Canada's Research-Based Pharmaceutical Companies

Making Canada Better

2015 Annual Report

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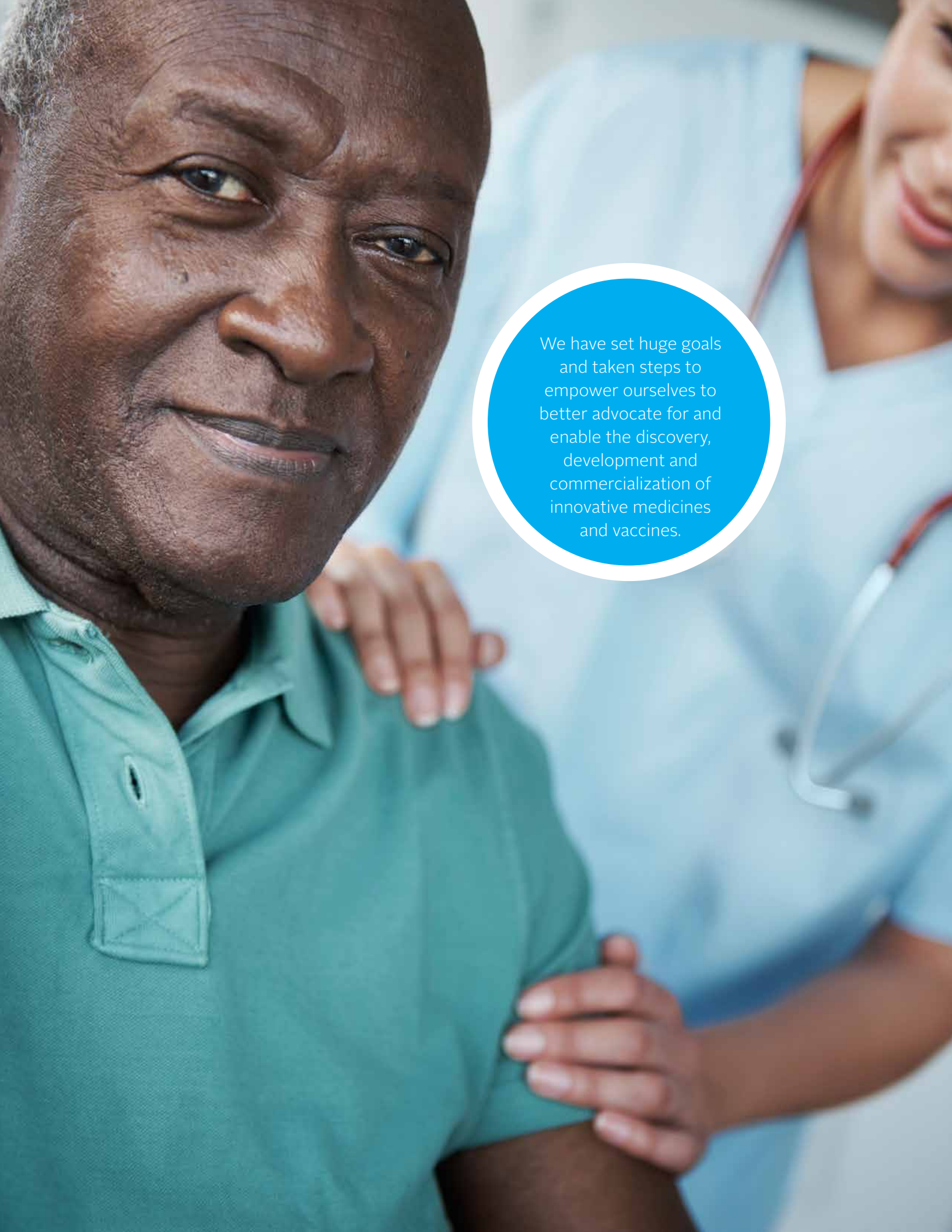

We have set huge goals and taken steps to empower ourselves to better advocate for and enable the discovery, development and commercialization of innovative medicines and vaccines.

Message from the President

Canada's Research-Based Pharmaceutical Companies (Rx&D) is the national association representing Canada's innovative pharmaceutical industry. We have more than 50 members ranging from established companies to fledgling start-ups, all of which are innovating and revolutionizing healthcare in Canada, and contributing to the sustainability of our healthcare system.

Over the past year, our association has undergone significant change, on behalf of the industry. We have set huge goals and taken steps to empower ourselves to better advocate for and enable the discovery, development and commercialization of innovative medicines and vaccines.

The year 2015 was the first in a three-year strategic plan. Our Board of Directors identified the three following strategic priorities that guide our work, providing a clear path forward for our industry:

1. Become an authentic, solution-driven partner through effective alliances, policy and leadership;
2. Improve access and the regulatory environment in Canada; and
3. Advocate for a globally competitive intellectual property regime.

Improving access and the regulatory environment in Canada means working for greater and timelier access to innovative medicines and vaccines in both the public and private markets. It means streamlined, predictable and evidence-based health technology assessment processes. It calls for an efficient regulatory pathway and a competitive national environment to attract clinical trials. Ultimately, it means Canadians shouldn't have to wait for life-changing—and often life-saving—innovative medicines.

Advocating for a globally competitive intellectual property (IP) regime is about making sure Canada can compete for a larger share of the international investment in the discovery and development of new medicines. That can happen if we ensure our laws are consistent with those of other developed nations, and if innovators can be assured their investments are protected in Canada.

Becoming an authentic, solution-driven partner is really about *how* we can achieve better access and competitive IP. It's about building a network of collaborative alliances focused on finding and implementing solutions for a sustainable healthcare system, to promote economic development in a transparent, mutually beneficial way, where all partners are valued and well represented. It's about making sure these partnerships—on work that touches everything from policy to research, and from stakeholder outreach to communications—are strengthened to help us all achieve our common goals.

We know we face many challenges as we endeavour to deliver on our objectives. We are ready to work together with all partners—policy makers, governments, patients, healthcare professionals, payers and others—to ensure Canadians have the best access to the life-saving medicines and vaccines they need, when they need them.

Supported by a dedicated and multidisciplinary team at Rx&D and across the industry, composed both of staff and of member company employees, we are working to advance these strategic objectives and we are well on track. I am confident that over the next two years, we will continue to rise to the occasion to create the best life-sciences environment for Canada.

The 2015 Annual Report provides an overview of what we have delivered in the first of three years in our plan.

In health,

Russell Williams
President
Canada's Research-Based Pharmaceutical Companies (Rx&D)

Message from the Chair

It has been a great pleasure for me to Chair the Board of Director of Canada's Research-Based Pharmaceutical Companies. This past year has been one of significant change for our Association.

Our roadmap for the year: 3 Work Streams and 3 Strategic Pillars

Our efforts this year were guided by our three 2015–2018 strategic pillars and managed by three work streams:

1. **At the Board level**, we set out to improve the Association's governance model in order to facilitate quick decision-making and ensure diversity of competencies, while also allowing for the identification of trends and emerging environmental issues. As a result, we reduced our Board size to 12 members, using a comprehensive set of guidelines for the new Board composition in a clear and transparent fashion. We also extended the mandate of the Board Chair from a term of one year to two years in order to ensure consistent leadership to the Association over a longer planning horizon.
2. **At the membership level**, we set out to establish new and more effective ways to communicate with member companies and to engage them to ensure that all—not just Board members—could provide input into the strategic planning process and received all the information they needed to do so effectively. We created a CEO Steering Council, which is open to all member company CEOs and which meets on a quarterly basis to inform on Board strategy and key issues. We've also opened up our annual strategic planning session to all member companies, and have developed and implemented a comprehensive internal communications strategy.
3. **At the organization level**, we endeavoured to build a new, nimble and competency-based Association and Committee structure aligned with the strategic priorities. To this end, we adopted a new organizational model which puts alignment and teamwork at the forefront. These were major internal changes to the Association which we believe will allow members to see increased value while being strategically focused on key areas.

To address our **Access and Regulatory** strategic objective, we tackled and mitigated various Health Canada initiatives around transparency arising from Bill C-17 and continue to make progress with CADTH on backlog and accountability issues. We have also been successful in repositioning our industry pro-actively with Health Canada relating to drug

shortages and abuse deterrence files. We actively participated in pCPA consultations and have seen progress on pricing framework discussions with Alberta and Saskatchewan. We set up a rapid response team in British Columbia to address the threat of reference-based pricing and therapeutic substitution, and also participated in constructive dialogue with Ontario on issues of transparency of relationships with healthcare professionals.

We have made steady progress on the **Intellectual Property** objective. Together with the government, we were able to successfully amend the Patented Medicines (NOC) Regulations to address fixed-dose combination issues, as well as maintain our constructive dialogue with Industry Canada on intellectual property enhancements related to CETA implementation and the TPP opportunity.

On the **Authentic Alliances** strategic objective, we worked to ensure all Association interactions were conducted with respect and integrity, adhering to the principles and letter of our Code of Ethical Practices; and conducted ourselves with stakeholders in a manner that offers proactive solutions to address Canadian healthcare challenges. We also initiated a review and renewal of the Association's name, branding and narrative which will be launched imminently.

While we have seen progress on many fronts this year, the external environment and cost-containment measures being seen across the country continue to pose challenges for our industry. Deliberate and continued focus by the Board and our members on advancing our strategic pillars is still required.

I am honoured to have had the opportunity to steer the Association during this year of change, and would be remiss if I did not recognize and sincerely thank all Board colleagues. Given the magnitude of the changes made this year, none of it would have been possible without their support and leadership of various initiatives. Russell Williams and all Association staff should also be commended for their numerous contributions to our collective achievements.

I would also like to wish much success to the new Board Chair, Michael Tremblay, President of Astellas Pharma Canada, who will be our first Chair to serve a two-year mandate. I have full confidence that he will continue the excellent work that we have started together.

John Helou
Chair of the Board of Directors

The Association's New Structure

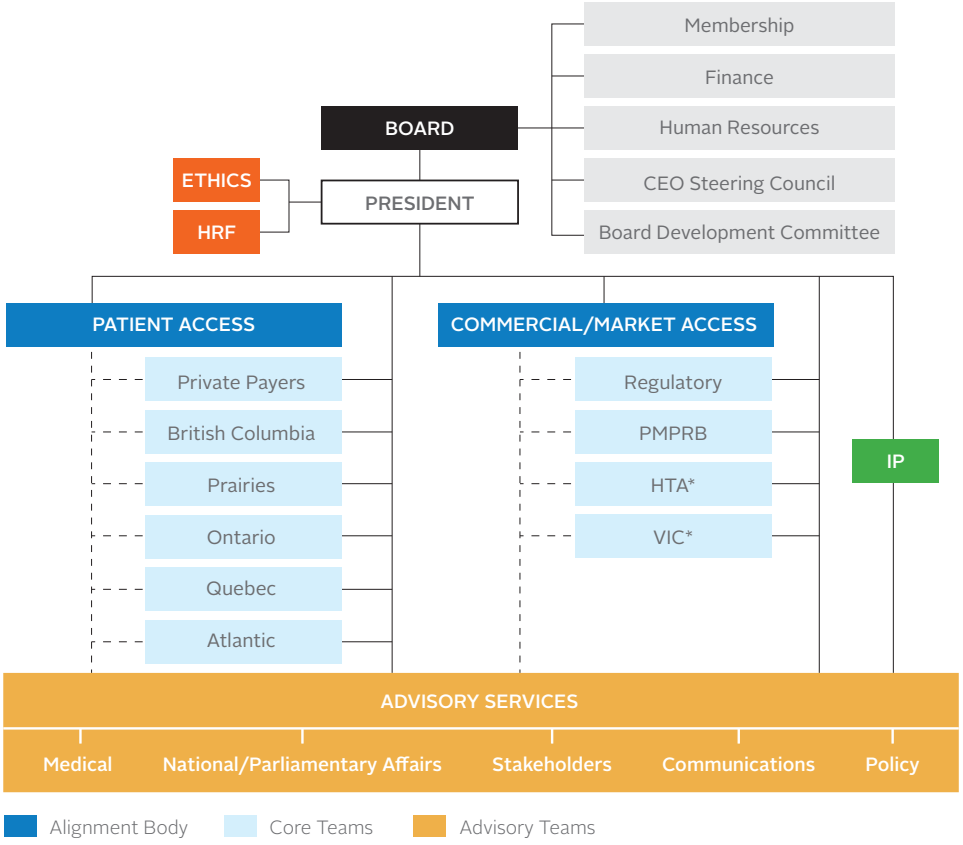
We have designed a new team structure to be better positioned to meet the objectives set out in our strategic plan.

Alignment Bodies: Ensure alignment within their respective priority areas and ensure we connect the dots between our strategies for patient access, commercial access and intellectual property.

Core Teams: Mandated to strategically advance and achieve our objectives by creating project teams, in consultation with our pool of expert advisory services.

Advisory Teams: Consist of key subject-matter experts who can provide thought leadership, insight and advice to Core Teams.

Figure 1: Our New Organizational Structure




Ensuring Canadians have access to the innovative treatments they need, when they need them, is a fundamental part of ensuring healthcare system sustainability for generations to come.

Can Canadians have world-class access to innovative medicines and vaccines as part of a sustainable healthcare system?

Yes, we can.

Canadians should benefit from world-class healthcare in an ethical, efficient and sustainable way, and have the best access to innovative medicines.

Ensuring Canadians have access to the innovative treatments they need, when they need them, is a fundamental part of ensuring healthcare system sustainability for generations to come.

The value of innovative medicines to the healthcare system is substantial. A ground-breaking 2012 study by Dr. Frank Lichtenberg from Columbia University found that life expectancy was significantly higher in countries that had access to, and used, newer medications. An earlier study by Dr. Lichtenberg concluded that investing in innovative medications saves money elsewhere in the healthcare system by a significant margin. For every dollar spent on new medications, non-medication healthcare expenses dropped by more than seven dollars.

A 2013 study published by the Conference Board of Canada examined the health and economic benefits associated with pharmaceutical spending in Ontario from 2007 to 2012. The research concluded that spending $1.22 billion generated offsetting health and societal benefits of nearly $2.44 billion—a 2:1 benefit-to-cost ratio that increases over time. Some of the benefits included reduced demand for hospital services and increased productivity in the workplace. And that's not to mention the fact that innovative treatments have also helped us manage—and often eradicate—diseases that were once devastating and very costly to our healthcare system.

Plainly put, innovative medicines provide major health and economic benefits. Preventing or curing diseases not only helps Canadians' health, it also benefits our healthcare system and our economy, as we spend more time enjoying life and being productive members of our communities.

But the fact is Canadians don't have timely access to innovative medicines.

In fact, Canadians face wait times of over 460 days to get access to new, potentially life-saving medicines in public drug plans. And many new approved medicines aren't reimbursed at all.

On the one hand, Canada's regulatory system is complex and slow. The systems regulating, assessing value and reimbursing medicines and vaccines in Canada are, sometimes by design, hindered by duplication issues, inefficiencies, delays and a lack of predictability. This environment can lead to delays in bringing innovative medicines and vaccines to Canadian patients, who may be counting on these medicines to improve their quality of life.

On the other hand, Canada continues to face significant challenges in its ability to compete with other developed countries for investments into the research and development of medicines and vaccines. But we know that health research is fundamental to ensuring we all lead better, healthier lives. Bringing research investments to Canada is important for Canadians, as it can directly translate to clinical trials that offer innovative treatments here at home sooner rather than later.

Canada's innovative pharmaceutical sector knows our country can reach its full potential.

Canada has world-class research facilities, and scientists and researchers who have contributed to the numerous groundbreaking discoveries influencing global health. Canada is also one of the most cost-competitive developed countries in which to conduct research.

We have one of the largest clusters of life-sciences companies and investment capital in the world. Our business environment is attractive, with progressive policies, processes and financial benefits for life-sciences organizations.

Over the last decade, there have also been some improvements in the global regulatory review process, leading to shorter approval times for new medicines and vaccines, while maintaining a high standard of scrutiny on the safety and efficacy of medicines.

Our industry is moving toward newer types of investment models that promote innovation. By partnering with academic/clinical research institutes, commercialization centres and virtual research centres, our industry is expanding its capacity to conduct research and development work in Canada.

We are capable of so much more. All it takes is for the partners in Canada's healthcare system to agree on and work toward a common national vision. Canada's innovative

pharmaceutical industry is committed to helping our country reach its full potential in providing quality healthcare to Canadians and to growing the economy.

Making our country globally competitive and ensuring Canadians have timely access to innovative medicines and vaccines are essential.

A competitive intellectual property (IP) regime can help grow wealth in Canada, advance our knowledge-based life-sciences economy, generate new effective therapies and ensure that companies are provided with the incentive to conduct research right here at home. Competitive IP protections encourage innovative companies to introduce new medicines and vaccines to the Canadian market, because they have a reasonable assurance of getting a return on investment, which can then be reinvested into further research. This not only benefits our healthcare system, it helps patients and healthcare systems worldwide.

It's also part of our global responsibility. Canada is a prosperous nation with a role to play in protecting and promoting competitive IP in order to foster innovation around the globe. That's why we continue to work diligently on encouraging the Government of Canada to move quickly on approving and implementing the Comprehensive Economic and Trade Agreement (CETA), to rectify issues with patent utility and to promote the implementation of the national orphan drug strategy.

We can work together to reduce duplication, and identify and fix inefficiencies in our regulatory system, thereby reducing delays for Canadians' access to innovative medicines and creating a predictable environment.

We have ideas and have rolled up our sleeves.

In addition to researching, developing and distributing life-saving innovative medicines and vaccines to all Canadians, our industry's responsibility extends to providing leadership in ideas and solutions that will both create a better healthcare system model and grow a prosperous knowledge-based life-sciences economy for generations to come.

We have set high ethical standards to guide how we work with our partners. Guided by the Rx&D Code of Ethical Practices—a Code that evolves with practices and sees regular reform—we and our members are grateful for the opportunity to work with our country's best academic institutions, patient advocates, researchers, healthcare practitioners and policy makers. This work is founded on our commitment to shared principles of ethical collaboration, and on a joint consensus framework for ethical collaboration between these partners, in support of high quality patient care.


We were only able
to make such great strides
because of the authentic
relationships we are
committed to building
and maintaining.

Report on Priority 1

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

Over the past two years, we have embarked on an adventure of self-discovery. We started by engaging our stakeholders from across the country and listening to what they had to tell us. Nothing was off the table. We quickly learned that, while our industry's contributions were well respected and regarded, and while we often had objectives in common with our partners, we needed to take a hard look at ourselves and our relationships, to really ensure they were mutually beneficial.

The last decade of pharmaceutical innovation in Canada and around the world has also shown us just how indispensable partnerships are in fostering innovation. As such, we have set out to build a network of collaborative alliances focused on implementing solutions for a sustainable healthcare system, and to promote economic development.

We accomplished a lot in this first year of our three-year strategic plan. We were only able to make such great strides because of the authentic relationships we are committed to building and maintaining.

We have heard from our partners that one of the ways we can contribute is to bring people together. Convening stakeholders to facilitate dialogue and solutions to healthcare sustainability can take us a long way toward achieving shared goals and objectives.

We have helped create a series of working groups, discussions and events, be it to promote Canada's life-sciences ecosystem abroad or to continue building awareness of our sector here at home. From coast to coast, we have brought together our partners to help show policy leaders and decision makers the value of our industry and of the life-sciences sector.

In British Columbia, we created and sustained relationships with political caucuses to build awareness of our role and value, and to illustrate how we can be partners for sustainability through value-demonstrating initiatives and a holistic view of investments in our sector. We strengthened our partnership with the province's health- and life-sciences community, and were featured prominently at four LifeSciences BC events. This culminated in efforts to provide leadership to key groups and organizations, as we worked together to help the provincial government see the value in proper consultation processes when making major regulatory changes.

We have partnered with BIOAlberta and the Life Sciences Association of Manitoba on access issues and in promoting the life-sciences environment, and with Alberta Innovates Health Solutions for a one day seminar on collaborative solution-building with key Alberta Strategic Clinical Networks.

In the Atlantic Provinces, we hosted a strategic meeting which provided an opportunity for the innovative pharmaceutical industry to set the stage for our involvement in shaping increased collaboration for Atlantic Canada, while sharing our positions on health policy issues and on the need for a predictable access environment for both government and industry.

Our sector coming together also meant that Canada was well represented at the BIO 2015 conference. In Quebec, we partnered with other stakeholders to present a rich program for delegates, including a session on public/private research, where we welcomed the province's Minister of Health. In Ontario, we worked with Life Sciences Ontario to create as vibrant a presence at the conference as our sector is in the province. We have built on this momentum and continue to work together, along with the Ontario Ministry of Research and Innovation, in the hopes of bringing the BIO conference to Toronto in 2019.

Building meaningful relationships can lead to great success. This year, Rx&D received an order in council from the Government of New Brunswick, appointing the Rx&D Regional Director for the Atlantic Provinces to the New Brunswick Health Research Foundation Board of Directors for a three-year term. This appointment allows Rx&D to be part of the Foundation's discussions on the value of medicines, cost containment and investments in life-sciences in the province.

Our work also extended to the private payer market, where we continued the Meet the Payer Program and hosted presentations by several insurance companies. We partnered with Rogers and with Benefits Canada to deliver key modules of our Pharma 101 educational program to advisors and brokers, and we held discussions with insurers regarding potential value-demonstrating initiatives in the private market.

As the industry association, we have a key role to play in promoting the value of research.

As our members demonstrate through their contributions to healthcare, innovation is what helps us improve the lives of Canadians every single day. But innovation can happen outside medical facilities. The Rx&D Health Research Foundation (HRF) has focused its

support on applied research projects that build efficiencies in the healthcare system. It is committed to working with the provinces and provincial health research foundations to fill a gap in the funding for health-system-improvement research. This year, nine different Canadian universities received one million dollars through the new Academic Interdisciplinary Health Research Grant program, aimed at encouraging universities and researchers to look at healthcare more holistically.

The HRF also strives to promote the value of health research in Canada. It held a Life Sciences Research Awards Gala, in partnership with Research Canada and Prix Galien Canada, where it awarded its Medal of Honour to Dr. Robert Young and Dr. Charles Tator for their incredible achievements in the Canadian health sciences and in clinical and research work. Dr. Young is credited with the discovery and development of Singulair, which changed the way asthma is treated. Dr. Tator is responsible for cutting-edge work in the field of brain and spinal cord injuries.

We learned that we have to continue to listen, and that meaningful consultation must be ongoing.

In the spring of 2015, we worked with an independent research firm to build the Rx&D Advisory Panel of Healthcare Leaders, which provides participants with the opportunity to share and exchange ideas on the future of healthcare and issues related to innovative medicines.

We have worked to fully map our stakeholder environment, an exercise that will continue to inform the association's engagement strategies. Additionally, we are currently working with a group of health charities and patient groups from across the country as they advise us on some of their key issues. We also heard from government leaders and private market representatives during our committee and Board meetings.

In an effort to be more approachable and more forthcoming about who we are and what we stand for, we have created a new web presence and have joined the blogosphere. We have also taken stock of the invaluable data and research projects we support, and are working to make it easier for our partners to use these tools. In 2015, the research projects published or sponsored by Rx&D included reporting on how Canada compares to other countries in providing access to new medicines in public drug plans, and examining the impact of pharmaceutical innovation on premature cancer mortality in Canada.

Governments and patient groups are increasingly focused on openness and transparency. So are we.

The pharmaceutical industry collaborates with its partners in the healthcare system in many critical ways to support scientific advancement, in the best interest of patients. These relationships have a profound positive influence on quality of care and on future research. The relationships that exist between healthcare professionals and Canada's innovative pharmaceutical companies are already based on strong ethical principles and are already transparent. For member companies moving forward with payment disclosure (proactively and voluntarily disclosing the payments they make to partners in exchange for services and to fund charitable, educational and scientific activities), the association has developed a voluntary framework to help guide them through the process.

Transparency and openness are also integral to how we collaborate with our partners. Supported by Rx&D, the International Federation of Pharmaceutical Manufacturers & Associations established a Stakeholders' Roundtable on Ethical Promotion, bringing together key stakeholders, such as the World Medical Association, International Council of Nurses (ICN), International Pharmaceutical Federation, International Alliance of Patients' Organizations, World Health Organization and Health Action International, to have an open exchange about the role each organization plays in ensuring medicines are promoted ethically, and to discuss progress and challenges in this area.

Rx&D has also led a similar effort to develop the Canadian Consensus Framework for Ethical Collaboration. Leading Canadian health organizations have joined together to create a set of ethical standards to help guide collaboration between healthcare professionals, patient organizations and the pharmaceutical industry.

The Framework aims to enhance credibility, dialogue, trust and respect between organizations; increase public confidence in professionals, institutions and the healthcare system; and ultimately, improve health outcomes. It puts patients at the core of our activities, and promotes transparency and accountability.

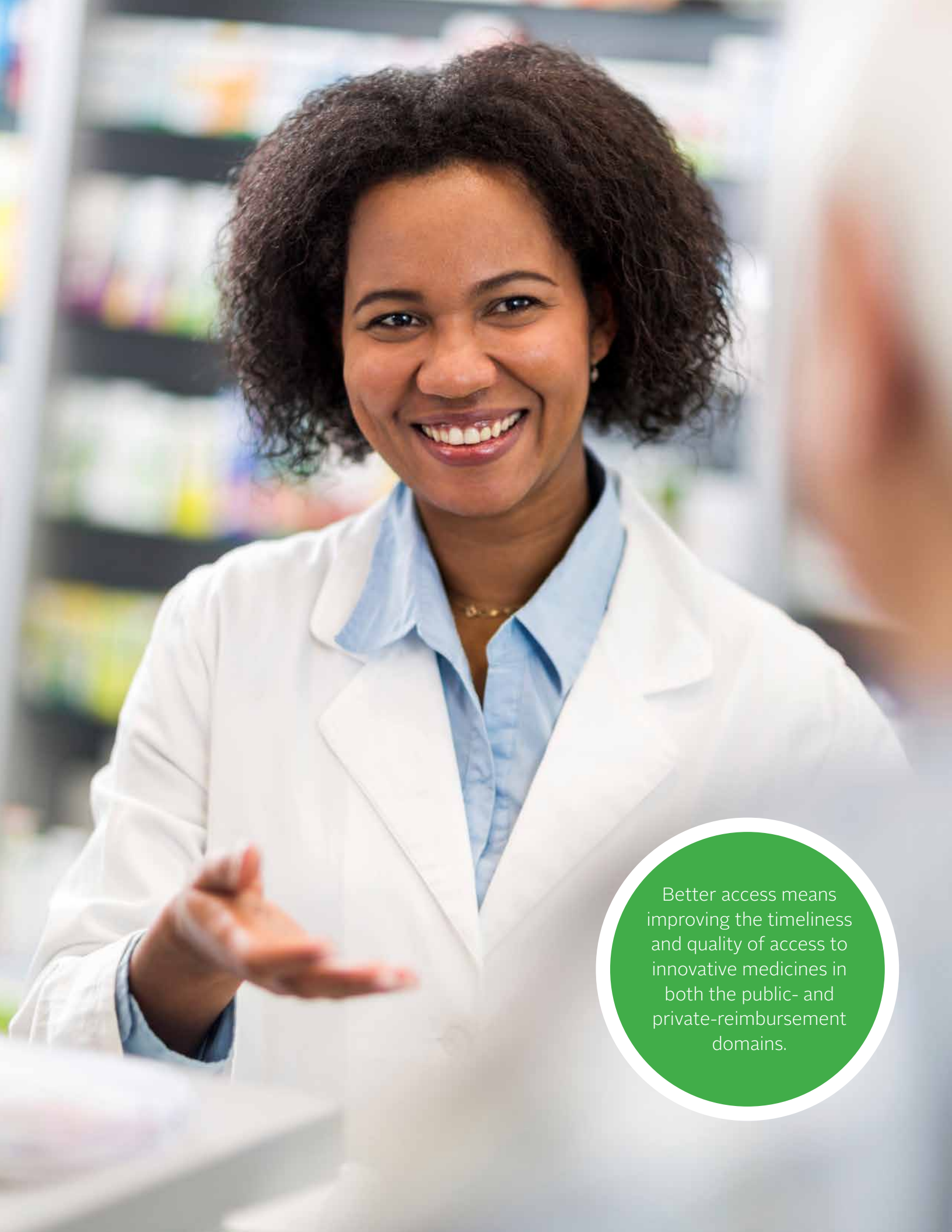
Trust and confidence are key to building strong, productive and mutually beneficial relationships.

All of our members are bound by the Code of Ethical Practices, which maintains strict standards on what is acceptable in our work with healthcare practitioners, and we publicly report any violations of the Code. And, as the environment evolves, so do our standards. In 2015, section 14 of the Code of Ethical Practices was updated to include patient support programs and medical practice activities, to better reflect current practices and capture trends as these programs evolve. Our online training modules are being updated to offer member company employees the opportunity to learn about the changes and fully embody all Code principles.

We have also been working to develop an enhanced training experience for our members. In addition to continually updating training on the Code in both official languages, we have produced new tools and learning opportunities. These include a mobile-friendly Rx&D Code of Ethical Practices e-training site and a new Vendor Credentialing e-training course (in partnership with the Healthcare Supply Chain Network) to assist our members and guide them through the accreditation process.

We are highly engaged with the Canadian government in paving the way for authentic, mutually beneficial relationships internationally.

In 2012, the Asia-Pacific Economic Cooperation (APEC) forum launched a comprehensive initiative to strengthen ethical standards in the biopharmaceutical sector across 21 Asia-Pacific member economies. The Business Ethics for APEC SMEs initiative has supported the adoption of or is achieving formal progress toward 22 new biopharmaceutical sector codes in six economies where they previously did not exist, thereby expanding the high-standard APEC principles to nearly 8,000 biopharmaceutical enterprises across the region. With goals that include universal code adoption by all industry associations in the region by 2020 and supporting the development of ethics codes, Rx&D has played and continues to play a leadership role in the initiative. Rx&D President Russell Williams was invited by the U.S. Department of Commerce this year to serve as an Industry Co-Chair for the newly formed APEC Biopharmaceutical Working Group on Ethics.


Better access means improving the timeliness and quality of access to innovative medicines in both the public- and private-reimbursement domains.

Report on Priority 2
Improve access and the regulatory environment in Canada.

Ensuring Canadians have the best access to innovative medicines and vaccines is our core business.

For us, that means improving the timeliness and quality of access to innovative medicines in both the public- and private-reimbursement domains. It means ensuring our regulatory system is world-class, and its processes are based on evidence, best practices, clinician collaboration and patient involvement, and includes industry consultation. It also means showcasing Canada as a receptive, attractive and globally competitive environment where clinical trials should take place in greater numbers.

It also means staying closely involved in discussions and decisions that could impact our industry, and working to help decision makers see innovative medicines as part of the way forward in managing costs and health outcomes in Canada's national healthcare system. We have established working groups with our partners on topics ranging from pharmacoeconomics to therapeutic reviews, to advocate for our industry and for the best possible health outcomes for Canadians.

These efforts have led to great steps forward in certain parts of the country. For example, Prince Edward Island's Minister of Health and Wellness recently made a commitment that the province will continue to reinvest savings from its drug plan back into the plan, noting that "better access to required medications will also improve the overall health of Islanders, leading to reduced pressure on our healthcare system." In the same province, we were able to successfully advocate for the prescriber's ability to choose the best treatment for patients, which means that the province's new Generic Drug Plan does not limit the uninsured patient exclusively to generic drugs.

Building on the pro-science movement's momentum as a means to combat the falsehoods of the anti-vaccine movement, our member companies held their first vaccine advocacy day at the Ontario Legislative Assembly. The day culminated in the Ontario Minister of Health making a statement promoting the value of vaccines and acknowledging the significant role they can play in public health and wellness.

In Quebec, we worked to ensure the province's policy on listing agreements enabled negotiations that provided access to innovative medicines for patients, while safeguarding the public drug plan's long-term sustainability.

Approximately twenty million Canadians rely on private plans for coverage. Benefit plans that cover innovative medicines and vaccines help employers support the health and wellness of employees and their families. Benefit plans allow employers to sustain a healthy and productive workplace and help them retain quality employees, improve morale and demonstrate social responsibility.

With that in mind, we continue to work with insurers. This has included helping to ensure the newly adopted Preferred Provider Networks did not disrupt access for patients. We have continued to share the findings of the five-year private drug-plan drug-cost forecast by way of the 2014 scorecard analysis, to demonstrate that growth in this area is in the single digits and is sustainable. And we have developed training for the private market, including a detailed guide to help advisors and brokers understand plan design elements and their impact on patient/employee access. Regionally, we are developing and enhancing our relationships with private payers and are working to promote the value of innovative research for their clients.

Canada's regulatory pathway is complex. We take great pride in helping to inform and improve processes with Canadians' best interests in mind.

Canadians must have access to the innovative medicines they need. Ensuring a predictable and timely drug-approval system is critical to achieving that goal. Backlogs—be they on the drug approval or special access front—delay our ability to get life-changing medicines into the hands of the people who need them.

In some areas, like with the Common Drug Review, our association monitors delays, and reports them to members and stakeholders to ensure they are aware of any possible issues. In other areas, we work collaboratively with our partners to help them address challenges.

Working closely with the Director of Ontario's Exceptional Access Program provided us with the opportunity to successfully address application delays. This level of collaboration has also paved the way for government and industry to work together in the context of issues and challenges related to the Ontario Public Drug Programs.

In collaboration with the Ministry of Health and Long-Term Care and with the Ministry of the Attorney General, we negotiated several improvements to the Ontario Product Listing Agreement's standard terms that will benefit our members.

In Quebec, our ongoing dialogue and consultations with the *Institut national d'excellence en santé et en services sociaux* and with the *Régie de l'assurance maladie du Québec* to improve the access environment for patients has resulted in a more interactive and transparent drug listing process.

We work diligently to create a holistic vision of our healthcare system to allow payers to see how investments in medicines help offset healthcare and other societal costs. Across the country, we develop relationships and strategies to broaden the discussions around formulary management and the broad issue of access to medicines. We monitor key issues that affect our industry—such as the pan-Canadian Pharmaceutical Alliance and therapeutic class reviews—and are able to predict when our input is appropriate and make suitable, constructive submissions. Provincial and territorial governments face significant pressure when establishing health budgets and policies.

Although cost-containment initiatives continue, Canada's innovative pharmaceutical companies have a crucial role to play in helping governments achieve their healthcare goals. For example, we provided a detailed submission to the Government of New Brunswick's Strategic Program Review of its pharmacare plan, and presented an overview of the following: the value of and true costs of medicines, examples of value-demonstrating initiatives, the importance of adherence and proper utilization for sustainability, the impact that lack of access has on uninsured Canadians, and guiding principles for policy and program design.

By forging public/private partnerships and investing in value-demonstrating initiatives, we are successfully finding system efficiencies and showing how investing in innovative medicines goes a long way.

The Rx&D Health Research Foundation's (HRF) Partnerships for Patients program recognizes this and is creating innovative solutions to contribute to a sustainable healthcare system. These two projects were launched this year:

- The HRF contributed $300,000 to help fund a new research project led by Dr. Martin Dawes at the University of British Columbia (UBC) that will apply a genomic approach to screen for 33 markers in five genes of a patient's DNA that are linked to potentially clinically actionable gene-drug

associations. Called The Implementation of Pharmacogenomics in Primary Care in British Columbia, this novel project is valued at over $720,000, and is being funded through Genome BC's User Partnership Program, Rx&D's Health Research Foundation and other partners.

- A Pathway to Better Care for Patients with Lung Disease: Innovation in Healthcare Comes in Various Forms. In Northern Ontario's district of Temiskaming, this arrived recently as a new way to address one of the area's most persistent health challenges—the high prevalence of chronic obstructive pulmonary disease (COPD). The new model is based on a simple premise: that better patient care requires a systems approach involving hospitals, primary care and a range of other community-based health services, to deliver all aspects of inter-professional care. As a result, patients receive the services they need when they need them. In Ontario, almost 12 per cent of people aged 35 and older have COPD, and its prevalence is increasing, especially among women. Flare-ups are a frequent cause of emergency department visits and hospital admissions and re-admissions, making COPD patients among the highest healthcare users in the province.

In Manitoba, two initiatives are underway to explore leveraging the province's rich data resources and capacity for real-world effectiveness. One is an industry event exploring the opportunity with the life-sciences association and Manitoba Health, and the other is a partnership project to demonstrate proof of concept in the province.

Canada's innovative pharmaceutical companies invest more than $1 billion every year into research and development. These investments support local economies and offer Canadian doctors and hospitals access to innovative new therapies, allowing them to provide better care to Canadians. Creating a receptive, attractive and globally competitive national environment to attract, maintain and grow clinical trials is fundamental to delivering cutting-edge healthcare in Canada.

At present, there are more than 500 new products under development in Canada, including therapies focused on cancer, infectious diseases and vaccines. These products have the potential to help Canadians and people all over the world lead longer and healthier lives.

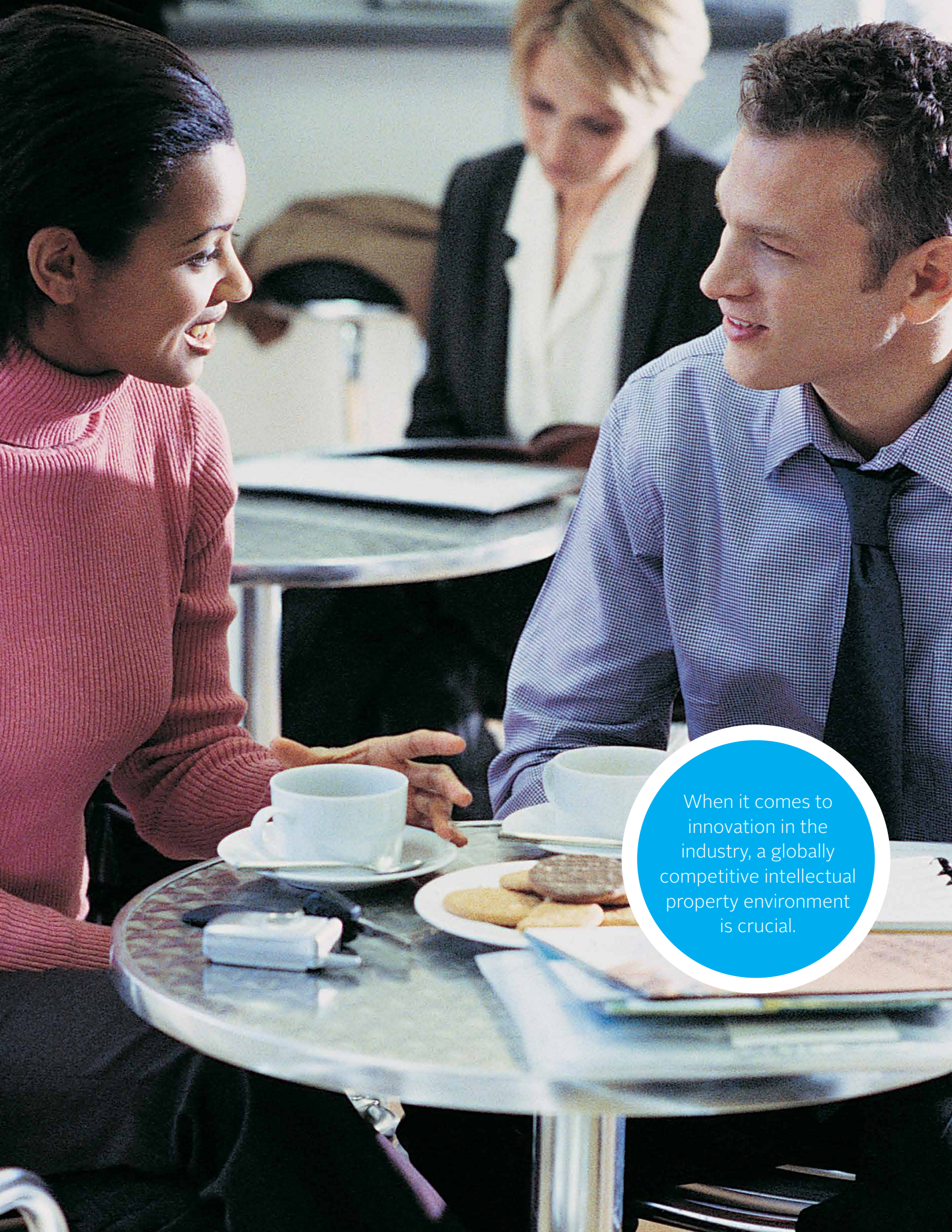
While we are working hard to continue medical research and development in our country, the reality is that Canada only attracts approximately one per cent of pharmaceutical research and development investment in the world. Canada has an immense opportunity to attract foreign investment—and more clinical trials—but only if we support our industry and create a regulatory environment on par with the rest of the world.

Rx&D has played a key role in providing expert advice and strategic and scientific thought leadership on the implementation of the Clinical Trials Action Plan and the activities of the Canadian Clinical Trials Coordinating Centre (CCTCC). Progress has been made on how we measure, monitor and track clinical trial metrics, and we have updated the clinical trial business case used by Canadian trade commissioners internationally.

We have also launched the Canadian Clinical Trials Asset Map (CCTAM), a pan-Canadian database showcasing Canada's clinical research capacities. The CCTAM is helping Canada regain its position as a leading destination for clinical trials in the global marketplace, providing a comprehensive picture of the breadth and depth of Canada's clinical research assets. It offers tremendous marketing benefits to clinical research organizations and investigators, and will allow clinical trial sponsors to place trials effectively and efficiently.

The CCTCC is launching a pilot online contracting tool to help reduce the time spent on clinical trial agreements and to improve clinical trial start-up times in Canada. The organization, with support from Rx&D and from the Government of Canada through the Canadian Institutes of Health Research and HealthCareCAN, is now turning its focus to delivering a National Patient Recruitment Strategy, Patient Registries, and on advancing issues related to Research Ethics Board accreditation in ethics reviews.

This has not been a strictly national endeavour. In Quebec, for example, Rx&D helped drive the creation of a working group focused on the province's life-sciences sector to ensure actions that affect it are coherent and predictable, and work to improve the life-sciences environment. Four government departments participate in this working group, as do other representatives from Quebec's life-sciences ecosystem. Subgroups have been created and are working to provide concrete recommendations around innovation integration and industry, research and promotion. Further, Rx&D is proud to have entered into a partnership with the Montreal InVivo early clinical research initiative and with three university hospitals, to improve the clinical research environment and attract more clinical trials to Montreal.


When it comes to innovation in the industry, a globally competitive intellectual property environment is crucial.

Report on Priority 3

Advocate for a globally competitive intellectual property regime.

When it comes to innovation in the industry, a globally competitive intellectual property environment is crucial.

To this end, we work diligently toward the following goals:

- *A Patent Act* that provides both protections and incentives similar to other developed nations, one enforced in the context of comparative international norms such as patent utility;
- *Patented Medicines (Notice of Compliance) Regulations* that are more balanced, predictable and equitable for innovators;
- Data protection regulations that protect exclusivity to all innovative medicines and provide exclusivity incentives for new indications and orphan drugs; and
- Patented medicines regulations that provide the Patented Medicine Prices Review Board with a clear and limited mandate that accurately reflects industry investment in Canada.

In 2015, we worked diligently, and successfully amended the *Patented Medicines (Notice of Compliance) Regulations* to address the listing of patents on fixed-dose combination products. These amendments restored the stability lost as a result of judicial rulings that had overturned Health Canada's longstanding and reasonable guidance to the industry on this issue.

In the fall of 2014, the Government of Canada recognized the role that the innovative pharmaceutical industry plays in Canada's health, social and economic well-being and took steps to improve intellectual property protection in Canada by finalizing the text of the Comprehensive Economic and Trade Agreement (CETA). This historic agreement is an essential step in strengthening Canada's position on the international life-sciences stage. CETA includes these life-sciences intellectual property improvements:

- Patent term restoration, which will offer research-based pharmaceutical companies the potential to recover up to two years of time lost on their patent as a result of lengthy regulatory and government approval processes. Prior to CETA, Canada was the only G7 nation not providing any form of patent term restoration.
- The right of appeal, which will allow innovative pharmaceutical companies to more effectively appeal court decisions where a patent is ruled invalid, a process that to date has been available to challengers but not patent-owners.

As such, we have maintained a constructive dialogue with Industry Canada on the intellectual property enhancements related to CETA implementation despite slow progress due to treaty approval issues.

Finally, we have updated the Rx&D Competition Law Guidelines and the Competition Guidelines Regarding Rx&D Meetings, and have also made several submissions to the Competition Bureau on their proposed changes to the IP Enforcement Guidelines.

The Association's 2015 Board of Directors

Rx&D has an effective and engaged Board of Directors that enables member companies to achieve common objectives.

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Our Members

Canada's Research-Based Pharmaceutical Companies is the national association representing the voice of Canada's innovative pharmaceutical industry.

We serve our membership by advocating policies that enable the discovery, development and delivery of innovative medicines and vaccines to improve the lives of all Canadians. We support our membership's commitment to being a valued partner in the Canadian healthcare system. We represent more than 50 companies investing over $1 billion in R&D annually, fuelling Canada's knowledge-based economy, while contributing over $3 billion overall to Canada's economy. Guided by our Code of Ethical Practices, we work with governments, private payers, healthcare professionals and stakeholders in a highly ethical manner.

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