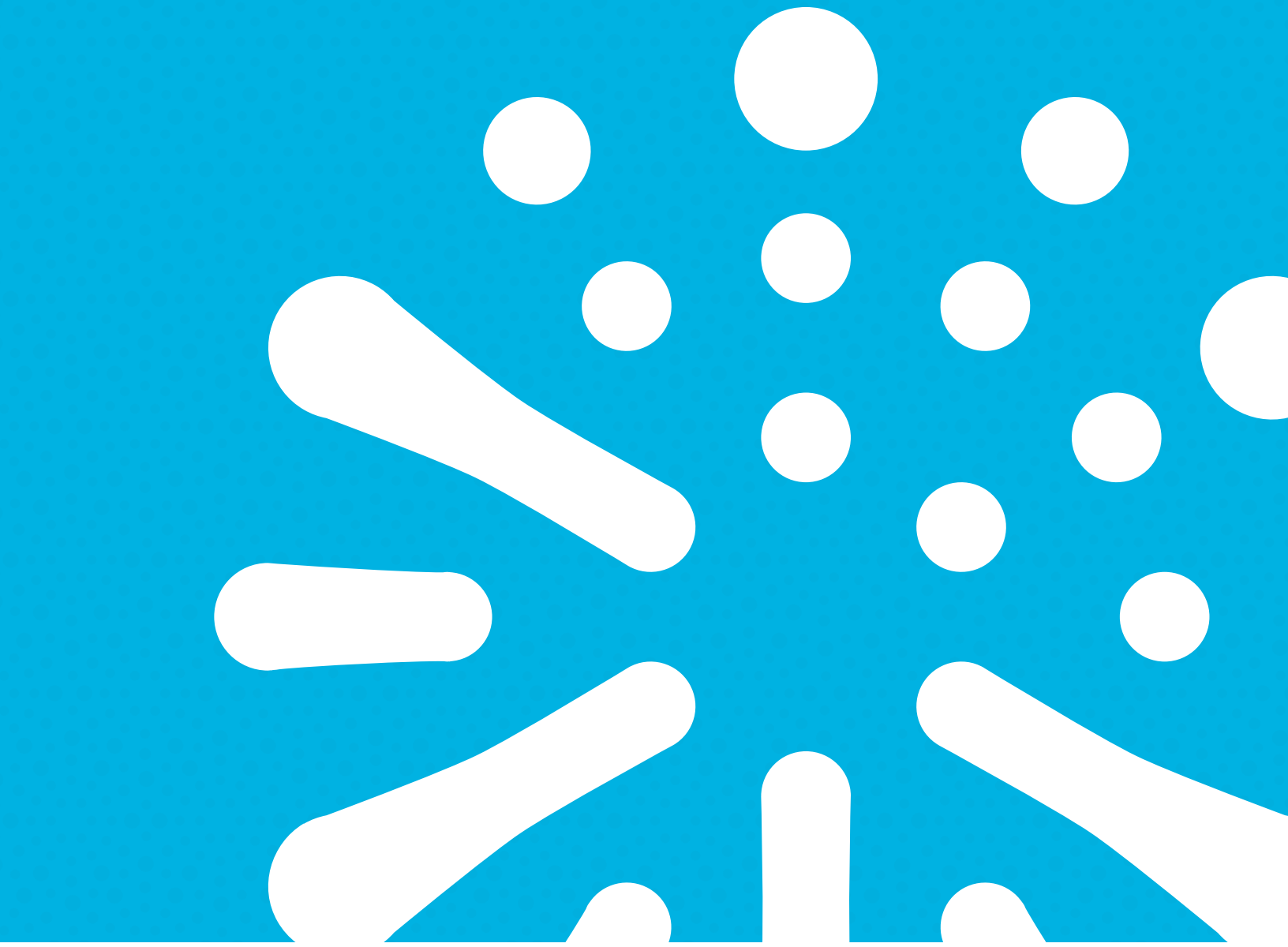
2018 ANNUAL REPORT



INNOVATIVE MEDICINES CANADA

START

TABLE OF CONTENTS

OUR MEMBERSHIP IS STEADFAST IN ITS DESIRE TO WORK IN PARTNERSHIP WITH GOVERNMENT AND STAKEHOLDERS ALIKE TO BUILD A SUSTAINABLE FUTURE FOR OUR HEALTH SYSTEMS.

LETTER FROM THE PRESIDENT

Innovative Medicines Canada (IMC) is the national voice for the research-based pharmaceutical industry in Canada. Our members make significant contributions to the country's knowledge economy through R&D investments, the creation of high value jobs and support for homegrown startups. They are also key contributors to the success of our health systems: The 500 new products that are currently in development in Canada, including therapies focused on cancer treatments, infectious diseases and vaccines, have the potential to help Canadians and people all over the world live longer and healthier lives, and save money for health systems in the process.

I am extremely proud of the work accomplished by IMC's Board of Directors, member companies, core and advisory teams and staff over the course of what was a particularly challenging year for the industry. Through proposed changes to the Patented Medicines Price Review Board (PMPRB), the federal government introduced what former Health Minister called "the most significant suite of changes" to Canada's pharmaceutical drug regime in three decades. These proposed changes are of grave concern to Canada's innovative pharmaceutical industry, putting at risk the timely access to new medicines that Canadian patients have enjoyed for decades and impacting our ability to invest in health research.

Despite uncertainty in the regulatory environment, Canada's innovative pharmaceutical industry has shown leadership, resilience and an enduring commitment to partnership and collaboration in an effort to ensure that Canadian patients will continue to have access to the medicines that they need, when they need them.

Tackling this immense challenge is only possible through working closely with stakeholders to develop data-driven policies and offer health-system solutions that improve Canadians' lives and provide increased opportunities to unlock Canada's innovation economy. Throughout the year, we have valued working with policy makers from all levels of Canadian governments, health professionals, patient groups, think-tanks, chambers of commerce, private payer groups, life sciences and research organizations, among countless others.

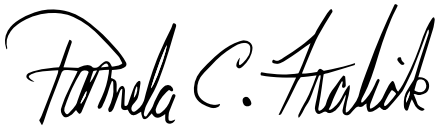
We delivered a speaking tour from coast to coast to advocate for a regulatory environment that promotes innovation and supports intellectual property (IP) protection and evidence-based solutions that are in the best interest of all Canadians.

LETTER FROM THE PRESIDENT

While we are working hard to advance medical research and development in our country, the reality is Canada only attracts approximately one per cent of global pharmaceutical research and development investment. If Canada is to meet the government's goal of becoming a top-three global hub for the health and biosciences sector by 2025, we need "whole of government" solutions to ensure that Canada strikes an appropriate balance between addressing the need for affordable medicines and encouraging a competitive economic environment for the life sciences sector. Our membership is steadfast in its desire to work in partnership with government and stakeholders alike, to find that balance and to build a sustainable future for our health systems.

As we look towards the future, it seems that change is the new normal. While that can be daunting for some, I am confident that our continued commitment to partnership and collaboration—with stakeholders and each other—will lead us to the best possible outcomes for Canadian patients, for our industry, and for the future of healthcare in Canada.

Sincerely,



Pamela C. Fralick

LETTER FROM THE CHAIR

Canada's innovative pharmaceutical industry has a long and proud tradition of discovering new medicines that help Canadians to lead longer, healthier lives.

As my term as Chair reaches its mid-way point, I am proud of all that our membership has accomplished in a year of challenge and change for our industry. Guided by a commitment to collaboration, our members, together with IMC President Pamela Fralick and her team, continue to better position the industry as a trusted partner by putting forward data-driven policies, building and strengthening alliances with federal, provincial and territorial governments and stakeholders, and advocating for a regulatory environment that promotes investment and innovation, and supports intellectual property (IP) protection.

The government's proposed changes to the PMPRB regulatory framework dominated our collective attention in 2018. Working closely with Ms. Fralick and her team, our Board and CEO Steering Council were highly engaged in guiding IMC's response to the proposed changes which will have serious financial implications for our industry, including our ability to invest in Canada and on the welfare of Canadian patients who need access to innovative medicines. Significant time and attention was devoted to putting forward constructive alternative solutions to the current PMPRB proposals that would support the government's commitment to accessible and affordable medicines.

In addition, the industry proposed a range of options to government for an investment framework that will strengthen Canada's life sciences sector. As an important driver of innovation, the innovative pharmaceutical industry supports over 30,000 high-quality jobs and contributes over $19.2-billion to our economy. The recommendations made by the Government of Canada's Health/Biosciences Economic Strategy Table (HBEST) Report released in September were a strong signal that the government recognizes the value that our member companies contribute to Canada's innovation economy and that it is prepared to work collaboratively to enhance sectoral competitiveness.

LETTER FROM THE CHAIR

The PMPRB was not our only focus. The Board of Directors also came together to develop the three foundational principles which will shape industry's position on pharmacare, an initiative that will likely be at the forefront of the government's agenda in the coming year. As an industry, we support a national pharmacare program that reflects the value of the current mixed public-private model, addresses the unmet needs of uninsured or underinsured Canadians, is affordable and ensures the sustainability of our health systems.

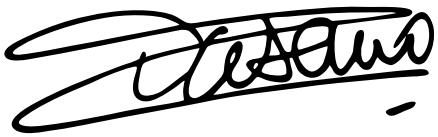
As the innovative pharmaceutical industry evolves, so too must our strategic direction. To ensure our association continues to promote and advance industry priorities in the coming years, the Board dedicated time and effort to developing a new strategic plan for the next three years. This framework is based on a set of guiding principles that are core to our industry's value proposition and will set the standard for how we engage and communicate with stakeholders, government and Canada's health systems more broadly.

In the coming years our engagement will continue to be based on promoting trust, collaboration and partnership, as we proactively offer solutions to address Canadian health systems challenges. We will also manage emerging issues in a way that is consistent with the member CEO Code of Conduct and the IMC Code of Ethical Practices.

Executing this new forward-looking strategy will help us continue to do what we do best: create and deliver innovative medicines and vaccines to support the health and wellbeing of Canadians.

As Chair, I would like to express my sincere thanks to my fellow board members and to the entire staff at IMC for their efforts in supporting our industry this past year. We have much to be proud of as we continue to build on a year of hard work and achievements to secure an even brighter future—not only for our industry, but also for Canadian patients.

Thank you,



Frédéric Fasano

CANADA'S INNOVATIVE PHARMACEUTICAL COMPANIES ARE A CRITICAL PART OF THE LIFE SCIENCES SECTOR AND ARE COMMITTED TO PROVIDING VALUE TO PATIENTS, TO OUR HEALTH SYSTEMS AND TO THE CANADIAN ECONOMY.

OVERVIEW

IMC is proud to be an integral part of our country's world-class health systems. We work to ensure Canadian patients have the best access to innovative medicines and vaccines. Canada's innovative pharmaceutical companies are a critical part of the life sciences sector and are committed to providing value to patients, to our health systems and to the Canadian economy.

Creating better outcomes for patients is our raison d'être. Working with patient groups and governments alike, IMC advocates for better access to the ground-breaking new innovative medicines that help Canadians lead longer, healthier lives. New therapies help Canadians avoid costly hospital stays, invasive surgical procedures, and what can sometimes be a lifetime of dealing with a chronic illness. Our industry also plays an important role as a driver of innovation in Canada's life sciences sector. Investments made by our industry not only help scientists discover and develop new treatments and vaccines, they support over 30,000 high-quality jobs and contribute more than $19.2-billion to our economy. Approximately 10 per cent of industry gross patented medicines revenues are invested into R&D. (Source: EY, 2017)

Our investment in R&D ranges from collaborative initiatives with Canadian universities, hospitals, and centres of excellence, to funding for early stage biopharmaceutical companies and health charities. Globally and in Canada, we have also seen a move towards newer types of investment models, such as targeted financing and virtual research and open innovation models. By partnering with academic/clinical research institutes, commercialization centres and virtual research centres, our industry is expanding its capacity to conduct R&D work across Canada and expand our economic footprint.

OVERVIEW

As an association, IMC works to support its members through effective engagement with stakeholders in the public and private sector, and governments at the federal, provincial and territorial levels. Our activities in 2018 were guided by the following three priorities as set out in our three-year strategic plan.

They are:

1. *Becoming an authentic, solution-driven partner through effective alliances, policy and leadership.*
2. *Improving the access and regulatory environment in Canada.*
3. *Advocating for a globally competitive intellectual property (IP) regime.*

2018 marked a year of challenge for our industry in the federal regulatory space. Proposed changes to the PMPRB, which sets the ceiling price for new drugs in Canada, have the potential to dramatically change to the way regulatory ceiling prices are set in Canada. If implemented, these changes pose significant risks for our industry's ability to invest in health research, and for patients' ability to access new medicines if Canada is de-prioritized for new drug launches.

IMC President Pamela Fralick led a nation-wide consultation tour outlining the impacts of the government's proposed changes and pressing for more meaningful and interactive consultation with industry. IMC engaged with well over 100 stakeholders and government officials across Canada to raise awareness about the impacts of PMPRB changes and to garner support on a national level. Through our research and policy analysis, the association provided knowledge and critical data to inform discussions pertinent to the PMPRB regulatory changes. The association mobilized a diverse coalition of life sciences organizations, patient advocacy groups, business groups and Chambers of Commerce, as well as academics and healthcare professionals to share their concerns about the impact of the proposed changes with the federal government.

IMC quantified the substantial repercussions of the changes including the use of proposed health technology assessments and pharmacoeconomic factors. Significant analysis was also conducted to inform IMC's alternative solution to the current PMPRB proposals, which balances the need for more affordable medicines with a competitive regulatory environment for health research.

In addition to the PMPRB file, IMC also worked to advance several other important initiatives in 2018. First, the association created a National Pharmacare Project Team to further develop and update IMC's position on a national pharmacare program and actively participated and contributed to the government consultations across the country. Working with The Conference Board of Canada, IMC led the development of important new data and contributed to an analysis of the uninsured and underinsured in Canada which helped to inform not only the association's position on the issue, but that of other stakeholders.

In addition, IMC designed and conducted public relations and awareness campaigns to improve overall perceptions of the industry and provided continuing support for the Canadian Clinical Trials Coordinating Center to further develop clinical trial metrics to augment existing financial footprint data.

Working with Health Canada, IMC contributed to the revision of the government's user fee proposal, which reduced planned fee increases for industry by approximately $131-million between 2019 and 2023. IMC's Regulatory Affairs Committee also conducted regular meetings to ensure Health Canada has a greater line of sight to the views of industry as they undertake regulatory modernization initiatives to make the Canadian regulatory regime more agile, transparent and responsive.

IMC also presented its work on timelines to achieve reimbursement in Canada's public drug plans at the Canadian Agency for Drugs and Technologies in Health (CADTH) symposium in April. This was an ideal opportunity to engage stakeholders in the regulatory and public reimbursement system to build awareness on the key challenges that are leading to long delays, and advocate for a more streamlined, transparent, and predictable process that speeds up access for patients. IMC's analyses on time to listing also enabled more targeted and successful engagement by various IMC regional core teams with their local stakeholders and governments.

Further, IMC's Private Payers Core Team delivered policy tools and published studies with the goal of shaping policy to maintain a vibrant private reimbursement market in Canada. This included an extensive public speaking tour.

These are just a few examples of the important work IMC and its various committees advanced in 2018. By working together with industry and a broad group of stakeholders from governments, patient groups, health charities, life sciences organizations and the business community, the association will continue to provide thoughtful, data-driven solutions to advocate for a policy and regulatory environment that enables Canada's innovative pharmaceutical companies to unlock their full potential.

As we look towards 2019 and beyond, IMC will be implementing a new three-year strategic plan. This plan will be based on four strategic priorities, designed to position our industry for success:

1 ***Optimal regulatory environment:***
A globally competitive, patient-oriented, modern and innovation-friendly regulatory environment in Canada.

2 ***High-performing health systems:***
Solutions to improve health systems effectiveness and patient access.

3 ***Data driven policy:***
Policies, shaped through credible data, that recognize the value of the industry to patients, health systems and the economy.

4 ***Respected partner:***
Enhanced industry credibility through impactful relationships, proactive communication and ethics.

Each of these strategic priorities are backed by measurable goals and benchmarks further outlined in this year's report.

THE ASSOCIATION WILL CONTINUE TO PROVIDE THOUGHTFUL, DATA-DRIVEN SOLUTIONS TO ADVOCATE FOR A POLICY AND REGULATORY ENVIRONMENT THAT ENABLES CANADA'S INNOVATIVE PHARMACEUTICAL COMPANIES TO UNLOCK THEIR FULL POTENTIAL.

PRIORITY 1: BECOME AN AUTHENTIC, SOLUTION-DRIVEN PARTNER THROUGH EFFECTIVE ALLIANCES, POLICY AND LEADERSHIP

Over the past several years, IMC has engaged in constructive collaboration with stakeholders to build and strengthen relationships in order to advance effective and sustainable solutions to urgent challenges for our health systems.

Guided by our Code of Ethical Practices, IMC and its member companies are committed to maintaining the highest ethical standards when interacting with stakeholders and governments. In a year when our industry is facing significant challenges, these investments in partnerships and alliances have been critical.

Across Canada, and in provinces from coast to coast to coast, IMC has engaged with federal, provincial, and territorial governments and stakeholders on several important initiatives, including:

- *Health Canada's proposed changes to the PMPRB.*
- *The creation of a national pharmacare program.*
- *Continued support for the Health Research Foundation.*
- *Maintaining strong relationships with patient groups.*
- *Promoting transparency between industry and government.*
- *Addressing time to listing of innovative medicines on public drug benefit plans.*

PMPRB

IMC's advocacy work with respect to Health Canada's proposed PMPRB regulatory changes was a significant part of the organization's partnership activities in 2018.

At the national level, IMC provided a credible voice in leading and participating in government outreach sessions, engaging with stakeholders and helping to guide discussions among our membership. Specific to PMPRB, IMC developed and executed effective federal and provincial government outreach plans to raise awareness about the impacts of the proposed regulatory changes to the innovative pharmaceutical industry. As part of this engagement, the association offered practical solutions which would provide a more balanced approach to the need for affordable medicines with a positive climate for investment. Subsequent to these efforts, provincial governments in Quebec and Ontario formally shared their concerns with the federal government about the need for a broad consultation given the potential impact of these regulatory changes.

A major milestone in IMC's government engagement was a meeting between President Pamela Fralick and global pharmaceutical executives with Canada's Minister of Innovation, Science and Economic Development (ISED) Navdeep Bains at the World Economic Forum in Davos, Switzerland. Together, industry representatives and Ms. Fralick highlighted the risks that the PMPRB regulatory changes would pose to government's ability to achieve its goals for innovation in the life sciences sector.

Ms. Fralick also successfully concluded a cross-country speaking tour with events that were well-attended by a broad cross-section of stakeholders. The tour provided a forum to enable representatives from the business, patient group and health research communities to voice their shared concerns on the proposed PMPRB changes. Multiple webinars and in-person meetings with a diverse range of patient and life sciences organizations were also supported by IMC's Stakeholder Advisory Team. Through this initiative, a number of stakeholders wrote submissions to Health Canada in opposition to the proposed changes to regulations.

In addition, IMC hosted a meeting with the Pan-Canadian Pharmaceutical Alliance (pCPA) executive oversight team to provide information on the economic impacts of the proposed PMPRB regulatory changes to the pCPA Governance Committee. This important interaction led to further information sessions and engagement with key stakeholders throughout 2018.

PHARMACARE

With pharmacare identified as a priority area for the federal government, IMC assembled a Pharmacare Project Team in early 2018 to be responsible for further developing and updating industry's position. In collaboration with the project team, IMC developed a principles-based approach to the issue which advocates for a national pharmacare program that:

- *Reflects the value of the current mixed public-private model.*
- *Addresses the unmet needs of uninsured or underinsured Canadians.*
- *Is affordable and ensures the sustainability of our health systems.*

This position was partly informed by the data produced by a joint report funded by IMC, The Conference Board of Canada and the Canadian Life and Health Insurance Association on the uninsured in Canada. The report filled a significant void in evidence and has since been quoted by numerous media articles and referenced by government including the Advisory Council on the Implementation of National Pharmacare, led by Dr. Eric Hoskins.

The association also continued to be part of The Conference Board of Canada's National Pharmacare Initiative (NPI). NPI hosted a Thought-Leaders Roundtable in the spring and published a post-roundtable policy paper that provided policy insights and discussion on next steps of the NPI. The work of NPI will culminate with the National Summit on Pharmacare in November.

IMC actively participated in the cross-country consultations by the Advisory Council on the Implementation of National Pharmacare in the summer and fall, with members closely connected to each province attending roundtable discussions and providing critical input. In addition, IMC and BIOTECanada hosted a special session with the advisory council in September to share observations on research undertaken by IMC, as well as to identify opportunities for industry to support the work of the Council.

The association engaged with a variety of other stakeholders on the topic of pharmacare over the course of 2018, leveraging analytical findings on the important differences in public reimbursement systems within other countries, and to provide possible options to help shape the national conversation on what a Canadian pharmacare program could look like. Looking toward 2019, IMC will identify public engagement opportunities and thought leadership events and will continue its participation in national conversation on this important issue.

HEALTH RESEARCH FOUNDATION

The Health Research Foundation (HRF) is a non-profit organization that invests in health research in Canadian academic centres and promotes the benefits and values of research-driven health innovation in Canada. IMC members generously contribute to the HRF, ensuring such research will continue to benefit Canadians for years to come.

In 2018, the HRF continued to support the association's objective of becoming an authentic, solution-driven partner through effective alliances, policy and leadership.

First, the HRF continued its focus on initiatives through a variety of partnership organizations with the aim of improving patient outcomes and health system efficiencies through the following investments:

- *In Ontario, IMC implemented a multidisciplinary approach for improved care for chronic obstructive pulmonary disease in partnership with the Ontario Lung Association.*
- *In British Columbia, IMC spear-headed the implementation and evaluation of pharmacogenomics in primary care lead communities with the University of British Columbia. IMC also committed to the study of methods taken to avoid cardiovascular events.*
- *In Saskatchewan, the University of Saskatchewan collected and reported data regarding increasing adherence rates through collaborative practice.*
- *In Manitoba, IMC partnered with the Manitoba Centre for Health Policy and Manitoba Health to study appropriate prescribing for diabetes.*
- *In Prince Edward Island, IMC engaged the province to examine value-based pricing and procurement of innovative medicines.*

Second, the HRF continued to advance an initiative focused on value-based pricing and procurement. As part of this initiative, the Foundation continued to leverage case studies of successful frameworks in foreign jurisdictions and in Canada. These studies were produced by The Conference Board of Canada and used as examples of options within the context of the pharmacare debate.

Third, the 2018 HRF Medal of Honour was awarded during the HRF Gala in November. Since its inception in 1945, the Medal of Honour has been awarded to outstanding individuals whose research, and contribution to public policies supportive of research and development in Canada, have achieved international recognition. All recipients have made a notable or pivotal contribution to the advancement of knowledge in the health sciences and the improvement of therapeutics healthcare.

Alongside these projects, HRF successfully raised over $250,000 in funds through the 2018 HRF Golf Classic, which had a strong turnout of industry participants and CEOs.

PROMOTING THE VALUE OF INDUSTRY

To highlight and champion the value of innovative medicines in Canada, IMC executed public relations and awareness campaigns, including a national campaign with *Postmedia* and a Quebec-focused campaign with *La Presse*. These initiatives were supported by the ongoing Innovate for Life digital campaign. Launched in October 2017, Innovate for Life has helped to raise awareness of the value of innovative medicines and the unintended consequences of major changes to the PMPRB regulations.

IMC has also raised awareness about the valuable role that the innovative pharmaceutical industry plays in contributing to Canada's health systems and in the life sciences sector, through a series of events across the country.

In Montreal, IMC held its annual conference for Quebec-based patient groups in May, with more than 100 participants in attendance. This year's theme was the Quebec Election 2018: Healthcare & the Role of Patients. The Quebec Health Minister, along with health critics for the *Parti Québécois* and the *Coalition Avenir Québec*, presented their parties' respective visions for the future. All three spoke of the need to improve on time to listing and access to medicines in the province.

In Winnipeg, IMC hosted a reception at the June 2018 meeting of federal, provincial and territorial health ministers, which provided another opportunity to engage and share information with key government stakeholders from across Canada.

Internationally, IMC had a strong presence at the BIO International Convention in Boston, Massachusetts. With more than 15 member companies represented (including 13 CEOs), the industry held constructive bi-lateral meetings with representatives from the Nova Scotia, New Brunswick, Quebec, Ontario, Manitoba, Alberta and British Columbia provincial governments, and represented the industry at all Canadian-hosted events. As a delegation, IMC either introduced or reinforced our solutions-oriented approach to the federal regulatory challenges with a goal of preserving our ability to innovate in Canada. Several announcements of partnership projects with members and the Canadian and Quebec governments were made, reinforcing our industry's support of research in Canada.

TRANSPARENCY

As a matter of principle, IMC believes in transparent relationships with all industry stakeholders, including healthcare professionals (HCPs) and healthcare organizations (HCOs).

Starting in 2016, IMC spearheaded the Canadian Framework for Ethical Collaboration, a domestic implementation of an international Asia-Pacific Economic Cooperation (APEC) framework which aims to build crucial partnerships. The Best Medicines Coalition, the Health Charities Coalition of Canada, the Canadian Medical Association, the Canadian Nurses Association, and the Canadian Pharmacists Association developed the framework with IMC to create a set of ethical standards to guide collaboration among patient organizations, health professionals and the pharmaceutical industry. The framework sets out four overarching principles:

1. *Ensures patients' best interests are at the core of our activities.*
2. *Promotes transparent and accountable conduct.*
3. *Sets clear rules on gifts, funding and conferences, continuing health education and clinical research.*
4. *Guides national ethical leadership.*

As part of our industry's contribution to Canada's health systems, IMC works with health professionals and healthcare organizations to contribute positively to scientific advancement, physician education and patient care programs designed to enhance health outcomes.

IMC continues to closely follow any developments on the issue of payment transparency. In 2018, the association actively participated in the consultation process regarding the Ontario government's *Bill 160*, *Strengthening Quality and Accountability for Patients Act*. A particular area of focus was the changes to Schedule 4, the *Health Sector Payment Transparency Act* and its regulations. While the Bill has passed, it has not been implemented by the new Ontario government.

IMC was also involved in consultations with the Government of British Columbia on the potential implementation of a health sector transparency program. IMC continues to engage with the BC government to ensure the industry's voice is heard and considered.

PRIORITY 2: IMPROVING ACCESS AND THE REGULATORY ENVIRONMENT IN CANADA

Timely access to treatment depends on a regulatory environment that supports innovation. IMC remains committed to creating more predictable and sustainable health systems that best serve the needs of all Canadians. In support of this important objective, IMC put forward important analyses and policy proposals to support advocacy efforts on the need to improve access and regulatory environments in Canada. This year the focus was on three key initiatives:

- *Policy analysis and research to support IMC's position on the PMPRB.*
- *Engagement with Health Canada on other regulatory issues.*
- *Aligning members and providing information to stakeholders on reimbursement challenges.*

PMPRB

The concerns industry has identified in the proposed changes to the PMPRB regulations include changing the list of countries used to compare Canadian ceiling prices, the inclusion of Health Technology Assessment (HTA) factors as part of price regulation, and the introduction of both affordability and Canadian expenditure elements—in addition to several important technical changes, seriously threaten the business viability of innovative pharmaceutical companies in Canada and their important investments in our health systems. As a result, the association has worked hard to develop and propose meaningful alternatives which would accomplish the government's health and investment goals while ensuring Canada continues to grow its innovative life sciences sector.

To support advocacy efforts with governments and stakeholders, IMC undertook several research initiatives in relation to proposed changes.

The association continued its work with the Canadian Clinical Trials Coordinating Center (CCTCC) to develop the "Clinical Trials—The Canadian Advantage" research study, an in-depth narrative communicating Canada's clinical trials advantages globally in terms of population demographics and diversity, speed, quality and incentives. This study was key in supporting engagement and dialogue with government stakeholders—particularly ISED — about Canada's status as a top destination for clinical trials and the potential risks to this status should the proposed PMPRB changes be implemented.

The association commissioned EY to undertake an independent analysis of the potential impacts of the draft PMPRB Guidelines Modernization framework related to the proposed new HTA factor. These guidelines are critical to understanding how PMPRB intends to determine the ceiling price of patented drugs in Canada. The EY analysis showed potential ceiling price reductions ranging from 40 to 90 per cent and was a critical input in IMC's policy position on the use of HTA factors in the proposed regulations.

WORKING WITH GOVERNMENT ON REGULATORY AFFAIRS

In 2018, IMC continued its engagement with Health Canada officials on a variety of regulatory affairs issues. One area of focus involved consultations as part of the government's Regulatory Reform of Drugs and Devices (R2D2) process. Health Canada is proposing substantial regulatory changes with the goals of finding greater efficiencies, more timely access to therapeutic products and creating closer linkages between drug regulations and health systems as a whole. IMC engaged with Health Canada officials throughout the year to leverage internal analyses and highlight challenges.

IMC engaged with the government on proposed modifications to the regulatory cost recovery regime (user fees) which lessened the proposed fee increases by $131-million over four years. As part of this engagement, the association welcomed the government's decision to implement a negotiated phased-in fee increase every four years.

Another area of focus was the engagement on Health Canada's policy and procedures and the release of clinical data, which aligned with the policies of the European Medicines Agency. This outcome reduced compliance costs and risks to members of the release of confidential business information.

IMC is also actively participating in Health Canada and Treasury Board Secretariat's efforts to help the Canadian regulatory system become more agile, transparent and responsive. This initiative is linked to the government's Economic Strategy Tables which have set ambitious growth targets designed to drive long-term and sustainable economic growth, particularly in key targeted sectors including health and biosciences.

RESEARCH AND ADVOCACY ON PRIVATE PAYER SYSTEMS

Throughout 2018, IMC's Private Payers Core Team delivered on several key objectives to help shape policy and maintain a competitive private market and prevent the erosion of access for working Canadians who have come to value their private drug plans. This included a significantly increased presence at numerous key stakeholder conferences and public speaking opportunities to promote IMC's positions on key policy issues. Events included: Benefits Canada, Northwinds, Benefits Breakfast Club (BBC) of the Canadian Pensions and Benefits Association (CPBI), the Human Resources Professionals Association and the Best Medicines Coalition. For the fifth year, IMC also organized a private payers event on the value, challenges and future of private payer plans in Quebec.

IMC facilitated the creation of a Quebec Joint Private Sector Working Group between private insurers and industry to foster greater dialogue and to identify opportunities for collaboration. This led to the creation of a Value Demonstrative Initiative (VDI), a study which demonstrated the value of pharmaceutical treatments and their impact on reducing employee absenteeism and increasing workplace productivity.

Stakeholder engagement efforts were supported by IMC-commissioned research publications such as the Cost Drivers Analysis of Private Drug Plans in Canada 2012–16 and the 2017–19 Private Drug Plan Forecast. New tools were also developed and included a revamped Pharma 101 program for brokers and redesign of the Better Access, Better Health website.

The Private Payers Core Team also laid the groundwork for the development of a private payer summit concept forum, which was later adopted and became the National Pharmacare Initiative (NPI) hosted by The Conference Board of Canada. This represents a key piece in IMC's national pharmacare strategy and demonstrates a high level of cooperation between the private and public stakeholders.

IMPROVING PAN-CANADIAN ACCESS TO MEDICINES

As part of ongoing efforts to improve access to medicines across Canada, IMC conducted a public reimbursement timelines analysis, which was presented at the CADTH symposium. This data also contributed to work by various core teams including the regional teams, the pCPA team, the Joint Health Technology Assessment Team, as well as the Joint Oncology Project Team. More work is ongoing including an international comparison of public reimbursement access metrics.

IMC also engaged with several provincial governments on improving access for patients.

In British Columbia, IMC provided data analytics and value-based examples to demonstrate the patient benefits from improved access as well as the potential cost savings that may be realized in other parts of the BC health care system.

In Manitoba, IMC worked with the drug plan to incorporate important changes to the province's new Product Listing Agreement (PLA) template and its ongoing listing requirements to ensure an improved access approach for members.

In Quebec, IMC executed a plan to ensure the province's life science strategy incorporated measures to create faster drug access, better clinical trials, improved time to listing metrics, an improved research and development environment and better access to health data.

IMC also collaborated with the *Institut national d'excellence en santé et en services sociaux* (INESSS) on their updated framework for drug reviews and drug evaluation process. IMC's engagement led to a better alignment between INESSS and CADTH, greater consideration of patient groups' input, more interaction with industry, and improved timeliness for receiving the INESSS recommendations.

PRIORITY 3: ADVOCATE FOR A GLOBALLY-COMPETITIVE INTELLECTUAL PROPERTY REGIME

In the year following the implementation of the Canada-European Union Comprehensive and Economic Trade Agreement (CETA), IMC has paid close attention to trade-related commitments and negotiations, respecting IP and their impact on industry. As CETA continues to be implemented across government, IMC will monitor and share information to ensure that IP-related trade developments will not negatively impact Canada's relations with major trading partners or undermine existing commitments.

As part of this work, IMC met with European Commission delegates to express concerns regarding the impact of the proposed PMPRB changes on Canada's Tier 1 status as a country to launch drugs and, by extension, the ability of patentees to meet eligibility requirements under Canada's new Certificates of Supplementary Protection system that was created following the conclusion of CETA. IMC is coordinating activities related to this issue in the EU with our sister association, the European Federation of Pharmaceutical Industries and Associations (EFPIA). IMC has also identified metrics that will serve as a tool for evaluating CETA's implementation, notably with respect to the major changes that were introduced to the PMPRB (Notice of Compliance) Regulations.

IMC has carefully monitored negotiations with the United States and Mexico on a new North American Free Trade Agreement (USMCA). This work included analysis of the agreement's extension of data protection for biologics in Canada from eight to ten years.

In August of 2018, the Federal Court of Appeal (FCA) granted IMC's motion for leave to intervene in *The Attorney General of Canada v. Galderma Canada Inc.* This gave IMC the right to participate in the proceedings before the FCA and provide comment on the legal issues being considered. The rationale behind the court's intervention was that the PMPRB only has jurisdiction under the *Patent Act* "if an invention pertains to a medicine." The proper construction of this phrase affects the jurisdiction of PMPRB and the obligations of patentees. While *Galderma* was successful at the Federal Court Trial Division, the Attorney General of Canada (AGC) is appealing the decision.

In the fall of 2018, IMC made a submission to the Canadian Intellectual Property Office's (CIPO's) public consultation on proposed new patent examination guidelines for pharmaceutical solid forms, including polymorphs, salts, hydrates, solvates, desolvates and co-crystals. IMC raised the concern that, compared to current examination practices, the proposed guidelines set heightened requirements with respect to non-obviousness and utility of certain inventions relating to crystalline forms of small molecules. At the time of writing, it remains unclear if and how CIPO will respond to IMC's recommendations.

In addition to the work involving IP, IMC and MEDEC made a joint submission to the Law Commission of Ontario (LCO) in response to its class actions law review—the first independent, evidence-based, and comprehensive review of class actions in Ontario since the enactment of the *Class Proceedings Act* in 1993. Given many of IMC's members have experience with Ontario's class proceedings regime, as defendants or potential defendants to class actions, we made a proposal to the LCO for a more fair, balanced and efficient class proceedings regime in Ontario.

A NEW STRATEGIC PLAN FOR A CHANGING WORLD

The innovative pharmaceutical sector is changing: new technologies such as artificial intelligence are helping researchers discover new treatments faster, health systems have greater access to patient data, public expectations are changing as national pharmacare gain prominence, and competition for investment dollars remains fierce.

As our environment changes, so too must our strategic focus. Over the past several months, the IMC executive team has been working closely with member CEOs and the Board of Directors to develop a new three-year strategic plan.

This plan is supported by our vision: A future in which all Canadians are living healthy and longer lives through sustainable access to innovative medicines and vaccines. As the voice of Canada's research-based pharmaceutical companies, it is the association's mission to promote and support the policies that enable the discovery, development and commercialization of innovative medicines and vaccines that enhance the lives of all Canadians.

CLICK HERE TO SEE INNOVATIVE MEDICINES' STRATEGIC PLAN

Guided by this vision and mission, IMC has identified four strategic pillars which will shape the association's priorities from January 2019 to 2021:

1 ***Optimal regulatory environment:*** *A globally competitive, patient-oriented, modern and innovation-friendly regulatory environment in Canada.*

2 ***High-performing health systems:*** *Solutions to improve health systems effectiveness and patient access.*

3 ***Data driven policy:*** *Policies, shaped through credible data, that recognize the value of the industry to patients, health systems and the economy.*

4 ***Respected partner:*** *Enhanced credibility of the industry through impactful relationships, proactive communication, and ethics.*

For each of these strategic pillars, IMC has established clear goals and benchmarks for success to be completed by 2021.

First, as the association looks to create an optimal regulatory environment by 2021, IMC will have:

1 *Collaborated with government and stakeholders to achieve a PMPRB outcome that preserves innovation, a vibrant life sciences sector and patient access.*

2 *Partnered with Health Canada as part of its Regulatory Review of Drugs and Devices to optimize a drug approval system which is scientifically sound, attracts innovation, improves time to approval and includes evidence-based use of HTA.*

3 *Advocated for Intellectual Property (IP) and confidentiality protections that ensure Canada keeps pace with other G7 nations.*

Second, to ensure high-performing health systems by 2021, IMC will have:

1 *Worked in partnership with the pan-Canadian Pharmaceutical Alliance (pCPA) to ensure that reimbursement arrangements in the health system(s) recognize the value of medicines, budget sustainability and timely access.*

2 *Contributed to a pharmacare system that includes both private and public payers, focuses on filling coverage gaps and increases access for all Canadians.*

3 *Facilitated improvements in care and delivery standards within our health systems.*

Third, to help put data-driven policy at the centre of health system solutions by 2021, IMC will have:

1. *Facilitated the development of a "Real-World Evidence platform" in Canada to support access to medicines and a higher standard of care.*
2. *Contributed to the development of a modernized widely accepted definition of life sciences sector investment.*
3. *Produced a recognized and comprehensive data set that demonstrates the value of the industry.*

Finally, being viewed as a respected partner means that by 2021, IMC will have:

1. *Become a lead, sought-after expert and contributor to government policy and health systems.*
2. *Generated an increased understanding by key partners and the engaged public of the value of innovative medicines to Canadians and the economy.*
3. *Become a proactive leader on industry ethics.*

In support of these four pillars is a set of guiding principles that recognize the important role our industry plays in shaping policies and improving health systems, while setting standards for how we engage with our stakeholders and members of the broader health system. They include the following:

1. *We promote trust, collaboration and partnership and are respectful in all our working relationships.*
2. *We proactively offer solutions to address Canadian health system challenges.*
3. *We are nimble and will manage change in the spirit of maintaining alignment and focus on the four pillars of the strategic plan.*
4. *We act in accordance with an established Board/CEO code of conduct that endorses industry alignment.*

As the new strategic plan is implemented, IMC will review its internal committee and team structure to ensure the association is best positioned to achieve its goals. This new structure will be more adaptable, accountable and aligned to deliver streamlined workflows and improved communications—both internally among members and across the broader health systems, and through our network of stakeholders.

INNOVATIVE MEDICINES CANADA
STRATEGIC DIRECTION AND CONSIDERATIONS
2019–2021

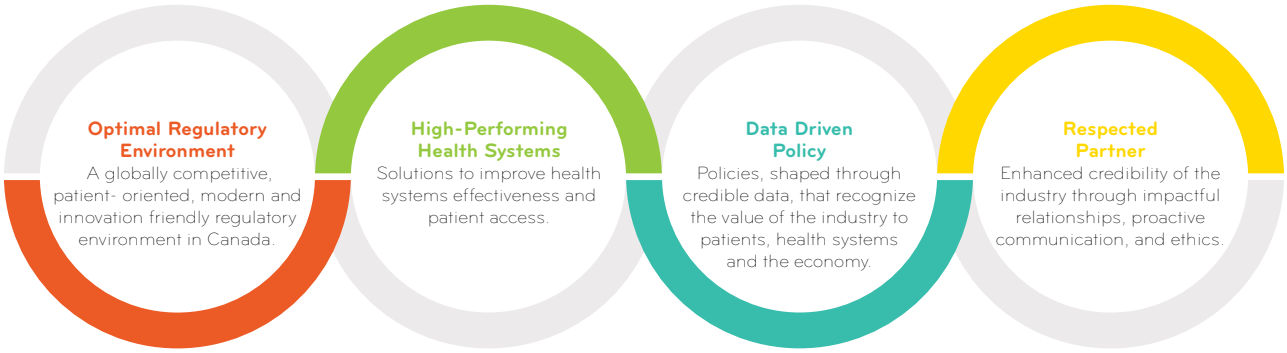
Vision Statement

All Canadians living healthy and long lives through sustainable access to innovative medicines and vaccines.

Mission Statement

As the voice of research-based pharmaceutical companies, Innovative Medicines Canada promotes and supports policies that enable the discovery, development and commercialization of innovative medicines and vaccines that enhance the lives of all Canadians.

Strategic Pillars



BY THE END OF 2021, WE WILL HAVE:

1. Collaborated with government and stakeholders to achieve a PMPRB outcome that preserves innovation, a vibrant life sciences sector and patient access.
2. Partnered with Health Canada as part of its Regulatory Review of Drugs and Devices to optimize a drug approval system which is scientifically sound, attracts innovation, improves time to approval, and includes evidence-based use of Health Technology Assessments (HTA).
3. Advocated for Intellectual Property (IP) and confidentiality protections that ensure Canada keeps pace with other G7 nations.

1. Worked in partnership with the pan-Canadian Pharmaceutical Alliance (pCPA), to ensure that reimbursement arrangements in the health system(s) recognize the value of medicines, budget sustainability, and timely access.
2. Contributed to a Pharmacare system that includes both private and public payers, focuses on filling coverage gaps and increases access for all Canadians.
3. Facilitated improvement in care and delivery standards within our health systems.

1. Facilitated the development of a Real-World Evidence platform in Canada to support access to medicines and a higher standard of care.
2. Contributed to the development of a modernized and widely accepted definition of life sciences sector investment.
3. Produced a recognized and comprehensive data set that demonstrates the value of the industry.

1. Become a lead, sought-after expert and contributor to government policy and health systems.
2. Generated an increased understanding by key partners and the engaged public of the value of innovative medicines to Canadians and the economy.
3. Become a pro-active leader on industry ethics.

Guiding Principles

1. We promote trust, collaboration and partnership, and are respectful in all our working relationships.
2. We pro-actively offer solutions to address Canadian health systems challenges.
3. We are nimble and will manage change in the spirit of maintaining alignment and focus on the four pillars of the Strategic Plan.
4. We act in accordance with an established Board/CEO code of conduct that endorses industry alignment.

PMPRB: Patented Medicine Prices Review Board
R2D2: Regulatory Review of Drugs and Devices
HTA: Health Technology Assessment
pCPA: pan-Canadian Pharmaceutical Alliance

Approved – September 2018

AS THE VOICE OF CANADA'S INNOVATIVE PHARMACEUTICAL COMPANIES, IT IS THE ASSOCIATION'S MISSION TO PROMOTE AND SUPPORT THE POLICIES THAT ENABLE THE DISCOVERY, DEVELOPMENT AND COMMERCIALIZATION OF INNOVATIVE MEDICINES AND VACCINES THAT ENHANCE THE LIVES OF ALL CANADIANS.

INNOVATIVE MEDICINES CANADA MEMBER COMPANIES

MEMBER COMPANIES	
AbbVie Corporation	JSS Medical Research
Akcea Therapeutics Canada Inc.	KalGene Pharmaceuticals Inc.
Amgen Canada Inc.	Knight Therapeutics Inc.
Astellas Pharma Canada, Inc.	LEO Pharma Inc.
AstraZeneca Canada Inc.	Lundbeck Canada Inc.
Bayer Inc.	Medicago
BioVectra Inc.	Merck Canada Inc.
Boehringer Ingelheim (Canada) Ltd.	Novartis Pharmaceuticals Canada Inc.
Bristol-Myers Squibb Canada	Novo Nordisk Canada Inc.
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
Gilead Sciences Canada, Inc.	Sanofi Pasteur Limited
GlaxoSmithKline Inc.	Servier Canada Inc.
GLyPharma Therapeutic Inc.	Shire Pharma Canada ULC
Hoffmann-La Roche Limited	Sunovion Pharmaceuticals Canada Inc.
Horizon Therapeutics Canada	Takeda Canada Inc.
Innoviva Inc.	Theratechnologies Inc.
Ipsen Biopharmaceuticals Canada, Inc.	Vantage BioTrials Inc.
Janssen Inc.	

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2018 ANNUAL REPORT

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