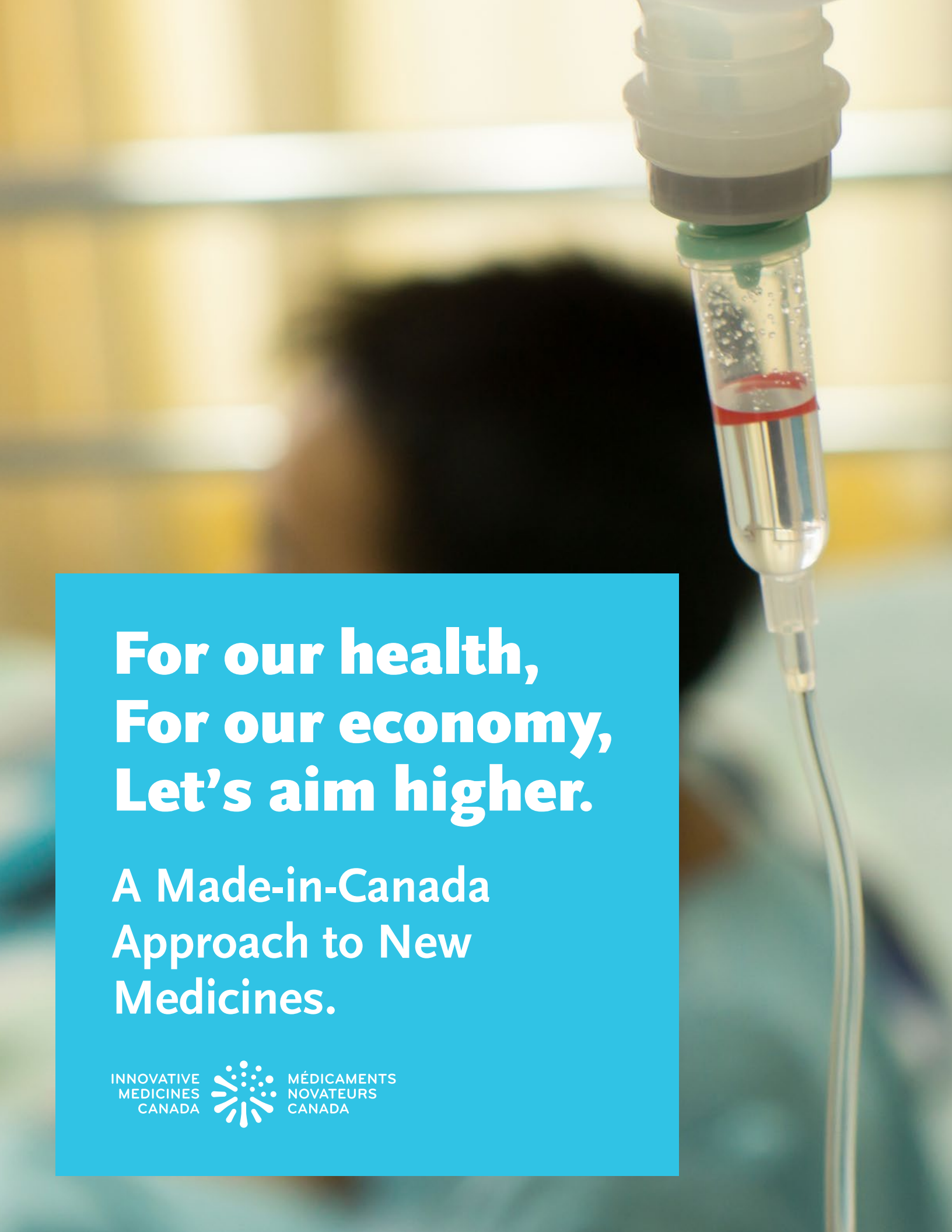


For our health, For our economy, Let's aim higher.

A Made-in-Canada Approach to New Medicines.

INNOVATIVE MEDICINES CANADA
MÉDICAMENTS NOVATEURS CANADA

For more information on Innovative Medicines Canada, please visit:
www.innovativemedicines.ca

www.innovateforlife.ca
#innovateforlife

Contents

A Made-in-Canada Approach to New Medicines.

We believe it's time for a new approach to address patients' needs when it comes to prescription medicines while at the same time enhancing life sciences innovation and investment. Let's develop a unique, made-in-Canada solution.

Canadians don't often think about it or boast about it, but we have developed a unique and successful Canadian way in many important areas:

- Conflict and the military? We have been a leader in peacekeeping efforts.
- People of different beliefs and orientations? We embrace diversity.
- Isolationism? We continue to keep our doors open to the world.
- Healthcare? We have our unique system that prides itself on providing quality care for all.

When it comes to creating the environment for medical research, innovation and more specifically new medicines, there are often two divergent perspectives. You can have a strong innovative pharmaceutical industry and ready access for patients to the newest medicines, but that means paying higher drug prices, such as the U.S. and Switzerland. Or you can use the power of the state to enforce low drug prices but sacrifice research, innovation and timely access by patients to new therapies, like in the case of New Zealand. This approach, in turn, leads to poorer health outcomes and increased spending in other areas of the health system, such as hospitals.[1]

Over the past 50 years, Canada has wavered between these two contrasting worlds, swinging between different policies that have at different times benefited and disadvantaged patients, the pharmaceutical industry, the research community and our healthcare system — all while costing or saving money in different areas, depending on the policy, the political party in power and one's point of view.

Now, political, scientific, medical and economic forces are all calling for Canada to examine its policies in this crucial area. In fact, the federal government has embarked on the first of a number of regulatory reforms, with the goal of updating and/or modernizing how innovative drugs enter the Canadian marketplace. We are at a pivot point at which important decisions will be taken that will have profound impacts on our health system, research ecosystem and economy for decades to come. Now is the opportunity to get it right.

Federal Government's Proposed Drug Price Reform

The federal government is proposing to change how it regulates the prices of patented medicines. The Patented Medicine Prices Review Board (PMPRB) is an arm's length, quasi-judicial federal agency that regulates the sale of all patented medicines. The changes to regulations would require the PMPRB to compare the prices of medicines in Canada with those of countries with lower drug prices and apply restrictive and unpredictable economic factors.[2] This will introduce additional layers of oversight for reviewing prices of medicines, when prices are already the subject of evaluation and negotiations at several stages before patients can access them. The proposed changes will also reduce the pharmaceutical industry's financial capacity to invest in Canada.[3]

As a result of these changes, patient access to new medicines will be slower or more limited, as new medicines tend to be available first in countries that allow for globally competitive public prices.[4] The reform will also lead to job losses in the life sciences industry and the research ecosystem and reduced research and development investments in Canada, which means fewer clinical trials.[5] Investment priorities by pharmaceutical companies are evaluated country by country and region by region and determined based on key factors including research and development, the cost of doing business, commercialization and pricing. Also, as fewer medicines enter the Canadian market, it will be more difficult for companies to conduct clinical trials in this country. This is because clinical trials involve comparing new medicines to standard-of-care treatments and this won't be possible to do if these treatments are not available in Canada.

Unfortunately, the tendency has generally been to revert to traditional perspectives, compromising patient access to new medicines and weakening Canada's competitive position when it comes to attracting new investments. The federal government's proposed drug price reform is an example of this. The draft price regulations will compare Canada to countries that have lower prices but that also have slower and more limited access to new medicines.[6] This reform will also lead to decreased research investments and clinical trials in Canada. The federal government appears determined to move forward on this reform despite the lack of meaningful engagement with stakeholders to date and without addressing important concerns raised by various stakeholders.

While we understand the government's interest in wanting to obtain lower prices for medicines and vaccines, we believe a more nuanced approach is needed. Low prices should not be the only goal of pharmaceutical policy. It is crucial to consider carefully the impact of pricing and reimbursement policy on industry investment and jobs, the research ecosystem and access for Canadians to new medicines through clinical studies and prompt launches of new treatments in Canada.

This paper calls for new thinking on our approach to innovative medicines. It makes concrete proposals to address the accessibility, the affordability and the appropriate use of medicines while also supporting investment and innovation. It challenges us to aim higher.

As we have done in other key areas, we need a vision for excellence and courageous leadership to create a new policy environment for innovative medicines. If we get it right, Canadians will be able to have access to the best possible care while also creating a quality, sustainable and affordable healthcare system for generations to come. If we get it right, we can help fuel research and innovation in this country, create thousands of quality jobs and become a key engine of Canada's knowledge-based economy.

Let's build our unique, made-in-Canada policy approach for innovative medicines.

Summary: Developing a Made-in-Canada Approach to New Medicines

A made-in-Canada approach to new medicines includes the following four key goals and concrete proposals to achieve each of these objectives.

Goal #1: Accessible Medicines for All Canadians

1. Develop a plan to educate Canadians on drug insurance programs to help them understand and make use of the drug coverage they have access to currently.
2. Develop a solution to ensure that Canadians who are not currently eligible for insurance coverage have access to the medicines they need.
3. Support faster reimbursement of new medicines by setting specific timeframes for price negotiations between pharmaceutical companies and public drug plans under the pan-Canadian Pharmaceutical Alliance (pCPA) and for the listing of medicines on public drug plan formularies.
4. Maintain the current dual system of public and private insurance for the reimbursement of medicines, while addressing coverage gaps as recommended above.

Goal #2: Affordable Medicines

5. Provide an opportunity for the biopharmaceutical industry to discuss drug prices with Canadian governments and health insurance organizations, with the goal of finding a balanced approach that ensures prices of medicines and vaccines are affordable and accessible while also encouraging the introduction of new medicines and investments in Canada's health system and life sciences sector.
6. Enhance the efficiency of the pCPA by establishing a consistent and clear negotiation process with set timelines, performance indicators and annual evaluation and reporting on these performance measurements.
7. Increase the flexibility in how medicines are funded by allowing for more value-based agreements. These agreements value the impact of medicines — such as better health outcomes — rather than focus solely on the price.
8. Improve efficiencies in the supply chain for new medicines to support affordable and streamlined patient access to medicines.

Goal #3: Appropriate Use of Medicines

9. Increase the use of big data by governments, industry and the research community to monitor, measure and promote the appropriate use of medicines and vaccines.
10. Establish integrated data platforms, systems, coding standards and patient registries that can analyze and track patient prescriptions, drug utilization, genomic data and outcomes, and link these data sets together to generate insights to support a sustainable system for all Canadians.
11. Work with healthcare professionals, patients and industry to standardize the appropriate use of pharmaceuticals in the context of developing and maintaining care pathways for various diseases and conditions.

Goal #4: Investment and Innovation

12. Develop a partnership strategy and approach that delivers systematic and significant growth of the life sciences industry in Canada, including meaningful, measurable and specific investment targets over set timeframes.
13. Modernize the formula used by the federal government to calculate the pharmaceutical industry's investments in research and development in Canada.

Why Is Canada Unique and Why Does It Deserve Its Own Unique Approach?

There are many aspects that make Canada unique and explain why we need to develop our own path forward:

- **Healthcare system:** Canada has a universal, publicly funded healthcare system based on national principles. The delivery of healthcare is the mandate of each province and territory. They administer public healthcare systems for their citizens. While access to pharmaceutical coverage in the community setting is not guaranteed under our public healthcare system, Canada has developed a unique public/private pharmacare approach. This generally serves Canadians very well, though action needs to be taken to ensure people do not fall through the cracks because of their financial circumstances.

- **Biopharmaceutical industry:** The biopharma industry in Canada is strong and well respected around the world. We have a vital base of educated and experienced people working for companies ranging from the smallest start-ups to the largest multinationals. There are clusters of excellence and a life sciences/biotech organization in every province, from Life Sciences Ontario to Montréal InVivo to the Prince Edward Island BioAlliance and national organizations, notably Innovative Medicines Canada and BIOTECanada. The innovative medicines industry contributes to a strong Canadian economy by employing 13,000 Canadians directly, supporting over 30,000 jobs in total and driving over $19 billion in annual economic activity. Compared to other economic sectors, the life sciences sector ranks 3rd in terms of combined total research and development (R&D) spending in Canada, behind only the aerospace and software and computer services sectors.[7]

- **Research ecosystem:** Canada is one of the best places in the world to conduct medical research, due to our research talent and infrastructure, our proximity to the U.S., our demographics, our cultural diversity and our mix of urban and rural environments. We worked hard to build this research ecosystem in Canada over the past 30 years. Modern medical research is not done in isolation. One person may have an idea or hunch, but it takes a strong and multi-faceted 'village' to bring it from an idea to a product or technique that helps patients. Our research ecosystem is strong and growing, but it can only continue to do so with a supportive policy environment that encourages growth and investment. It needs to be nurtured.

We clearly have the necessary foundation for great success — both for a strong and prosperous economy and for the benefit of Canadian patients. Federal and provincial innovation strategies and drug coverage programs are significant assets. Individually, however, they won't be sufficient to make Canada a world-leader in health research and innovation.

Finally, developing a customized approach to ensuring high quality access to pharmaceuticals is not a unique or special request. The United States and Europe have also developed tailored approaches to ensure citizens have the best possible access to emerging therapies that drive improved health outcomes.

What Do We Want to Achieve?

We believe Canadians likely agree on the goals we should aspire to achieve when it comes to our healthcare system. Common goals could include:

1. **Accessible medicines for all Canadians:** A health system that ensures all Canadians get the medicines and vaccines they need, when they need them, regardless of their financial situation or geographical location. This includes the opportunity to participate in clinical trials for emerging therapies that have the potential to improve survival rates and deliver better quality of life.

2. **Affordable medicines:** Make medicines and vaccines affordable for governments and private insurance companies to support their respective beneficiaries and maintain a sustainable, high-quality health system.

3. **Appropriate use of medicines:** Promote appropriate use of medicines to ensure better health outcomes and a high-performing and efficient health system.

4. **Investment and innovation:** A globally competitive Canadian biopharma research and innovation ecosystem that includes universities, research centres and companies focused on outcomes that matter to patients, the health system and the economy.

Looking for Solutions: Building a Made-in-Canada Approach for New Medicines

How do we accomplish these four key goals? Each goal is described in more detail below along with concrete proposals on how they can be achieved.

Goal #1: Accessible Medicines for All Canadians

The federal government transfers monies to the provinces and territories to pay for physician and inpatient hospital services. The authority to do this is dictated by the terms and conditions of the *Canada Health Act*. However, the requirement to pay for medicines used outside of the hospital is not included in the legislation. Medicines are therefore paid for by Canadians in various ways, including provincial public drug plans (usually for lower-income residents, citizens 65 years and older and for certain medical conditions), private group insurance plans and individual insured plans and cash payments out of pocket. Some provinces also make drug insurance available to all citizens. For instance, Quebec requires everyone to be covered either by a private plan or, failing that, through the public plan.

Most Canadians have or are eligible for some type of drug coverage. In fact, the number of Canadians that are uninsured or underinsured is lower than originally thought. According to a recent study, 1.8% of the Canadian population is uninsured. Many Canadians may not, however, be aware that they actually have access to a drug coverage program (approximately 4.1 million Canadians who do not have private insurance and are eligible for public coverage do not enroll in the public plan).[8] A recent large national study also shows that less than 1% of Canadians failed to fill or complete their prescription due to cost.[9]

While there appear to be fewer uninsured Canadians than originally thought, no Canadian should go without the medicines they need for cost reasons. So how can we close the coverage gaps?

Options under discussion range from a new federal national public program to the expansion of provincial best practices and models. The Quebec universal drug insurance program, which is a dual private/public system, is one model that could be considered. As currently done with other elements of health through the *Canada Health Act*, the federal government could establish national standards of universality and minimum coverage levels for medicines and leave it to the provinces to decide how best to fill the gaps.

The current federal drug price reform is being promoted as an opportunity to expand access by lowering prices. However, the additional price controls and reporting obligations on industry proposed by the federal government will, in fact, slow or limit access to new innovations in Canada *(for more information, see call out box on page 5 of this paper)*.

It is possible to develop an approach or a program that ensures that no Canadian goes without adequate access to the medicines they need. We just need to develop a model that closes those gaps without denying Canadians access to a range of medicines that are appropriate for their medical condition to promote good health outcomes and prevent illnesses. The system also needs to be strengthened so that Canadians have timely access to medicines.

Proposal:

The biopharmaceutical industry proposes the following concrete actions to improve access to new medicines:

- Develop a plan to educate Canadians on drug insurance programs to help them understand and make use of the drug coverage they have access to currently.
- Develop a solution to ensure that Canadians who are not currently eligible for insurance coverage have access to the medicines they need.
- Support faster reimbursement of new medicines by setting specific timeframes for price negotiations between pharmaceutical companies and public drug plans under the pan-Canadian Pharmaceutical Alliance (pCPA) and for the listing of medicines on public drug plan formularies.
- Maintain the current dual system of public and private insurance for the reimbursement of medicines, while addressing coverage gaps as recommended above. Preserving private insurance for medicines would help support patient choice by allowing Canadians who currently benefit from this type of coverage to continue to do so and would help minimize cost to government and tax payers. Solutions are also being explored to improve the value of investments by employers in their health benefit plans.

Goal #2: Make Medicines Affordable

Let's have an open conversation about what Canadians — individually and through our public and private insurance systems — can afford and how we can get greater value from the health system as a whole. It's an issue closely related to the access gap, and the solution requires a nuanced approach to address affordability challenges while at the same time ensuring continued investments to find cures, treatments and vaccines.

There are a number of myths in the public domain pertaining to drug prices that need to be addressed. Often, drug prices are claimed to be responsible for bankrupting the health system. However, when you look at the system as a whole, costs of medicines are not an unmanageable burden. In fact, because medicines are paid in large part by private insurers, the provinces collectively spend less than 4% of their healthcare budget on patented medicines, if you remove the costs of distribution and pharmacy fees.[10] Despite accounting for a very small portion of public health spending, medicines are subject to many more layers of price and cost control than other healthcare costs, which account for much larger shares.[11] The value of medicines should be assessed in the broader context of healthcare spending overall to ensure that healthcare resources are allocated to the health interventions that deliver the best outcomes for patients. Evaluation of the impact of medicines should be consistent with how the performance of other key sectors in healthcare are evaluated, drawing on the approaches of the health quality councils and the Canadian Foundation for Healthcare Improvement.

We also often hear about how drug prices are going up and are out of control. However, according to a recent report published by the federal government, average prices of patented pharmaceuticals in Canada decreased 0.5% in Canada in 2016. Average prices have not increased more than 1% or exceeded inflation in any of the past 24 years and have decreased in 12 of those years.[12]

As well, Canadian prices have fared well compared to other developed countries. They have been below the median prices in the seven countries that the federal government currently compares with (i.e., Switzerland, Germany, Sweden, Italy, France, the UK and the US) on a consistent basis, falling to 25% below in 2016.[13] According to some studies, the prices of new patented medicines without generic competition rank 6th out of 8 countries.[14] Of note, these studies are all based on public list prices and do not take into account the significant price discounts provided by companies through negotiations with government drug plans through the pCPA.

In fact, medicine prices in Canada are already subject to several additional levels of cost control that have been put in place to improve the affordability of medicines:

- Evaluations for effectiveness or health technology assessments (HTA): The extensive HTA processes undertaken before a new treatment is paid for by public drug plans help ensure that payers know they are paying not just for clinically effective treatments but for cost-effective ones.
- Negotiated price reductions: Companies negotiate lower prices with public drug plans through the pCPA. Public plans have saved billions of dollars as a result of pCPA.[15] As well, biopharmaceutical companies often negotiate lower drug prices with private insurance companies. This means that in most cases, neither governments nor private insurance companies are paying the full public list prices of medicines.
- Value-based agreements (pay for performance): Increasingly, agreements between pharmaceutical companies and drug programs are based on the value received or where the companies share the risk for higher than expected use and cost.

All of the above contribute to the affordability of pharmaceuticals in Canada today and in the future by ensuring high value is received for the investment made. Competition among pharmaceutical companies also plays a role in bringing better treatments to market and reducing drug prices.

Making Healthcare More Affordable

The industry is also doing its part to innovate and bring solutions to make healthcare more affordable, including:

- **Targeted therapies and predictive tests:** Treatments, particularly in cancer, are becoming more targeted to the specific genetic makeup of tumours. Tests have been developed to determine in advance which patients are likely to benefit from the treatment, greatly increasing the likelihood that a given treatment will be effective and limiting the amount spent on treatments that have no positive effect. Targeted therapies and predictive tests therefore improve health outcomes and avoid unnecessary costs.

- **Vaccines and preventative therapies:** Preventing illness is usually the least expensive way of treating an illness. New vaccines offer potential to prevent more and different illnesses, including certain cancers, adding costs for the vaccine but preventing much greater treatment costs later, such as the HPV vaccines. New treatments to cure hepatitis C infection add to drug costs but prevent the inevitable other healthcare costs that result if the infection is not treated, including liver failure and the need for a liver transplant.
- **Value-based agreements (pay for performance):** Pharmaceutical companies are negotiating with drug programs agreements based on the value received.

That said, there is still room for improvement, and pharmaceutical companies can and want to do better. The industry can better demonstrate the impact of the collective investments and the value of the cost savings generated through evaluation and negotiation throughout the system so that issues around price, budgets and affordability can be clearly understood and discussed by Canadians.

There is also an understandable need for payers — ultimately all Canadians — to seek lower prices for medicines and vaccines to enable our healthcare system to keep up with demand. Having said that, a balanced approach is needed here and securing low prices should not be the only goal of pharmaceutical policy. While writing on the proposed federal pricing reform, The Globe and Mail columnist André Picard summed it well by saying: "[F]air drug prices are not necessarily cheap drug prices. The analysis we really need from government is not how we can generate savings within a flawed system, but how we can build a drug-pricing regime that gives us value for money."[16]

It is crucial to consider carefully the impact of pricing and reimbursement policy on industry investment and jobs, the research ecosystem and access for Canadians to new medicines through clinical studies and prompt launches of new medicines in Canada. It is also important to remember that investing in the health of Canadians leads to a more productive working population, resulting in a stronger Canadian economy.

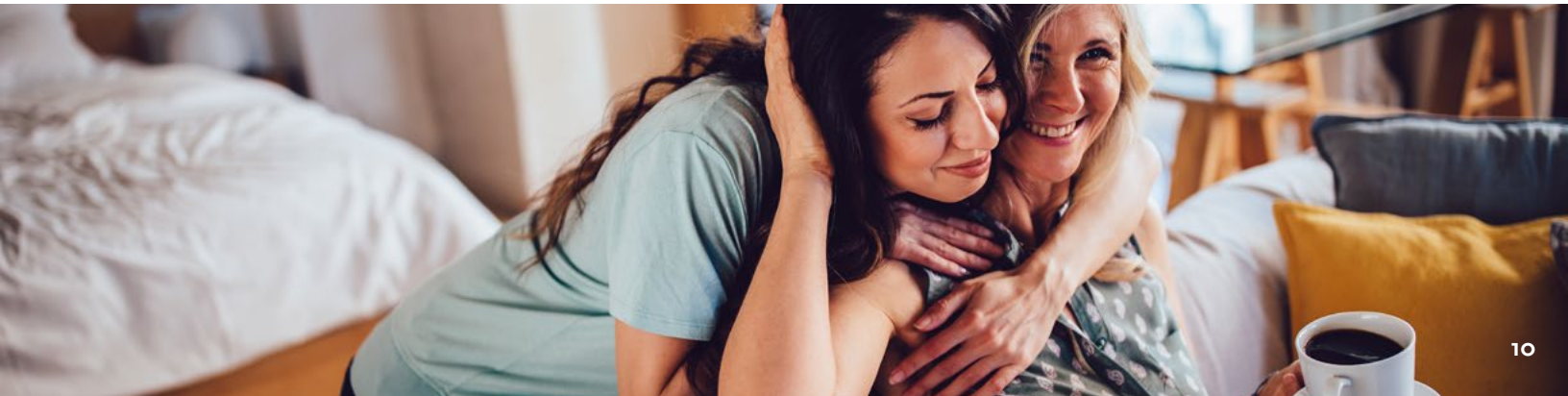
The federal government's proposed reform to change how prices of medicines are regulated will have important negative consequences on patient access to new medicines, life sciences investments and jobs and, ultimately, the Canadian economy. There are better ways to address concerns around pricing and achieve health system sustainability, as has been done successfully in other countries, such as the United Kingdom,[17] Israel, Singapore,[18] and Belgium,[19] among others.

Proposal:

The biopharmaceutical industry is seeking an opportunity to discuss drug prices with Canadian governments and health insurance organizations, with the goal of finding a balanced approach that ensures prices of medicines and vaccines are affordable and accessible. At the same time, this system would support and encourage the introduction of new medicines and investments in Canada's health system and life sciences sector.

The biopharmaceutical industry also proposes the following concrete actions to help improve the affordability of new medicines:

- Enhance the efficiency of the pCPA by establishing a consistent and clear negotiation process with set timelines, performance indicators and annual evaluation and reporting on these performance measurements.
- Increase the flexibility in how medicines are funded by allowing for more value-based agreements. These agreements value the impact of medicines — such as better health outcomes — rather than focus solely on the price.
- Improve efficiencies in the supply chain for new medicines to support affordable and streamlined patient access to medicines.



Goal #3: Appropriate Use of Medicines

As with any public or private investment, it is important to ensure that the money spent is being used appropriately to ensure the maximum return. With medicines, that comes through responsible prescribing and appropriate use by patients and clinicians. This also leads to improved health outcomes for patients.

It is important that all those involved — industry, healthcare professionals and regulators — work together to achieve the goals of improved prescribing and adherence of all pharmaceuticals.

Real-world evidence, which is data gathered about the use and outcomes of medicines by prescribers and patients, can play an important role in supporting these goals. New advances in technology and science are enhancing our ability to gather data from clinical practice to help us generate important findings on the appropriate use of medicines. This real-world evidence can help ensure that patients are using medicines only when needed and in the safest and most effective way. This is an opportunity to save money in drug expenditures while also helping patients.

Canada already has in place infrastructure that can be leveraged to allow for the collection of real-world evidence, such as information technology available through Canada Health Infoway, various provincial pharmacy data systems, data tracking and monitoring from the Canadian Institute for Health Information (CIHI) and national and provincial quality improvement organizations, like Health Quality Ontario. A key problem, however, is that most of these systems don't speak to each other since the data collection isn't standardized and the transfer of data across provincial boundaries hasn't been perfected.

Artificial intelligence systems, in which Canada is a world leader, may help in this area by monitoring, linking and interpreting the vast amounts of data generated in the real world (including drug utilization data, genomic data, and outcomes data) to identify trends and benefits that would be impossible for humans to track and discover.

While we have made progress, additional efforts and resources are needed to enhance our data infrastructure and collection systems. Canada can be a world leader given its strong health systems and information technology infrastructure.

Proposal:

The biopharmaceutical industry proposes the following concrete actions to help improve the appropriate use of new medicines:

- Increase the use of big data by governments, industry and the research community to monitor, measure and promote the appropriate use of medicines and vaccines.
- Establish integrated data platforms, systems, coding standards and patient registries that can analyze and track patient prescriptions, drug utilization, genomic data and outcomes, and link these data sets together to generate insights to support a sustainable system for all Canadians.
- Work with healthcare professionals, patients and industry to standardize the appropriate use of pharmaceuticals in the context of developing and maintaining care pathways for various diseases and conditions. Alberta's Strategic Clinical Networks are a good example of how this approach can deliver better outcomes while avoiding unnecessary costs.

Value-Based Healthcare

Collection of real-world evidence and appropriate use of medicines is a key component to achieving value-based healthcare, which is a way of managing our health system that is focused on patients and that delivers improved health outcomes at significantly lower cost.

The World Economic Forum indicates that a value-based approach to care rests on three key principles: "measuring systematically the health outcomes that matter to patients and the costs required to deliver those outcomes across the full cycle of care, tracking those outcomes and costs for defined population segments on an ongoing basis, and developing customized interventions to improve value for each population segment."[20] In the context of medicines, as referenced earlier in the paper, this could include the conclusion of value-based agreements. For instance, Amgen recently struck an agreement with Harvard Pilgram for its cholesterol medication, Repatha. Under this agreement, Amgen agreed to refund Harvard Pilgrim the cost of medication for patients who have a heart attack or stroke.

Other outcomes-based agreements have also been concluded in Canada. Canadians should explore ways to learn and expand on best practices in this area.

Goal #4: Investment and Innovation

Canada's life sciences industry is an important economic engine and one of the most innovative sectors in Canada. In fact, compared to other sectors, life sciences ranks third in terms of combined total R&D spending in Canada, behind only the aerospace and software and computer services sectors.[21]

The pharmaceutical industry contributes to a strong Canadian economy by employing 13,000 Canadians directly, supporting over 30,000 high-value jobs in total and driving over $19 billion in annual economic activity. Nearly 10% of its revenues are invested into R&D each year.[22]

Canada is renowned for producing robust clinical research, for its world-class hospitals and universities, as well as emerging innovation clusters and programs, such as the MaRS Discovery District, Alberta Innovates, the Centre for Drug Research and Development, CQDM and the NEOMED Institute that bring together universities, entrepreneurs, researchers, capital and a strong public healthcare system.

R&D Investments

While the pharmaceutical industry estimates it invests nearly 10% of its revenues into R&D each year, the federal government reports that this number is lower, at 4.9%.[23]

Some cite this lower figure to indicate that the industry has not lived up to its commitment to invest 10% of its revenues in R&D when patent protection measures were introduced in the 1980s. However, the reason why the federal government's figure is so low is that it uses an old formula that no longer applies to the modern approach to R&D of new medicines. The R&D approach has shifted from conducting in-house research to forming partnerships with Canadian universities, hospitals and biotech businesses and includes venture capital investments and clinical trials. Many of these investments, however, are not considered in the calculations by the federal government. For instance, with the creation of the life sciences incubator JLABS (more on this below), Johnson & Johnson decreased the headcount associated with traditional R&D, and re-assigned these resources instead to the incubator. This represents a new model for R&D.

A new formula for calculating pharmaceutical R&D should therefore be used to more accurately reflect investments made by the biopharmaceutical industry in Canada.

It is important to remember, however, that Canada's life sciences industry was not created overnight or by accident. It took 30 years of hard work to develop this industry in Canada. In fact, most other OECD countries took even longer to build their life sciences sectors — over a century in many cases. In Canada, the biopharmaceutical industry along with provincial and federal governments mobilized their efforts to put in place the right conditions and policies to allow it to develop and thrive. The federal government has also invested significant resources in basic clinical research and implemented other policies to incentivize research and development in Canada.

The changes related to pharmaceutical pricing proposed by the federal government represent the most important reform for the pharmaceutical sector in recent decades. It is moving forward without meaningful consultation with Canadians and with no case studies to demonstrate the impact of the proposed reform on Canada's leadership position in healthcare and innovation. We need to take the time to get this approach right, as this will be the foundation on which we build our biopharmaceutical research industry for the next 30 years.

An alternative made-in-Canada solution developed in collaboration with patients, healthcare professionals and industry would lead to more investment and innovation.

Rather than simply regulating prices to an arbitrary lower level for all companies as proposed by the federal government, we need to find ways to drive more economic value out of our collective investments in healthcare. Put simply, replace the "stick" of regulation and punishment with the "carrot": an environment that rewards positive behaviours of all stakeholders, while at the same time promoting the three first goals outlined in this paper — that of creating a pharmaceutical system that is accessible, affordable and appropriate.

The more individual companies and the industry as a whole invests, innovates and creates jobs and economic activity, the greater their return in the form of better health and healthcare for Canadians. This return does not necessarily have to mean higher prices but requires an enabling environment, which includes timely approval and reimbursement, lower government fees for services and partnerships with stakeholders, including governments. For instance, the UK government and the innovative pharmaceutical industry recently worked together to arrive at an agreement that addressed the interests of both parties. The deal, characterized as "transformative" by the government, resulted in immediate commitments for major new investments by 25 innovative companies.[24]

Canada's Strong Research Ecosystem

Our research ecosystem is rich and robust, and includes many various innovation hubs and sciences incubators:

MaRS Discovery District: Located in Toronto, it is one of the world's largest urban innovation hubs. MaRS supports promising ventures tackling key challenges in various areas, including the health sector, as they start, grow and scale.

JLABS: In 2016, Johnson & Johnson chose Toronto for its first JLABS life sciences incubator outside the United States, joining the ranks of outposts in major cities like Boston, San Francisco and New York. This incubator now hosts over 40 companies and provides these entrepreneurs shared lab space and offices, modular lab suites and access to scientific, industry and capital funding experts, with no-strings attached.

NEOMED: The NEOMED Institute is a not-for-profit organization that bridges the gap between basic research and the commercialization of new drugs by providing industrial expertise in drug discovery and development. NEOMED operates two research and development campuses in Montreal that function as open-access drug discovery hubs housing 30 independent commercial businesses. NEOMED is jointly funded by governments and several pharmaceutical partners, including AstraZeneca, Pfizer Canada, GlaxoSmithKline, Purdue Pharma Canada and Janssen Pharmaceuticals.

CQDM: Located in Montreal, this research consortium is driven by the mission to fund the development of breakthrough tools and technologies that enhance biopharmaceutical R&D productivity and accelerate the development of safer and more effective drugs. CQDM is also the catalyst where academia, governments and the pharmaceutical and the biotechnology industry converge to create practical solutions to complex medical challenges. There are many pharmaceutical industry partners, including founding partners AstraZeneca, Merck Canada and Pfizer Canada.

The Centre for Drug Research and Development (CDRD): Based in Vancouver, the CDRD provides specialized expertise and infrastructure to identify, validate and advance promising discoveries and transform them into commercially viable investment opportunities for the private sector — and ultimately into new health products for patients. The CDRD works in partnership with academia, industry, government and foundations.

Closer to home, the pharmaceutical industry and the Quebec Government worked together to develop the province's ambitious 2017-2027 Life Science Strategy.[25]

Collectively, we have the components necessary to make life sciences a key pillar of the knowledge-based economy for Canada, creating thousands of high-quality jobs and contributing to a diversified economy and a modern sustainable healthcare system. However, we can only achieve this if we get the other half of the innovation puzzle right. This requires an integrated strategy that attracts greater international R&D investments, commercializes and reimburses new medicines and other medical inventions in a more timely fashion, and uses healthcare technologies to the benefit of Canadian patients and the economy. Global pharmaceutical R&D spending is expected to grow globally by 2.8% annually to $182 billion in 2022 from $149.8 billion in 2015 (compared with a 1.7% growth between 2008 and 2015).[26] Canada can attract a significant share of this investment by continuing to build a globally competitive pharmaceutical research and reimbursement environment.

Modern and successful economies are increasingly based on knowledge rather than resources, the traditional mainstay of Canadian prosperity. Canada has taken large strides in building strong economic sectors in the knowledge economy, particularly information systems, computer technology and artificial intelligence. It is critical for our economic future to ensure we continue to have a strong and world-class health and biopharmaceutical industry.

Proposal:

The biopharmaceutical industry proposes the following concrete actions to help promote investment and innovation:

- Develop a partnership strategy and approach that delivers systematic and significant growth of the life sciences industry in Canada, including meaningful, measurable and specific investment targets over set timeframes.
- Modernize the formula used by the federal government to calculate the pharmaceutical industry's investments in R&D in Canada.

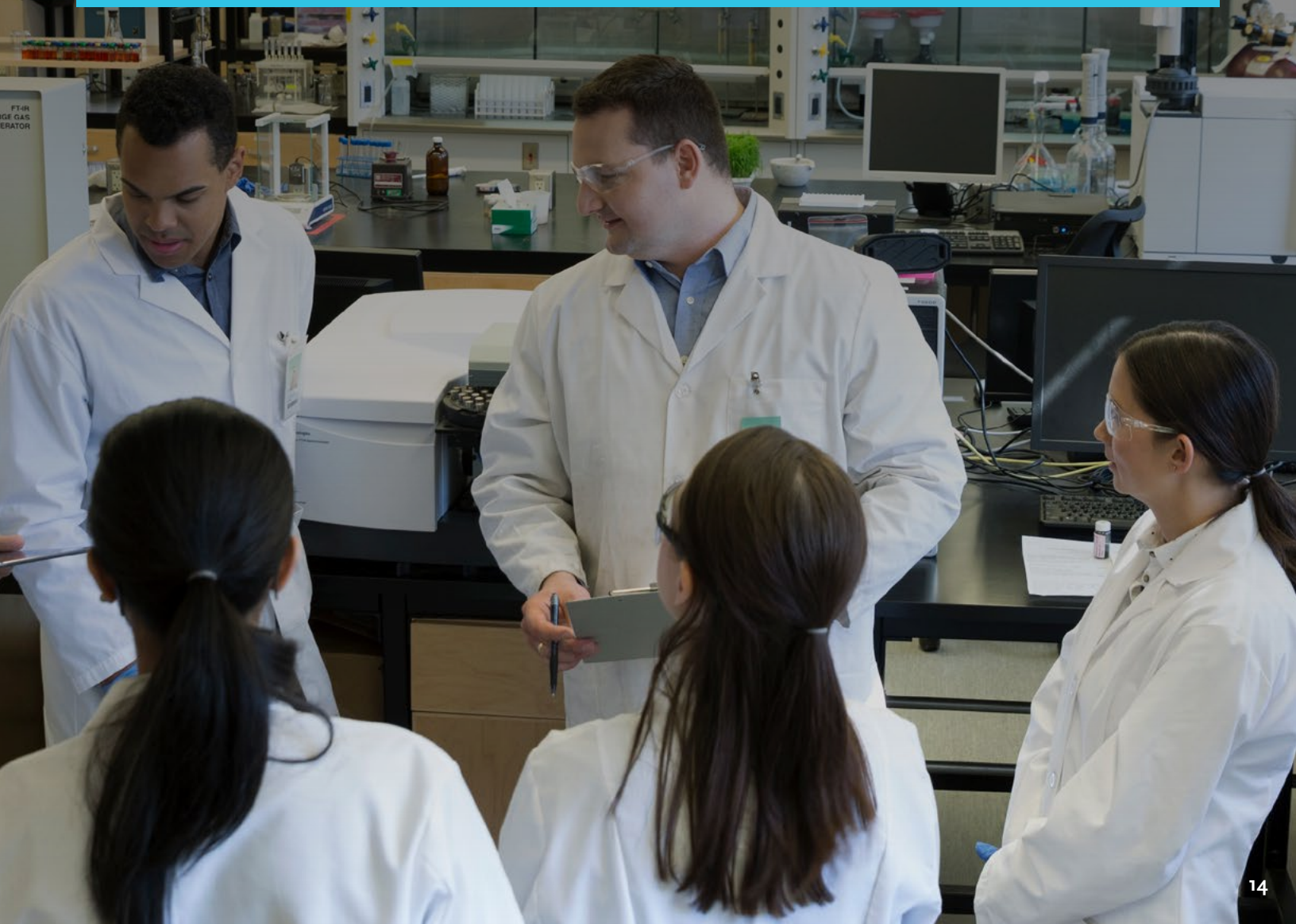
Success for Canadian Biotech Start-ups

Current Canadian biotech start-up companies are following in the footsteps of innovative Canadian pharmaceutical companies such as Charles E. Frosst, Ayerst and BioChem Pharma which have partnered with or been acquired by large multinational companies to bring their discoveries to patients around the world:

» **Parvus Therapeutics of Calgary** recently signed an agreement with Novartis granting Novartis exclusive, worldwide rights to use the Parvus Navacims nanomedicine technology for patients with type 1 diabetes. Novartis will take on the clinical and sales work for this program while Parvus will be in charge of the ongoing preclinical work for the type 1 diabetes program and filing an investigational new drug application with Novartis.

» **Zymeworks Inc. of Vancouver,** a company dedicated to the discovery, development and commercialization of next-generation multifunctional biotherapeutics, has partnered with several pharmaceutical companies to help bring its innovative therapies into clinical development, including GlaxoSmithKline, Merck & Co., Eli Lilly & Co., Celgene Corp. and Janssen Pharmaceutical Companies of Johnson & Johnson.

» **Xenon Pharmaceuticals Inc. of Vancouver,** a biopharmaceutical company focused on developing innovative therapeutics to improve the lives of patients with neurological disorders, such as epilepsy, is partnering with Genentech.



100 Years of Canadian Pharmaceutical Innovation

In three years, Canada will celebrate the centennial of the 1921 discovery of insulin in Toronto by Frederick Banting and Charles Best. This is perhaps the best known of Canada's contributions to modern medicine — turning diabetes from a death sentence into a chronic illness — but it is not the only one. Some important others:

- **Premarin®:** The first hormone replacement therapy, developed in the 1940s by the Canadian pharmaceutical company Ayerst (now part of Pfizer) and still manufactured at a facility in Brandon, Manitoba.
- **Polio and smallpox vaccines:** The development and production of these vaccines – at the Connaught Campus of Sanofi Pasteur – throughout the 20th century have saved millions of lives.
- **3TC (lamivudine):** This is one of the earliest drugs to treat HIV/AIDS infection and developed in the late 1980s and early 1990s by Montreal's BioChem Pharma (now part of Shire Pharmaceuticals). It is now on the World Health Organization's List of Essential Medicines.
- **Singulair®:** This innovative asthma and allergy treatment was discovered and developed by Merck in Montreal in the 1990s.
- **Entyvio™:** This new biologic treatment (approved in Canada in 2015) for inflammatory bowel diseases from Takeda Pharmaceutical was developed based on the discovery work of Dr. Andrew Lazarovits of London, Ontario, and Millennium Pharmaceuticals. Takeda's global clinical trials, which led to the treatment's approval, were headed by Dr. Brian Feagan at the Robarts Research Institute in London, Ontario.
- **Entresto®:** This new treatment (approved in 2016) for heart failure, one of the leading causes of death and hospitalization in Canada, was developed by Novartis building on the foundational research in the 1980s of a team led by Dr. Adolfo J. de Bold at Queen's University, Kingston, Ontario, and including others at the University of Toronto.

With the right policies in place, what amazing medical accomplishments will Canadians achieve, in Canada, over the coming century?

Let's Get Started

This is our vision for the future. It outlines a path for Canadian leadership and innovation. It is positive. It will generate investment and growth. It will help patients and improve healthcare across the country. It is the made-in-Canada and made-for-Canada solution that we need.

We can achieve the four ambitious goals outlined in this paper. Rather than choose which ones to achieve at the expense of the others, we can achieve all of them.

We can do so with a new attitude, a positive approach and imaginative policy solutions as innovative as the medicines the policy is about. All Canadians will be the winners, now and for years to come.

We have provided concrete proposals on how to address access gaps, improve affordability, ensure appropriate use and drive investments in Canada's knowledge-based economy and health system. We look forward to the exciting and constructive discussions that are required to implement these solutions.

We, as an industry, cannot achieve this vision alone. Let's work together — industry, policy makers, patients, health professionals and researchers — to put this plan into action to deliver the best and most innovative healthcare to Canadians.

Notes

1. Rawson N., Fewer treatment options for patients if Canada adopts New Zealand's prescription drug policies, Canadian Health Policy Institute, 2016: **https://www.canadianhealthpolicy.com/products/fewer-treatment-options-for-patients-if-canada-adopts-new-zealand--s-prescription-drug-policies-.html?buy_type=**. A recent analysis also shows how access to new medicines is significantly more restricted in New Zealand than in Canada: Salame R., Comparison of Access to Pharmaceutical Drugs in New Zealand and Canada Using Pan-Canadian Pharmaceutical Alliance Negotiated Products, 2017: **http://bv1ytw.m.attendify.com/app/sessions/9JWdNFCAgBZhBDpYxf/** details. See also the following article suggesting that lack of access to new cancer medicines is a factor in explaining why cancer patients in New Zealand have poorer health outcomes: Zalcberg J. R. and Wonder M., Mind the gap, revisited, Seminars in Oncology, August 2017: **https://www.sciencedirect.com/science/article/pii/S0093775417300933**.

2. Notice on Proposed Amendments to the Patented Medicines Regulations, December 2017: **https://www.canada.ca/en/health-canada/programs/notice-consultation-regulations-patented-medicine.html**.

3. The firm PDCI Market Access estimates loss of industry revenues of approximately 30% ($26.1 billion over ten years), using aggregate data and conservative assumptions (see PDCI Market Access, Proposed Amendments to the Patented Medicines Regulations: A critical appraisal of the cost-benefit analysis, 2018: **http://www.pdci.ca/pdci-critical-assessment-pm-regs-amendments/)**. Another analysis (publication pending) by Ernst & Young (EY) reviewed potential impacts on a sample of 36 products, and also forecasts 30% revenue loss with a range of impact on individual products from 15% to 90% (the variability is driven by the revenue mix between public and private payers in Canada). These analyses show that the federal government has significantly underestimated the impact of the changes on industry revenues.

4. NPDUIS, Patented Medicine Prices Review Board, Meds Entry Watch, 2015, April 2017, p. 27: **http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/NPDUIS_MedsEntryWatch_2015_e.pdf**. Canada has one of the highest percentages of new drug launches worldwide at 61%. That compares to 40% in Australia and 33% in South Korea – two of the countries that PMPRB plans to use as comparators.

5. According to the OECD, there is a high degree of correlation between pharmaceutical sales revenues and R&D expenditures. OECD 2006, Pharmaceutical Pricing Policies in a Global Market. See also Eger, S. and Mahlich, J., Pharmaceutical regulation in Europe and its impact on corporate R&D, Health Econ Rev., 2014; 4: 23: **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4502069/**.

6. NPDUIS, Patented Medicine Prices Review Board, Meds Entry Watch, 2015, April 2017, p. 27: **http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/NPDUIS_MedsEntryWatch_2015_e.pdf**. Canada has one of the highest percentages of new drug launches worldwide at 61%. That compares to 40% in Australia and 33% in South Korea – two of the countries that PMPRB plans to use as comparators.

7. Ernst & Young, Innovative Medicines Canada Data Analytics and Members' Economic Footprint and Impact in Canada, 2017: **http://innovativemedicines.ca/wp-content/uploads/2017/10/20171030_EY-REPORT_IMC_FINAL.pdf**.

8. Conference Board of Canada, Understanding the Gap: A Pan-Canadian Analysis of Prescription Drug Insurance Coverage, 2017: **http://innovativemedicines.ca/wp-content/uploads/2017/12/20170712-understanding-the-gap.pdf**.

9. Nanos Research survey dated November 20, 2017, telephone survey of 4,445 Canadians: **http://www.nanosresearch.com/sites/default/files/POLNAT-S15-T771.pdf**.

10. Research by the Canadian Health Policy Institute found that provincial government spending on patented medicines is just 3.7% of their total spending on healthcare (removing distribution, mark-ups and pharmacy fees), Facts about the costs of patented medicines, 2017 Edition: **https://www.canadianhealthpolicy.com/products/facts-about-the-cost-of-patented-drugs-in-canada.html**.

11. Canadian Institute for Health Information, National Health Expenditure Trends, 1975-2017, Data Table A.3.3.1: **https://www.cihi.ca/en/national-health-expenditure-trends** and Canadian Institute for Health Information (CIHI), Prescribed Drug Spending in Canada, 2017: A Focus on Public Drug Programs, p. 15: **https://www.cihi.ca/sites/default/files/document/pdex2017-report-en.pdf**.

12. Patented Medicine Prices Review Board, Annual Report 2016, Ottawa, 2017: **http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1334**.

13. Patented Medicine Prices Review Board, Annual Report 2016, Ottawa, 2017: **http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1334**.

14. Form 2 Block 5 data submitted to PMPRB, July-December 2015, Innovative Medicines Canada members.

15. pCPA website: **http://www.canadaspremiers.capan-canadian-pharmaceutical-alliance/**

16. Picard A., Prescription drug costs should be fair — not cheap, The Globe and Mail, December 4, 2017: **https://www.theglobeandmail.com/opinion/prescription-drug-costs-should-be-fair-not-cheap/article37178981/**.

17. UK Government, Press Release, December 6, 2017: **https://www.gov.uk/government/newsgovernment-and-life-sciences-sector-agree-transformative-sector-deal**.

18. Consilium P., Ascending to the Peak of Biopharmaceutical Innovation, Biopharmaceutical Competitiveness & Investment (BCI) Survey, 4th Edition, 2017: **http://www.pugatch-consilium.com/reports/BCI_2017_Report.pdf**.

19. How to Foster Pharma Innovation: Belgium's Pact for the Future 2015: **https://www.tforg.com/how-we-think/sweetspot-blog/2015/08/14/how-to-foster-pharma-innovation-belgiums-pact-for-the-future-2015/**.

20. World Economic Forum, Value in Healthcare: Laying the Foundation for Health System Transformation, April 2017: http://www3.weforum.org/docs/WEF_Insight_Report_Value_Healthcare_Laying_Foundation.pdf.

21. Ernst & Young, Innovative Medicines Canada Data Analytics and Members' Economic Footprint and Impact in Canada, 2017: **http://innovativemedicines.ca/wp-content/uploads/2017/10/20171030_EY-REPORT_IMC_FINAL.pdf**.

22. Ernst & Young, Innovative Medicines Canada Data Analytics and Members' Economic Footprint and Impact in Canada, 2017: **http://innovativemedicines.ca/wp-content/uploads/2017/10/20171030_EY-REPORT_IMC_FINAL.pdf**.

23. PMPRB Annual Report 2016: **http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1334.**

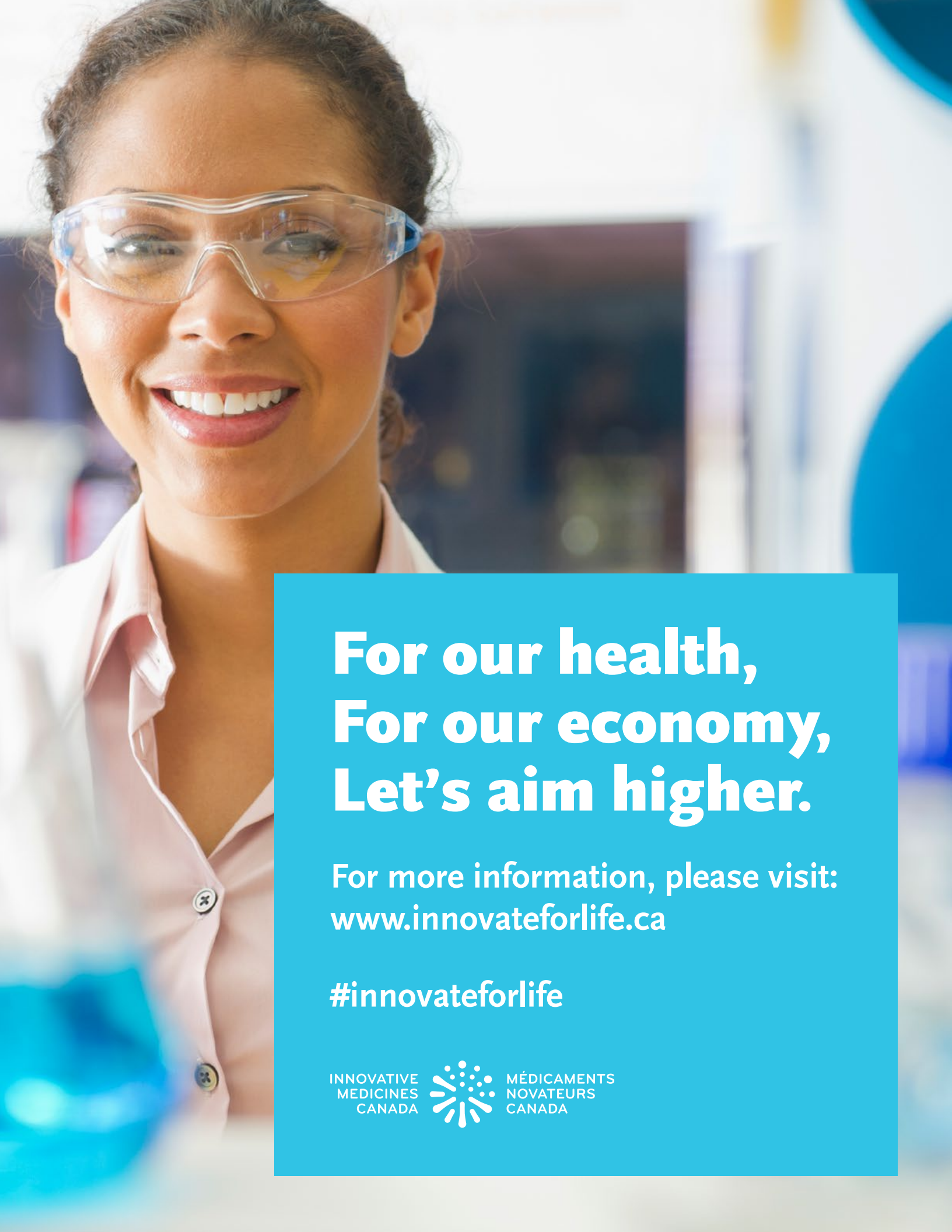
24. UK Government Press Release, December 6, 2017: **https://www.gov.uk/government/news/government-and-life-sciences-sector-agree-transformative-sector-deal**.

25. Government of Québec, Stratégie québecoise des sciences de la vie 2017-2027, May 5, 2017: **https://www.economie.gouv.qc.ca/fileadmin/contenu/publications/administratives/strategies/sciences_vie/strategie_sciences_vie.pdf.**

26. EvaluatePharma, World Preview 2016, Outlook to 2022, September 2016: **http://info.evaluategroup.com/rs/607-YGS-364/images/wp16.pdf**.

For more information on Innovative Medicines Canada, please visit:
www.innovativemedicines.ca

www.innovateforlife.ca
#innovateforlife



For our health, For our economy, Let's aim higher.

For more information, please visit:
www.innovateforlife.ca

#innovateforlife

INNOVATIVE MEDICINES CANADA

MÉDICAMENTS NOVATEURS CANADA