



INNOVATIVE
MEDICINES
CANADA

ANNUAL REPORT
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LETTER FROM THE PRESIDENT

Since the days of Banting and Best, innovative pharmaceutical companies have worked to translate the best available science into beneficial treatments which represent real hope for patients and families impacted by disease and suffering. And today the future of medicines is brighter than ever.

There are more than 500 new medicines currently in development in Canada and 93 per cent of this research is funded by industry. Innovative Medicines Canada's 40 member companies are working on exciting new treatments for multiple sclerosis, arthritis, cancer, diabetes, among others—and are using cutting edge research technologies to find new medicines faster and more effectively.

I am extremely proud of the work accomplished by the industry over the course of this difficult year. The regulatory changes to the Patented Medicine Prices Review Board are already being felt by our Canadian companies and affiliates. While the full impact of these changes is not yet known, many companies are reporting delays in launching new products, are downsizing their workforces, and are being forced to put Canadian research projects on hold.

We have complex challenges ahead of us, but our members are more aligned and united than ever to address them, for the health of all Canadians.

And we recognize that we cannot do it alone. With like-minded stakeholders we will continue to advocate for issues that are of critical importance to Canadians, including improving access to rare disease drugs and creating a national pharmacare program built on the strengths of our dual system, so that no Canadian falls through the cracks or loses the high standard of coverage they have today.



Progress depends on meaningful partnerships with governments, healthcare professionals and scientists, keeping patients at the centre of our work at all times. Guided by our updated Code of Ethical Practices, we continue our commitment to being respected partners, using data and research to inform our policy choices.

I am extremely proud to represent an industry that discovers, develops and delivers medicines that save and prolong lives, and enhance the quality of life for all Canadians. Our members work passionately and tirelessly to make a difference for patients, and for the future of our health systems. As Canada's regulatory environment and health systems evolve, we will continue to advocate for a holistic approach to ensure better access to new medicines and vaccines, and for a vibrant life sciences sector that encourages health research and innovation.

LETTER FROM THE CHAIR



In 2019, Innovative Medicines Canada (IMC) and its member companies continued to deliver value to Canadians through the discovery, development and commercialization of life-changing and lifesaving innovative medicines.

Our unwavering commitment to Canadian patients is why we are in this industry. We have seen how new treatments can make a difference in the lives of families; providing a better quality of life for those who suffer from chronic illnesses and giving new hope to those who need it most.

As I reflect on my two years as Chair, it is this commitment to ensuring Canadians have access to the medicines they need that has brought our industry together in the face of the most challenging environment in a generation.

Amendments to the *Patented Medicines Regulations*, which were passed in August, will limit our members' ability to launch new medicines, conduct clinical trials and make major investments in the Canadian market.

With the amended regulations expected to come into force in July 2020, our members will continue to raise concerns about the very real impacts these changes will have on Canadian

patients' access to innovative therapies and on the future of Canada's life sciences sector. We will advocate for a regulatory environment that protects and promotes innovation so that new and future discoveries such as gene therapies, cell therapies and personalized medicines can be discovered, developed and commercialized in Canada.

We will also continue to engage with governments and stakeholders on the development of a future national pharmacare program, which, if done right, could close the gaps in the current system and make medicines available and more affordable for uninsured and underinsured Canadians.

Despite the challenges of our current environment, Canada's innovative pharmaceutical industry has shown great leadership and resilience. IMC's Board of Directors remains pragmatic, realistic and focused on its priorities. In 2019, IMC launched a three-year Strategic Plan, which will guide the association through 2021. This framework is based on a set of guiding principles that set the standard for how we engage and communicate with stakeholders, governments and Canada's health systems more broadly with a united voice. The Board also approved updates to IMC's Code of Ethical Practices to ensure that relationships between industry and its external stakeholders continue to be held to the highest ethical standards.

Our industry also has to anticipate future trends in Canada's business environment and develop innovative solutions to strengthen the sustainability of our healthcare systems. Part of the answer is evolving our business models to the new digital economy and placing greater focus on data, Artificial Intelligence (AI) and outcome-based healthcare systems. The emergence

of AI offers the potential for revolutionary breakthroughs in Canadian healthcare research, which could strengthen the sustainability of our health systems and lead to better patient outcomes in the coming years. As innovators, we can and should be leaders in this space.

Another part of the answer is shifting the conversation from cost to value. As we look towards the future, we need to ensure we always measure and communicate the value we bring to patients, to the Canadian economy and to the healthcare system. The innovations we develop and deliver change millions of lives every day. We must continue to work for and with patients, in telling our story and in promoting patients' perspectives in all our interactions with governments and stakeholders. Improving

the lives of patients is our *raison d'être*. As my term as Chair comes to a close, I would like to express my sincere thanks to my fellow Board members, IMC President Pamela Fralick and her entire team for their continued efforts in supporting our industry.

It has been a privilege to represent our industry in Canada for the last two years. We have much to be proud of as we continue to build a brighter future for Canadian patients.

SINCE THE DAYS OF BANTING AND BEST, INNOVATIVE PHARMACEUTICAL COMPANIES HAVE WORKED TO TRANSLATE THE BEST AVAILABLE SCIENCE INTO BENEFICIAL TREATMENTS WHICH REPRESENT REAL HOPE FOR PATIENTS AND FAMILIES IMPACTED BY DISEASE AND SUFFERING.

OVERVIEW

Innovative Medicines Canada (IMC) is a national association representing 40 innovative pharmaceutical companies. Our members, which range from small Canadian start ups to established global organizations, discover, develop and deliver innovative medicines and vaccines.

As respected partners in Canada's healthcare systems, our vision is to help all Canadians live longer, healthier lives. Guided by a strict Code of Ethical Practices, IMC works to support its members through effective engagement with stakeholders in the public and private sectors, and governments at the federal, provincial and territorial levels, to advocate for better access to a broad range of ground-breaking new innovative medicines and vaccines. 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 high-quality jobs and contribute more to our economy. Approximately 10 per cent of industry gross patented medicines revenues are invested into R&D, which totaled more than \$19.2-billion in 2016. (Source: EY, 2017)



IMC's activities are guided by the four strategic pillars as set out in our three-year strategic plan.

- 1 Optimal regulatory environment:** Globally competitive, patient-oriented, modern and innovation friendly.
- 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.

OUR MEMBERS, WHICH RANGE FROM SMALL CANADIAN START UPS TO ESTABLISHED GLOBAL ORGANIZATIONS, DISCOVER, DEVELOP AND DELIVER INNOVATIVE MEDICINES AND VACCINES.

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

2019 marked a year of challenge for our industry, as the federal government passed amendments to the Patented Medicine Prices Review Board regulations which will dramatically change the way ceiling prices for new drugs are set in Canada. These changes will have serious impacts on the industry and for the thousands of Canadian patients who rely on our medicines. The new regulations, which are expected to come into force in July 2020, will delay or limit access to new medicines, lead to fewer clinical trials and significantly impact the level of investment in Canada's life sciences sector.

As companies evaluate how to manage through this challenging regulatory environment, IMC will continue to engage with stakeholders and governments at both the federal and provincial/territorial levels to mitigate some of the most damaging impacts of the changes on patients' access to medicines and future investment in Canada.

Ensuring Canadians maintain access to a broad range of cutting-edge medicines has also shaped the association's efforts in support of a national pharmacare program. IMC actively participated in the consultation process of the federal government's Advisory Council on the Implementation of National Pharmacare. The industry supports universal coverage for all Canadians to make prescription drugs more affordable and more accessible to all—regardless of income, age, or postal code. However, we believe that the continued existence of the private market is critical to help ensure that no Canadian will have to accept a lower level of coverage under a future pharmacare program than they currently have today. We also recognize

that Canadians who suffer from rare diseases face unique challenges and we have been exploring potential policy solutions to make these drugs more affordable and accessible.

Collaboration is essential to the success of national pharmacare in Canada. We look forward to working with federal, provincial and territorial governments and other stakeholders over the coming years to create a system that works for all Canadians.

2019 saw a renewed focus on policy and research for the association. Recognizing that new treatments are only as effective as the systems that deliver them, IMC is leveraging its data and research to proactively offer forward-thinking solutions to improve the effectiveness of Canada's health systems and deliver better health outcomes for Canadians. This includes analyses on the length of time between a drug's approval to the time it is covered under a public drug plan, a shared definition of what constitutes research and development that reflects the realities of the 21st century. In addition, our policy work in the private employer sponsored benefits' space helps employers and brokers better understand the value of medicines and effectively manage risk in a vibrant private reimbursement market.

As we look to 2020 and beyond, IMC will continue to prioritize patient-centred policies as it collaborates with a broad group of stakeholders from governments, patient groups, health charities, life sciences organizations, healthcare professional associations, academia and the broader Canadian business community. By providing thoughtful, data-driven solutions, IMC will advocate for a policy and regulatory environment that enables Canada's innovative pharmaceutical companies to unlock their full potential.

A NATIONAL VOICE

Canada's innovative pharmaceutical industry is active across the country, driving innovation in health research, and contributing to the growth of our economy.

NOVA SCOTIA

With companies investing close to \$20-million in research and development, an overall economic impact of \$30-million, and over 500 active clinical trials in the province, Nova Scotia is a hub for pharmaceutical innovation in the region and ranks number five in Canada.

NEWFOUNDLAND AND LABRADOR

Research and development partnerships in the province contribute close to \$3-million in economic activity and help support clinical providers, build better patient experiences and outcomes, and employ more than 270 jobs directly and indirectly in the pharmaceutical industry in Newfoundland and Labrador.

PRINCE EDWARD ISLAND

Homegrown Prince Edward Island company BioVectra, which employs approximately 300 people across Atlantic Canada, is also working with many global pharmaceutical companies to improve product development and manufacturing processes to best serve those who need it. By making treatment easily available to the approximately 1,000 Islanders suffering from hepatitis C, Prince Edward Island is on track to be the first province in Canada to eliminate the hepatitis C virus (HCV) within its population.

NEW BRUNSWICK

With an annual economic impact of \$11-million and close to 200 active clinical trials, the pharmaceutical industry in New Brunswick contributes significantly to the province, supporting 280 jobs directly and indirectly.



QUEBEC

The life sciences sector in Quebec is active and engaged, with strong partnerships among the private sector researchers, universities, and the financial sector. In 2016, the innovative pharmaceutical industry generated more than \$3.1-billion in direct economic benefits in Quebec (33 per cent of the Canadian total) and attracted 42 per cent of the jobs (13,000) in Canada.

ONTARIO

Our members in Ontario collaborate with government, universities, life sciences organizations, and the business community to promote and advocate for a vibrant pharmaceutical sector. The industry sustains over 7,000 jobs directly and 12,000 jobs indirectly. The sector is also very active in clinical trials and supports over 3,000 trials in the province.



MANITOBA

Manitoba is known for its strong research and development activity in immunobiology and health data analytics. In 2016, 52 clinical trials were completed across the province, with more than 70 per cent of the trials testing oncology treatments. These specialty areas within Manitoba's pharmaceutical industry have helped attract more than \$7.4-million of industry research and development investment over the past 10 years.

SASKATCHEWAN

Innovative Medicines Canada (IMC) and its members in the province have greatly benefited from partnerships with Saskatchewan's academic researchers in medicine and pharma. IMC's Health Research Foundation has invested in ground-breaking research at the University of Regina focused on the effectiveness of internet-based therapy to treat depression and anxiety. The presence of dozens of clinical trials treating a wide variety of diseases has given Saskatchewan patients and their caregivers access to innovative care. In 2016, this care was estimated at \$21-million.

ALBERTA

The innovative pharmaceutical industry in Alberta is working to tackle some of the most devastating diseases and chronic conditions including cancer, multiple sclerosis and Parkinson's through health partnership initiatives such as clinical trials, academic research innovation funds, artificial intelligence and virtual care. The pharmaceutical sector in Alberta attracts significant multi-million-dollar investments and helps employ about 3,500 Albertans directly and indirectly.

BRITISH COLUMBIA

From investments in research to licensing agreements with promising therapies in small and emerging companies, IMC members contribute substantially to the active biopharmaceutical cluster in British Columbia, such as the adMare BioInnovations Executive Institute, which helps ensure that the Canadian life sciences sector has the management talent it needs to lead the world.

The health and wellness of patients in the province is also a priority, with multi-million-dollar investments in initiatives around cancer research, cardiovascular care, diabetes and orphan diseases.

Source: EY Data Analytics and Members' Economic Footprint and Impact in Canada, October 2017

Healthcare is a shared responsibility in Canada, with both federal and provincial/territorial governments playing distinct roles in the regulation, approval and delivery of innovative medicines. IMC represents its members at both the federal and provincial/territorial levels, with its headquarters in Ottawa and regional directors and membership-driven teams representing five regions: Atlantic, Quebec, Ontario, Prairies and British Columbia.

In Ottawa, IMC engages with the federal government and national stakeholders including patient advocacy organizations and health charities, life sciences and health research organizations and business groups, to support policies that improve Canada's regulatory environment, increase access to innovative medicines and ensure the effective protection of intellectual property.

At the regional level, IMC works to support its members through effective engagement with provincial/territorial governments and stakeholders, including patient advocacy organizations and health charities, regional life sciences organizations and regional chambers of commerce and business organizations. IMC also actively engages with the Council

of the Federation to advocate for policies that improve patients' access to a broad range of medicines and to raise awareness about the industry's role as a driver of economic growth.

IMC and its membership also work with the provinces and the federal government through the pan-Canadian Pharmaceutical Alliance (pCPA) on purchasing solutions to make drug costs more affordable for Canada's public health insurance plans. According to the pCPA, negotiations up to March 31, 2019, have resulted in estimated savings of \$2.36-billion annually—with approximately two-thirds of the savings accounting for patented medicines (\$1.52-billion). Our advocacy with the pCPA is focused on improving processes that can help speed up access to new medicines across Canada.

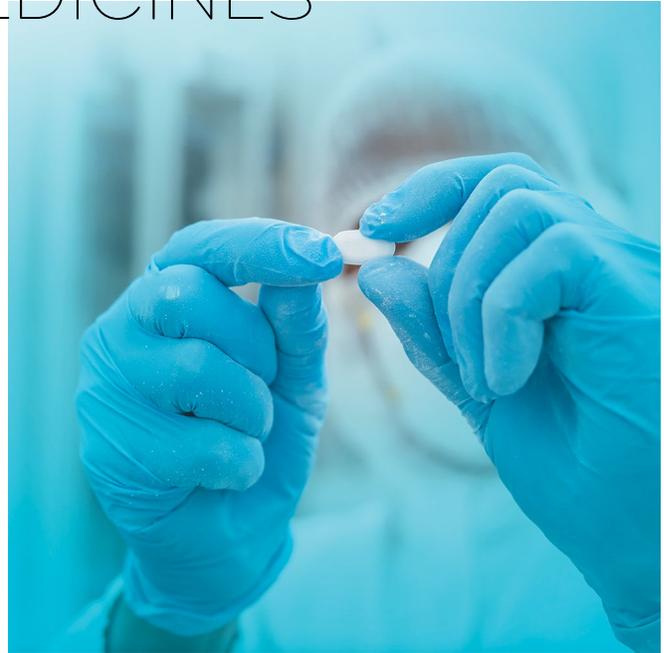
Looking to 2020 and beyond, the creation of a national pharmacare program will require governments and stakeholders at both the provincial and federal levels to work more closely than ever before. As a respected partner in Canada's health systems, IMC will continue to forge strong relationships with key stakeholders across the country to promote the value of our industry in enhancing the wellbeing of Canadians.

CANADA'S INNOVATIVE PHARMACEUTICAL INDUSTRY IS ACTIVE ACROSS THE COUNTRY, DRIVING INNOVATION IN HEALTH RESEARCH, AND CONTRIBUTING TO THE GROWTH OF OUR ECONOMY.

THE VALUE OF MEDICINES

New medicines deliver extraordinary value to individual Canadians, our healthcare institutions and overall health systems. They prevent or cure disease, extend lives, relieve suffering and improve an individual's quality of life.

Advances in new medicines have significantly increased Canadians chances of survival. For example, more than 66 per cent of people diagnosed with cancer today survive five years and longer, compared to 33 per cent in 1964. Approximately 83 per cent of these survival gains can be attributed to new treatments. In addition, the introduction of highly active anti-retroviral therapy (HAART) combinations in 1996 has transformed an HIV diagnosis from a death sentence to a treatable chronic disease in a single generation. A 20-year old diagnosed with HIV today can expect to live into his or her 70's. Dramatic declines in death rates did not occur with one single breakthrough drug, but rather a series of advances providing important treatment options for patients over time.



MADE IN CANADA TREATMENTS

Made-in-Canada innovative drugs are saving the lives of patients all over the world. The following are a few recent examples of drugs discovered and developed by IMC members here in Canada:

- Lamivudine (3TC, Heptovir™) which treats HIV and Hepatitis B—Biochem Pharma (1995)
- Montelukast (Singulair™) for asthma—Merck-Frosst (1998)
- Tesamorelin (Egrifta™) which treats lipodystrophy in patients with AIDS—Theratechnologies (2010)
- Doravirine (Pifeltro™) for HIV—Merck (2018)
- BAQSIMI™ for diabetes—Eli Lilly (2019)

In addition to discovering new treatments, our member companies also continue to refine existing products to reduce side effects and shorten treatment times. In the case of Hepatitis C, the virus is now curable in 95 per cent of patients with only 8-12 weeks of treatment, compared to a 41 per cent cure rate with 48 weeks of treatment 20 years ago. New therapies help Canadians return to work sooner and avoid costly hospital stays and invasive surgical procedures. They also generate significant savings to health systems through reduced hospital stays and fewer invasive surgical procedures, and contribute to societal benefits such as improved productivity, quality of life for caregivers, and reduced economic burden, among others.¹

Today, new drugs like biologics and cell and gene therapies are transforming the treatment of many diseases in ways that weren't possible just a short time ago. A critical step in bringing these and other new medicines safely to market is through clinical trials.

There are more than 4,500 clinical trials underway in Canada, contributing to the development of the latest cutting-edge (and in some cases lifesaving) treatments. Clinical trials not only provide Canadians with access to new, potentially lifesaving medications and therapies, they also increase the speed at which Canadian healthcare professionals and hospitals are able to adopt new medicines, allowing them to provide better care to their patients.

In addition, clinical trials generate significant savings to Canada's health systems. In May 2018, the Institute for Health Economics (IHE) in Alberta completed an important report quantifying the research-based pharmaceutical industry's clinical trial contribution to Canada's health systems. Using the Aggregate Analysis of [ClinicalTrials.gov](#) (AACT) database, the study examined 394 pharmaceutical clinical trials that

were completed in 2016 in more than 2,000 facilities across the country, with more than 20,000 Canadian patients. The authors found that the industry-sponsored clinical trials offset \$2.1-billion in costs to Canadian health systems, when measured in terms of market prices in Canada.

Clinical trials are an integral part of the life sciences industry and contribute to the Canadian economy by creating high-value jobs, attracting leading scientists and medical specialists to our universities and healthcare facilities and provide healthcare professionals with cutting-edge knowledge to increase the standard of care.

However, clinical trials require significant investments on the part of the drug developer—often taking up to 12 to 15 years of effort to bring a product to market, depending on the complexity of the medicine. This investment is at risk because of the recent changes to the *Patented Medicines Regulations*. One company has made the difficult decision to suspend clinical trials in Canada because of its ethical obligations to the patients they serve. If a clinical trial drug proves successful, it will be challenging to launch the drug in Canada under the new regulatory regime ([click here](#) to learn more about the regulatory changes).

Clinical trials are not always successful. There are many setbacks in developing new treatments, but with every setback comes new insights, eventually leading to a breakthrough that will change lives for the better.

¹ Conference Board of Canada, *Reducing the Health Care and Societal Costs of Disease: The Role of Pharmaceuticals*, July 2013

INVESTING IN INNOVATION



The innovative pharmaceutical sector in Canada is one of incredible promise. It is a sector that makes invaluable contributions not only to Canada's economy, but also to the health of Canadians.

The discovery, development and delivery of new medicines is a decades-long process, involving many failures as stepping stones to breakthrough discoveries and investments in the billions. Canada's innovative pharmaceutical companies are currently the third largest R&D funder in the country and 20 of our members are among the top 100 corporate R&D spenders. With more than \$1-billion spent in R&D every year (10 per cent of revenues), our members work tirelessly toward discovering the next innovative treatment. They are also fueling Canada's knowledge-based economy by generating over \$19.2-billion in economic activity (Source: EY 2017).

Canada is home to some of the best researchers, scientists and research infrastructure in the world. With more than 500 new therapies currently in development, our member companies partner with universities and research centres across the country, including the Ontario Institute for Cancer

Research, adMare BioInnovations and Toronto Acceleration Partners, to leverage their expertise and push the boundaries of medical innovation. This growing network of partnerships and collaboration represents tens of thousands of jobs and significant investments, including \$2.5-billion in hospitals and universities, over the past two decades.

The industry also supports advances in Canadian health research through Innovative Medicines Canada's (IMC) strong relationships with life sciences stakeholders. One such relationship is with Research Canada, the national voice for Canada's health research and innovation ecosystem. Since 2009, IMC and Research Canada have led the development and support for the all-party Health Research Caucus on Parliament Hill, whose mission is to increase awareness and seek support for health research happening in our country. In addition, **IMC's Health Research Foundation and Research Canada** recognize excellence in health research with the HRF Medal of Honour and the Leadership in Advocacy Award, presented each year.

IMC also works closely with provincial life sciences organizations, including Life Sciences Ontario, Montreal InVivo, Life Sciences Alberta, BioNova, PEI Bioalliance and Life Sciences BC, which champion Canadian innovation by promoting the life sciences sector with provincial governments as driver of economic development and highly skilled jobs. By engaging with these organizations, IMC is constantly exploring new opportunities to ensure the provinces' innovators and researchers will continue to thrive, create jobs, and improve health outcomes.

In Nova Scotia, there is more momentum than ever in the life sciences sector as industry delivers clear plans and strong results to drive the innovation ecosystem and better health for its citizens.

According to Startup Genome's *2019 Global Startup Ecosystem Report*, Halifax ranked first as a global health and life sciences startup ecosystem to watch and first as a global activation stage ecosystem for early-stage funding per startup.

Halifax was also listed as the third most cost-effective location for operating a life sciences research center in Canada and the USA.

As we head into 2020, our goal is simple—to demonstrate the broader strategic value of our companies and their expertise in solving the compelling issues facing our country. We know that our industry can be a transformative partner in delivering better system innovation and in contemplating a way forward for health care systems sustainability.

While we are working hard to continue supporting medical research and development in our country, recent changes to Canada's regulatory environment will make it more difficult for global companies to choose Canada as a place to invest and conduct clinical trials.

Our country's competitiveness challenges in the life sciences sector were identified by the Government of Canada through its Health/ Biosciences Economic Strategy Table (HBEST), the goal of which is to position Canada's health and biosciences sector to become a top-three global hub by 2025. This would involve doubling health and bioscience annual exports from \$13-billion to \$26-billion, doubling the number

of health and bioscience companies from 900 to 1,800 and doubling the number of high growth firms from 40 to 80.

However, to increase investment and growth, Canada needs a regulatory environment that fosters innovation. With changes to the *Patented Medicines Regulations* expected to come into force in July 2020, innovative pharmaceutical companies are faced with difficult choices about whether they can move forward in Canada's life sciences environment or be forced to consider another jurisdiction for research and commercialization of their medicines.

Canada benefits most when Industry and governments work together to better support our young researchers, help newly emerging companies to expand, and perhaps most important of all, ensure Canadian discoveries are brought to market so patients can benefit from the research happening in our country. We look forward to engaging with governments at all levels to create an environment that values Canadian innovation.

A PARTNER FOR PATIENTS

The innovative pharmaceutical industry and patient organizations are both tremendously passionate about keeping Canadians healthy and productive. Innovative Medicines Canada (IMC) members support, and often partner with, patient organizations and health charities on initiatives that facilitate research, generate awareness, and create educational programs that help patients better understand their treatments.

Patients are at the heart of our healthcare systems and their engagement is critical across the life cycle of a medicine. Patient groups play a vital role in sharing knowledge as equal and valued partners with pharmaceutical companies. They share valuable information and experiences concerning their diseases and conditions. Our member companies use this insight to inform medical research and to develop more patient-centered treatments. The collaboration between patient groups and pharmaceutical companies is key to ensuring patients have a voice in the development of the treatments.

IMC also supports the shared objective of promoting access to innovative medicines for all Canadians. Our partners include: Best Medicines Coalition (BMC), Health Charities Coalition of Canada (HCCC), Canadian Organization for Rare Disorders (CORD), Neurological Health Charities Canada (NHCC) and Canadian Cancer Survivor Network (CCSN).

In the absence of government funding, patient groups often look to the private sector for fundraising to survive. As the makers of the medicines that patients rely on, many pharmaceutical companies make charitable donations to patient groups, whose tireless work helps to raise awareness and support for people suffering with diseases and chronic conditions.



Patient groups always speak with their own voices, and the industry does not become involved in policy and decision-making activities of the recipients of funding in accordance with our **Code of Ethical Practices**.

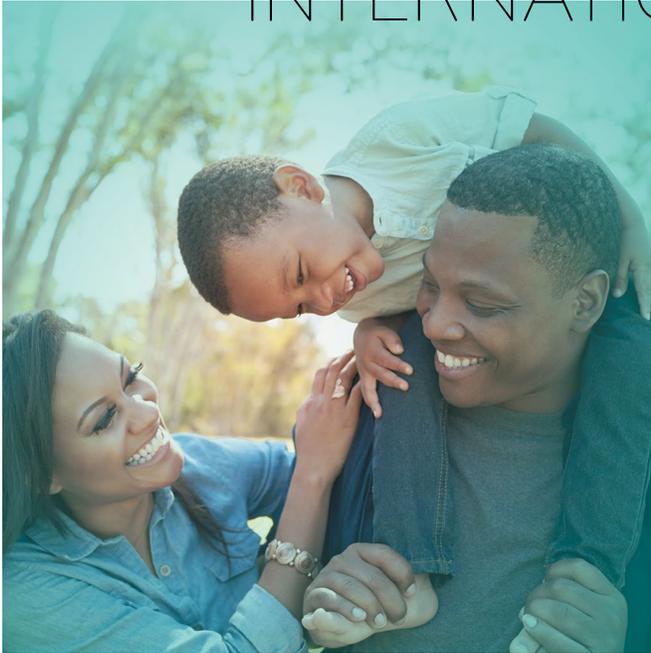
IMC and patients have a common goal: to make sure Canadians can access the medicine they need, when they need it. We will continue to work together to strengthen Canada's health systems and improve the lives of patients living with disease.

SUPPORTING ADHERENCE IN SASKATCHEWAN COMMUNITIES

Dr. David Blackburn, University of Saskatchewan College of Pharmacy, has focused much of his research career on improving patients' adherence to medication. A recent initiative in Saskatchewan, supported by IMC's Health Research Foundation, has already netted positive results, even before the final report has been written.

Based on his work improving adherence to medications for patients with high blood pressure and diabetes in the community of Sturgeon Lake under this initiative, pharmacist Alex Crawley was honoured as the 2019 Saskatchewan Pharmacist of the Year by the Pharmacy Association of Saskatchewan. Mr. Crawley has had such significant impact on improving the community's health outcomes, the Sturgeon Lake Cree Nation has hired him part-time to continue his work.

HEALTH PARTNERS INTERNATIONAL OF CANADA



Nearly a third of the world's population does not have access to basic healthcare. This problem is particularly prominent in the developing world. Founded in 1990 by several Innovative Medicines Canada (IMC) member companies, Health Partners International of Canada (HPIC) is a Canadian registered charity dedicated to increasing access to medicine and improving health for the most vulnerable people in the world. Today, Canada's pharmaceutical and healthcare industry works with HPIC to treat about 1 million people every year through HPIC's Canadian volunteer and global humanitarian network.

HPIC equips medical mission teams with medicines and stocks clinics and hospitals in impoverished communities. They also mobilize medical relief during emergencies and help to strengthen build the capacity of local health systems.

In collaborating with HPIC, IMC member companies have delivered *health and hope* by donating 11 million medicines to more than 110 countries.

On June 11, HPIC hosted a delegation of Ontario Members of Provincial Parliament to pack mobile medical kits containing medicines and supplies donated by Canada's pharmaceutical industry. MPPs Nina Tangri, Stephen Crawford, Effie Triantafilopoulos, Sheref Sabaway and Natalie Kusendova were joined by a number of IMC member company representatives.

The Humanitarian Medical Kits were delivered to healthcare facilities in Northern Iraq to provide care for Syrian refugees and internally displaced people.



A CHALLENGING REGULATORY ENVIRONMENT

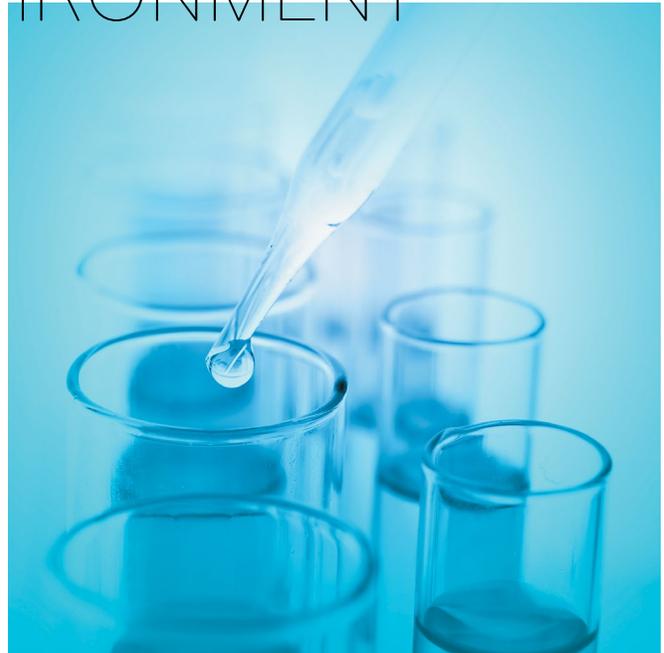
On August 21, the federal government published new regulations that will profoundly change the future of the pharmaceutical industry in Canada. Through amendments to the *Patented Medicines Regulations*, the federal government has put forward a number of changes that will limit Canadian patients' access to new innovative medicines and discourage investment in Canada's life sciences sector for years to come.

The Patented Medicines Regulations govern the activities of the Patented Medicine Prices Review Board (PMPRB), an arms' length government agency charged with setting the maximum price that can be charged for patented medicines in Canada, otherwise known as a ceiling price.

According to the PMPRB's own case studies, the amended regulations will reduce the maximum allowable price by up to 70 per cent, severely weakening the business case to launch new medicines in Canada. A recent EY study confirms that there is a correlation between market conditions and global drug launch decisions.²

The amended regulations will also have significant impacts on the future of Canada's life sciences sector, including a decline in investments and the loss of high value jobs across the country.

²EY, *An assessment of Canada's current and potential future attractiveness as a launch destination for innovative medicines*, January 2019



Since the regulations were published in August 2019, IMC's members have already reported job losses, delays in launching new drugs and Canadian investments being put on hold. A November survey of pharmaceutical and other life sciences leaders by Life Sciences Ontario have reported the following impacts:

- Virtually every executive expects PMPRB changes to result in "no launch" decisions and delayed launches in Canada.
- Oncology, followed by biologics, rare disease, rheumatology and gene therapy are expected to be most affected by the changes.
- 94 per cent of companies reported negative impacts to clinical trial research.
- 96 per cent of those surveyed expect a negative impact in employment in Canada.

For the full survey results, [click here](#).

Since the changes were first proposed nearly two years ago, IMC has been a credible voice on the impacts of these changes in its engagement with the federal government. The association and its members consistently approached Health Canada to find policy alternatives that would make medicines more affordable without jeopardizing the industry's ability to invest in Canada.

IMC's concerns about the impacts of the regulatory changes on patients' access to medicines and on the future of Canada's life sciences sector were shared by a wide cross section of stakeholder groups including provincial governments, patients, pharmacists, business groups and life sciences organizations.

The new regulations are scheduled to come into force in July 2020. IMC will continue to advocate for solutions to mitigate the impacts of these changes. For more information about IMC's activities in this space, please [click here](#).

FOCUS ON PHARMACARE



Pharmacare as a national program holds tremendous promise in helping Canadians access the medicines they need. Under the umbrella of national pharmacare, the federal government has committed to work with its partners on the creation of:

- The Canadian Drug Agency, a new national drug agency that would build on existing provincial and territorial successes, and take a coordinated approach to assessing effectiveness and negotiating prescription drug prices on behalf of Canadians.
- A national formulary—a comprehensive, evidence-based list of prescribed drugs, to be developed as part of the Canadian Drug Agency as the basis for a consistent approach to formulary listing and patient access across the country.
- A national strategy for high-cost drugs for rare diseases to help Canadians get better access to the effective treatments they need.

As the national voice of Canada's innovative pharmaceutical industry, Innovative Medicines Canada (IMC) supports comprehensive universal access to drugs for all Canadians—regardless of income, age, or postal code. We believe that the federal government can play an important role in improving universal access to medicines for Canadians by building on the strengths of our current system.

Any system of comprehensive universal access to drugs for all Canadians should leverage the strengths of our current mix of public and private coverage. The continued existence of the private market for drug coverage is critical to help to ensure that patients' standard of care is not disrupted if their medications are not listed on a future formulary.

Regardless of what model Canada ultimately adopts, any national pharmacare program must ensure that Canadians maintain access to at least the same range of cutting-edge medicines they rely on today to survive and maintain their quality of life.

DRUGS FOR RARE DISEASES

IMC is especially motivated to work with governments in the creation of a national strategy for drugs for rare diseases.

We recognize that governments and people with rare diseases are challenged by affordability. With this in mind, we created a working group of Canadian industry representatives to develop policy options for governments to consider in addressing the accessibility and affordability of drugs for rare diseases.

Partnership among all players in this space is critical to ensuring patients have access

to the drugs they need to survive. If we can work together to establish a national risk-sharing model among the pharmaceutical industry, governments and private insurers, we can help give all Canadians with a rare disease consistent and timely coverage.

This pan-Canadian approach could also represent an important starting point for a future system of national pharmacare that could be scaled over time to include a broader set of medicines.

Collaboration is essential to the success of national pharmacare in Canada. As the makers of cutting-edge innovative treatments, the innovative pharmaceutical industry is committed to working with all levels of government, as well as all stakeholders, to help create a national pharmacare program that mirrors the highest standard of coverage so that all Canadians can access the medicines they need, when they need them.

OUR COMMITMENT TO ETHICS

Trust and confidence are key to building strong, productive and mutually beneficial relationships.

Innovative Medicines Canada (IMC) and its members have set a high standard for ethical, transparent and open practices that respect the relationships among our member company employees, the life sciences sector, healthcare professionals and the Canadian public.

CODE OF ETHICAL PRACTICES

Since 1988, the Code of Ethical Practices (the "Code") has been a tangible demonstration of IMC's commitment to a relationship based on trust, openness and transparency with healthcare providers. It establishes clear guidelines to ensure the health and well-being of Canadians is always our first priority.

All members of IMC are bound by the association's Code, which maintains strict standards on what is acceptable in our work with the wider healthcare community.

AMENDMENTS TO THE CODE

Our members are committed to protecting the industry's reputation by removing potential, real or perceived conflicts of interest and/or undue influence as well as ensuring we continue to have robust ethical practices. Recent changes to the Code reflect our ongoing commitment to high ethical standards as the industry continues to evolve.

In April 2019, key amendments to the Code were approved by the Board of Directors and include the following:



1

Business meetings and events conducted by IMC members where external stakeholders are invited:

The updated Code provides members with additional clarity and guidance to assess the appropriateness of locations and venues when conducting business meetings and events. Locations should be selected to ensure they are not the main attraction of the event and cannot reasonably be perceived as such. Venues must not be lavish, extravagant or perceived as luxurious and must not be known for their entertainment, sports, leisure or vacation facilities.

2

Sponsored conferences and congresses:

The updated Code provides members with additional clarity and guidance to better assess the appropriateness of sponsorships of third-party conferences and congresses. Members should be guided by the same criteria for these events that apply when they are organizing their own business meetings. When deciding whether to sponsor a third-party conference, members should consider the proposed location and venue as well as reviewing detailed agendas to evaluate the conference's medical or scientific value.

3 Provisions of funding: The updated Code refines the various categories of funding provided by members which include grants, donations, sponsorships, collaborations and partnerships. It more clearly defines each category of funding and the standards that apply in each case. It also clarifies that, in most cases, member funding cannot be provided to individual stakeholders.

4 Patient Support Programs (PSPs) and Medical Practice Activities (MPAs): The updated Code generally prohibits members from providing direct and indirect payments or other benefits to prescribing health care professionals (HCPs) for services provided in the context of PSPs/MPAs to their own patients.

The updated IMC Code came into effect on January 1, 2020. However, and to facilitate an orderly transition from the current rules, the changes related to Patient Support Programs and Medical Practices Activities (Section 15) will come into effect on July 1, 2020, while those related to sponsoring third-party conferences and congresses (Section 10) will come into effect on January 1, 2021.

CANADIAN CONSENSUS FRAMEWORK FOR ETHICAL COLLABORATION

In January 2014, five global healthcare organizations—the International Alliance of Patients' Organizations, the International Council of Nurses, the International Federation of Pharmaceutical Manufacturers and Associations, the International Pharmaceutical Federation and the World Medical Association—established a Consensus Framework for Ethical Collaboration to support partnerships that aim to deliver greater patient benefits and support high quality patient care. Collaboration among patient organizations, healthcare professionals and the pharmaceutical industry is essential and

increasingly important to healthcare delivery and research. Canadians need to be assured that there are clear and transparent rules that strengthen collaboration and partnerships in education, clinical practice and research.

The Canadian Consensus Framework for Ethical Collaboration is endorsed by the Best Medicines Coalition, Health Charities Coalition of Canada, the Canadian Medical Association, the Canadian Nurses Association, the Canadian Pharmacists Association and IMC. The organizations are committed to ensuring that the relationships among patients, healthcare professionals and the pharmaceutical sector are based on ethical and responsible decisions.

The Framework provides guidance on activities such as clinical trials, continuing health education, conferences, accountability and funding, and sets out four overarching principles:

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

A GLOBAL COMMITMENT TO ETHICS

IMC is a member of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and adheres to the IFPMA Ethos—the foundation which shapes how the research-based biopharmaceutical industry sustains trust based on the core values of care, fairness, respect and honesty. This Ethos serves to instill the culture of ethics and integrity needed to guide our business behaviours and interactions between IFPMA members and the healthcare community.

THE HEALTH RESEARCH FOUNDATION

HEALTH RESEARCH FOUNDATION



FONDATION POUR LA RECHERCHE EN SANTÉ

The Health Research Foundation (HRF) of Innovative Medicines Canada was established in 1964 to support and increase the capacity for clinical research in Canada. During the early years of the foundation, many types of grants were given, including research grants. Through its 55 years, the HRF has remained a non-profit organization whose mission is to support health research in Canadian academic health centers and to promote the value of health research in Canada. The HRF, in collaboration with the Canadian Institutes of Health Research, has provided over \$30-million in funding to more than 1,700 researchers across Canada. An annual highlight for the HRF is the selection and presentation of the Medal of Honour. The award is presented to a truly outstanding individual whose research and contribution to public policies supportive of research and development in Canada have achieved international recognition. Throughout the years, recipients have made a notable contribution to the advancement of knowledge in the health sciences and the improvement of healthcare in Canada. Past winners have included: Sir Alexander Fleming, for the discovery of penicillin; Dr. Charles H. Best, for the co-discovery of insulin; Dr. Wilder Graves Penfield, for contributions to neurological sciences; and Dr. Julio Montaner, for life changing contributions

to the field of HIV/AIDS, including the development of Highly Active Antiretroviral and Treatment as Prevention Therapies.

In 2019, the HRF turned its focus to supporting research in the emerging field of Artificial Intelligence (AI). The Foundation believes AI will play an important role in the future of health research in Canada. Industry, government and stakeholder partnerships within this sector can make a positive impact on Canada's health systems as life sciences research becomes increasingly driven by AI platforms, tools and systems. From hospital care to clinical research, drug development and insurance, AI has the potential to revolutionize health system efficiencies and improve patient outcomes while attracting foreign investment to Canada.

With this in mind, in November, the HRF hosted a half-day conference titled, *Driving Healthcare Innovation: The Canadian Artificial Intelligence (AI) Advantage*, along with its partners, the Quebec Ministry of Economy and Innovation and Montreal International. The conference brought together more than 200 government representatives, researchers, public policy influencers and industry leaders from the pharmaceutical, AI and healthcare communities, and concluded with the presentation of two HRF Fellowship Awards focused on advancing the knowledge and understanding AI has on improving health system sustainability in provinces throughout Canada. University of Saskatchewan Resident Physician and PhD Candidate Scott Adams, and University of Ottawa Assistant Professor Steven Hawken, were each awarded HRF Fellowships in Artificial Intelligence Health Research. We look forward to their research results next year.

MAINTAINING A VIBRANT PRIVATE PAYERS MARKET

More than 24 million Canadians depend on access to medicines and vaccines through employer-sponsored private plans. Private plans provide coverage to an active working population and their dependents and ensure that their members have timely access to the medicines they need to get back to work as quickly as possible.

Innovative Medicines Canada (IMC) believes it is essential for optimal workplace health and productivity that employees and their families have access to medicines and services. That is why IMC and its member companies meet regularly with private market stakeholders to listen to their concerns, share ideas and talk about the value of access to affordable care.

ENGAGING AND EMPOWERING PLAN SPONSORS

To better inform private payers about the sustainability of their benefit plans, IMC conducts an annual cost drivers analysis. This report identifies which factors are driving costs in private drug plans. Over the years, it has become a valuable source of information for employers who want to manage drug costs within their plan.

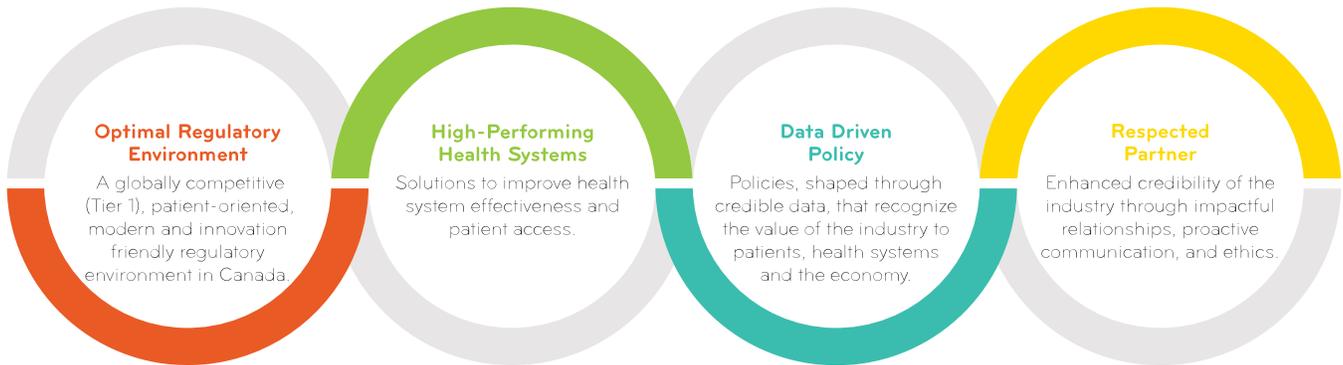
In addition, through its partnership with Benefits Canada, IMC speaks to advisors and drug plan managers about the value of innovative medicines.

New medicines can offer more effective treatment of illness, which in turn, results in improved health outcomes for plan members and their families, enabling greater workplace well-being and productivity. All workplaces have an interest in ensuring that plan members have optimal access to the best available treatments. IMC's collaboration with Canada's private payers helps contribute to making private drug plans more sustainable, to the benefit of Canadian patients.



On December 6, 2019, IMC organized the sixth annual conference for Quebec's private payers in Quebec City, with more than 200 attendees. The program celebrated the 20th anniversary of Quebec's drug plan and included discussions on national pharmacare. Guest speakers included *The Globe and Mail's* health columnist André Picard; Vice President of Product Development for Desjardins Louis Kerba; and Myeloma Canada Executive Director Martine Elias.

OUR STRATEGIC PLAN



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.

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

In 2019, Innovative Medicines Canada (IMC) launched a new strategic plan to guide the association's activities over a three-year period marked by significant challenges and change for the industry in Canada.

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

- 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:

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

- 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.
- Contributed to a pharmacare system that includes both private and public payers, focuses on filling coverage gaps and increases access for all Canadians.
- Facilitated improvements in care and delivery standards within our health systems.

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

- Facilitated the development of a “real-world evidence platform” in Canada to support access to medicines and a higher standard of care.

- Contributed to the development of a modernized and widely accepted definition of life sciences sector investment.
- 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:

- Become a lead, sought-after expert and contributor to government policy and health systems.
- Generated an increased understanding by key partners and the engaged public of the value of innovative medicines to Canadians and the economy.

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:

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

2019 marks the conclusion of year one of the strategic plan. The following sections will highlight the progress the association has made against its objectives, as well as a look ahead for 2020 and beyond.

YEAR 1 IN REVIEW

OPTIMAL REGULATORY ENVIRONMENT

The objective for the first pillar of the strategic plan is to ensure Canada has a regulatory system that is globally competitive, patient-oriented, modern, and innovation-friendly.

PMPRB

On PMPRB, the association's objective for 2019 was to ensure the best possible outcome for the industry and future sustainability of the sector. This saw the industry working in close collaboration with a wide cross-section of stakeholders from the life sciences, patient advocacy and business communities, as well as with provincial governments to raise awareness about the significant negative consequences that would result from the regulatory changes, as proposed.

With the final regulations published in *Canada Gazette Part II* in August, the association's focus is to work within the Guidelines consultations process, while continuing to raise awareness about the significant impacts the regulations are already having on drug launch and investment decisions.

In addition, two legal challenges have been filed with respect to the PMPRB. On September 6, Innovative Medicines Canada (IMC), on behalf of its members, filed a judicial review application with 16 member companies in the Federal Court of Canada on the basis that the federal government does not have the authority to fundamentally alter the role of the PMPRB through the recent changes to the *Patented Medicines Regulations*.

Six member companies have also filed a Constitutional Application in the Superior Court of Quebec. The companies are challenging



the constitutional jurisdiction of the PMPRB's legislative and regulatory framework, given that price regulation is a provincial responsibility. IMC is not party to this application and it is a separate legal proceeding to the judicial review.

IMC's legal challenge is a necessary step given the significant impact these regulations will have on patient access to medicines and the future of Canada's life sciences sector. The Federal Court will hear the application in April 2020, and the applicants are seeking a decision before the new regime is scheduled to come into effect on July 1, 2020.

For more information about the PMPRB changes, [click here](#).

R2D2

In 2019, IMC continued its engagement with Health Canada officials on a variety of regulatory affairs issues under the government's Regulatory Reform of Drugs and Devices (R2D2) process. This multi-year review by Health Canada proposes substantial 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.

Although the R2D2 process has experienced delays, IMC has had productive engagements with Health Canada officials throughout the year, sharing its internal analyses and highlighting challenges with proposed reforms. In particular, IMC's engagement has emphasized the need for Health Canada to align with the best practices of other major national and international

pharmaceutical regulators. In addition, and in light of potential threats to Canada's drug supply from U.S. importation initiatives, IMC has engaged constructively with Health Canada and Global Affairs Canada to discuss possible solutions to address this issue.

With many of the R2D2 regulatory initiatives expected to come into force in 2020, IMC will continue to advocate for the interests of the industry and help inform our members on how to prepare for changes before they take effect.

THE FACTS ON DRUG SHORTAGES

The causes of drug shortages are varied, and include:

- A problem with the maker of an active or key ingredient in a drug.
- A manufacturing issue (e.g. planned or temporary shutdown of production lines; natural disasters).
- Safety issues identified at the place of manufacture (whether in Canada or abroad).
- Regulatory delays (e.g. regulatory issues with labels, delays in inspection/site approval).
- Out-of-country factors: If a drug is in short supply in Canada, this may be due to out of country factors such as problems obtaining active product ingredients from overseas.
- Diversion of Canadian supply to foreign markets, which could occur due to recent U.S. drug importation legislation.

Approximately 80 per cent of drug shortages are related to generic drugs, according to a study published by CD Howe.³ However, because shortages of generic drugs will often cause unanticipated demand for off-patent innovative medicines, they can result in follow-on shortages of innovative medicines.

If a pharmaceutical company anticipates that it will experience delays in supplying the Canadian market with an approved medicine to meet expected patient demand (i.e. normal prescription volumes), the company will report this as a drug shortage to Health Canada and it will be posted on the Canadian Drug Shortage Database website, drugshortages.ca.

IMC members are committed to posting their shortages and discontinuances in a timely manner, and it is also a legal obligation for all drug manufacturers to report shortages to Health Canada. IMC also actively participates in Health Canada's Multi-Stakeholder Shortage Committee.

³ CD Howe, Assessing Canada's Drug Shortage Problem, June 2018.

https://www.cdhowe.org/sites/default/files/attachments/research_papers/mixed/Commentary_515.pdf

INTELLECTUAL PROPERTY AND CUSMA

On September 30, 2018, Canada, the US and Mexico announced a new trade agreement, the Canada-United States-Mexico Agreement ("CUSMA") that—if adopted by all three countries—would replace the North American Free Trade Agreement. In 2019, the ratification process began in the United States Congress, with Canada's ratification expected during the 43rd Parliament.

Additional negotiations were completed on December 10, 2019. As part of these new terms, the additional two years of data protection on new biologic drugs which appeared in the original text was removed from the final treaty text, representing a lost opportunity to improve Canada's life sciences IP regime.

This will discourage investment in Canadian health research and further erode Canada's life sciences sector, which is already facing significant challenges given the severe anticipated impact of the recent amendments to the *Patented Medicines Regulations*.

Despite this disappointing outcome, IMC remains committed to working together with government stakeholders to ensure that our public policy and regulatory frameworks keep pace with advances in medical research to help Canadians access the innovative medicines they need.

HIGH PERFORMING HEALTH SYSTEMS

The objective for the second pillar of the strategic plan is to develop solutions to improve health systems effectiveness and increase patients' access to medicines. In year one, IMC's focus under this pillar was on the industry's work with the pan-Canadian Pharmaceutical Alliance (pCPA) and on the topic of pharmacare.

pCPA

Since 2010, IMC and its membership have been working with the pCPA to ensure that Canadians get access to the medicines they need in a timely manner.

In an effort to improve the process, in 2019, IMC's pCPA Operational Team put forward policy proposals to the pCPA which would address some of the obstacles and accelerate access for patients covered by a public drug plan.

PHARMACARE

IMC has closely followed the pharmacare debate in 2019, from the initial commitments made by the federal government in Budget 2019 to the release of the Advisory Council on the Implementation of National Pharmacare's report in June, through the federal election campaign and the Speech from the Throne at the commencement of the 43rd Parliament.

Throughout the year, IMC's position on pharmacare has been consistent: the association supports universal access to medicines. However, no model of pharmacare should result in a lower level of coverage for Canadians than exists today. The role of the private market is instrumental to ensuring that patients' standard of care is not disrupted if their medications are not listed on a future public formulary.

Policy work is underway to estimate the costs to Canada's health systems of the various models of pharmacare that have been proposed. The association is also examining the opportunities and risks associated with the creation of a Canadian Drug Agency.

A third area of focus with respect to national pharmacare relates to the issue of drugs for rare diseases. In 2019, a working group of companies that manufacture rare disease

drugs was formed to develop policy options to address the affordability and accessibility challenges that often arise for governments and patients who suffer from a rare disease. IMC is engaging with provincial governments to begin a discussion on how industry and governments can work together to increase access for patients in a sustainable way.

IMC will continue to share this important work with stakeholders and governments at the provincial and federal levels, as the national conversation on pharmacare continues into 2020. For more information, [click here](#).

DATA DRIVEN POLICY

A new strategic area for IMC, the objective of this third pillar is to have policies shaped through credible data that recognize the value of the industry and its medicines to patients, health systems and the economy. This includes working with the federal government to create an updated definition that measures how R&D investment is made in today's business environment, as well as to position the association as a centre of credible expertise for industry-related data and research.

UPDATING HOW INVESTMENT IS MEASURED

The innovative pharmaceutical industry is an important contributor to Canada's innovation economy. A 2017 EY Report ranked the industry as the third largest R&D funder in Canada, investing \$1.2-billion in R&D every year. Over the years, our investment model has changed, moving from "in-house" R&D infrastructure to external financing and partnerships with academic facilities and research centres.

The method by which PMPRB calculates R&D in Canada has not evolved since it first began tracking this information over 30 years ago. The Government of Canada acknowledges the need to modernize how it measures our

industry's investment footprint, and in 2018 initiated a project to develop a new definition that reflects how R&D is conducted in today's business environment.

The industry has collaborated with Industry, Science and Innovation Canada (formerly Innovation, Science and Economic Development Canada) to develop a new R&D definition for the pharmaceutical sector which better captures R&D investments that fall outside the traditional government definition. Given the significant changes to how companies invest today, the association is pleased Statistics Canada will be including an updated guidance document which reflects these important changes as part of their 2018 Research and Development in Canadian Industry (RDCI) Survey. The survey was sent out to IMC's membership in the fall of 2019 with results expected in 2020.

DATA AND RESEARCH

As a new area of activity for the association, 2019 was a foundational year for creating the necessary infrastructure for research and data collection. A new policy and research team was created to begin the work of gathering data to establish a common factual understanding of key issues and help IMC become a trusted source of objective information on the industry.

To date, this data collection has focused on measuring the time it takes from a drug's approval in Canada to the time it is covered under a public drug plan (time to list), a database of public drug plans in Canada, as well as tracking the impacts of the PMPRB regulatory changes on company investment and product launch decisions. Work is also underway to support IMC policies on pharmacare and drugs for rare diseases, among others.

Another area of focus in 2019 has been on developing a platform to facilitate greater use of real world evidence (RWE) which is helping in assessing a medicine's value in cases where the availability of clinical evidence is limited. IMC is synthesizing information on what is currently being done on RWE in Canada with a view to creating an RWE policy statement in 2020.

RESPECTED PARTNER

The objective of the fourth pillar of the strategic plan is to increase the credibility of the industry through impactful relationships, proactive communications, and to demonstrate the association's ongoing commitment to ethical practices.

Throughout 2019, IMC worked with key partners to generate an increased awareness and understanding of the value innovative medicines and vaccines bring to patients, the Canadian health systems and the economy.

IMPACTFUL RELATIONSHIPS

With the release of PMPRB regulatory changes in *Canada Gazette Part II*, advocacy and outreach measures were amplified with federal, provincial and health systems stakeholders in 2019. IMC participated in and attended key meetings and events, elevating awareness of how the proposed amendments will negatively impact patients, investments and other business decisions.

An outreach and engagement strategy was developed during the post federal election period with the goal of strengthening existing relationships and to secure meetings with new key political staff unfamiliar with our sector, providing the opportunity to introduce them to our industry and to communicate matters of interest.

The association continues to reiterate the importance of working collaboratively with

governments and stakeholders on solutions for long-term health systems and industry sustainability.

PROACTIVE COMMUNICATIONS

Proactive media engagement in 2019 helped to build relationships with major Canadian news outlets and included the facilitation of background and technical briefings about relevant studies on pharmacare and the impacts of PMPRB regulatory changes, as well as to share knowledge about how the industry operates in Canada. The association also shared its views on issues such as national pharmacare and its work on drugs for rare diseases through speaking engagements and opinion editorials in national publications.

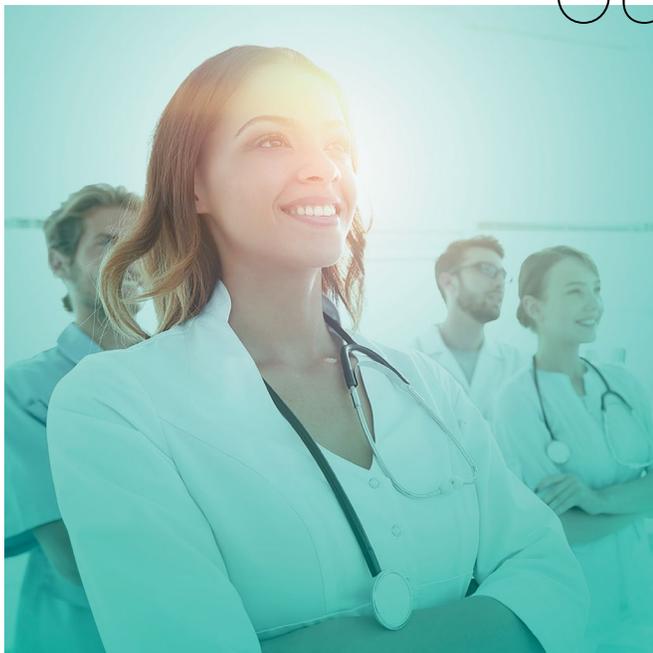
The value of Canada's pharmaceutical industry was promoted through the *Innovate for Life* national digital campaign. The campaign played an important role in communicating industry concerns about the negative impacts of the amendments. In the latter half of the year, a separate digital campaign elevated positive awareness of the role that the Canadian innovative pharmaceutical industry plays as drivers of innovation and hope.

ETHICS

IMC and its members continue to set a high standard for ethical, transparent and open practices that respect the relationships among our member company employees, the life sciences sector, healthcare professionals and the Canadian public.

Amendments to the Code of Ethical Practices were approved by IMC's Board of Directors and announced to the membership and external healthcare stakeholders in 2019. For more information about the changes to our Code, [click here](#).

OUTLOOK FOR 2020



As the association enters the second year of its strategic plan, it will continue to drive towards its objectives. IMC will advocate for patient centric solutions that promote access to medicines, and a regulatory environment that fosters innovation in Canada's life sciences sector.

In advance of IMC's Annual General Meeting in late 2019, the Board of Directors approved modifications to IMC's strategic objectives to reflect the emerging issue of U.S. importation of drugs from Canada and the important policy work underway in the rare diseases space.

With this in mind, an additional objective was added to the Optimal Regulatory Environment Pillar. By 2021, IMC will have:

- Worked in partnership with the federal government to ensure that U.S. drug importation and other U.S. policy initiatives do not adversely impact Canada's medicine supply or its regulatory/access environment.

To support this objective, an IMC project team was established in 2019 to monitor the issue and put forward recommendations to support the association's advocacy efforts.

Secondly, to reflect the Government of Canada's commitments in relation to national pharmacare, under the High Performing Health Systems pillar the following changes were made.

The addition of "or other emerging bodies" was added to the objective regarding pCPA reimbursement arrangements, to reflect the future creation of a Canadian Drug Agency which may combine the functions of the pCPA and CADTH into a single government entity.

To reflect IMC's commitment to collaborating with governments and stakeholders to make rare disease medicines more accessible and affordable, a third objective was added.

By 2021, IMC will have:

- Facilitated the launch of a national rare disease initiative that provides a pathway for timely access to treatment for patients and addresses payers' concerns about the cost of rare disease medicines.

Finally, under the Data Driven Policy Pillar, the objective regarding real world evidence was modified to reflect the role it will have in transforming future health systems.

The coming year will continue to be one of change, as the industry adjusts to a shifting regulatory environment and policies related to national pharmacare evolve. Throughout this period, IMC remains committed to working collaboratively with governments and stakeholders as a respected partner, and to promote the value of the industry as a driver of innovation, delivering better health outcomes for Canadians.

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