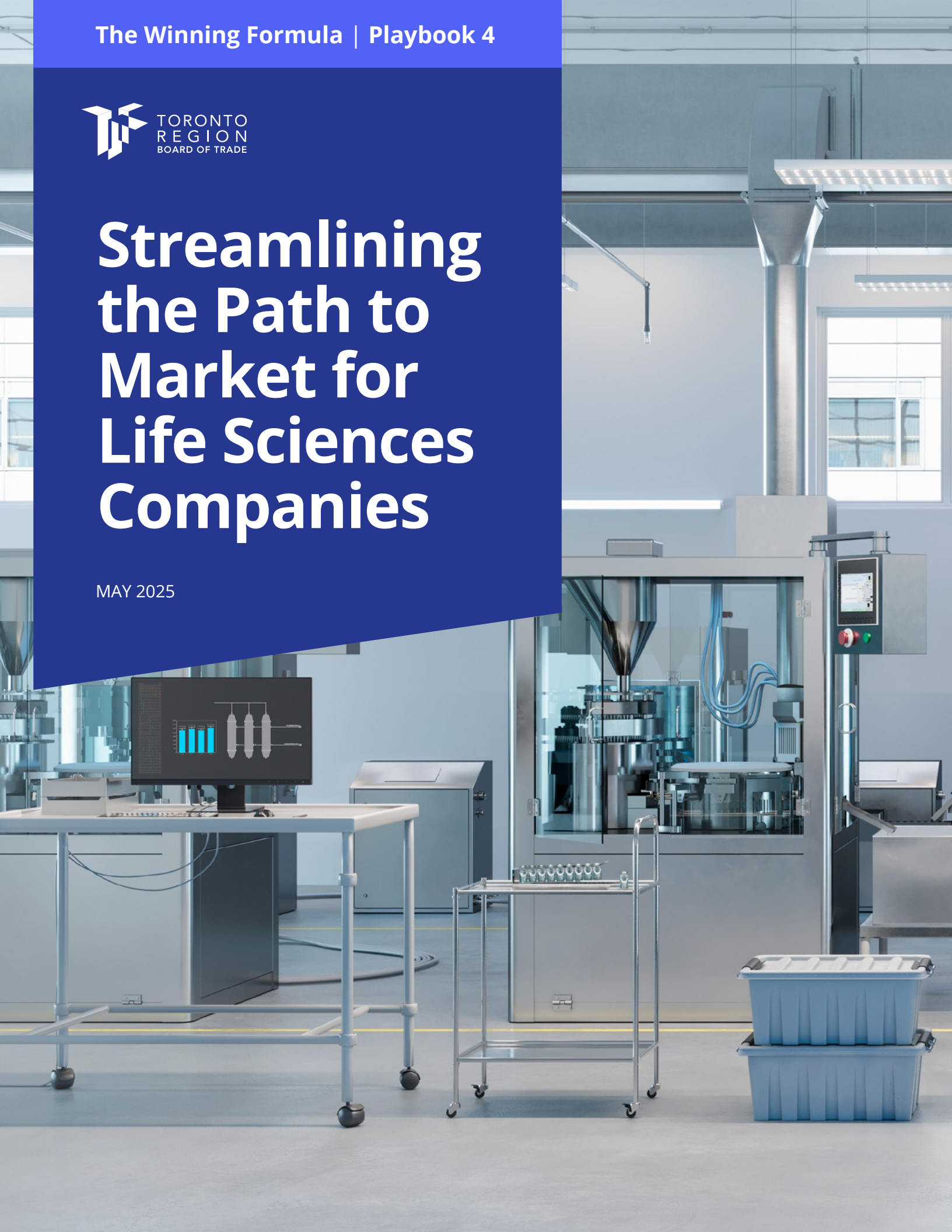
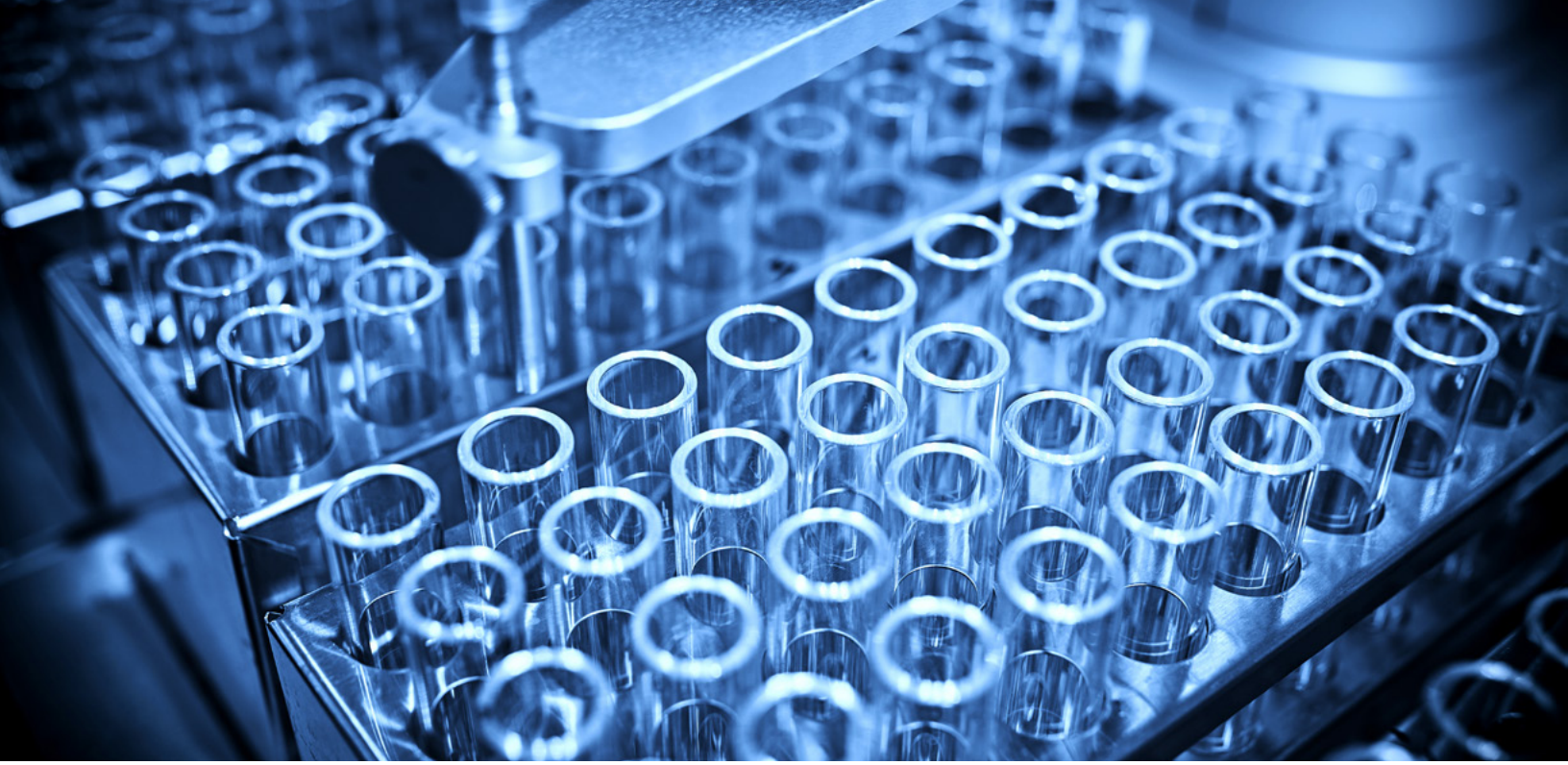
The Winning Formula | Playbook 4

TORONTO REGION BOARD OF TRADE

Streamlining the Path to Market for Life Sciences Companies

MAY 2025





Contents

About this playbook series

The 'Winning Formula' series offers an action plan for the Toronto region's life sciences sector, supported with four in-depth playbooks that identify the critical barriers holding the sector back.

The Toronto Region Board of Trade ('the Board') has long recognized the life sciences sector as a critical economic engine for the region. For over a decade, the Board has demonstrated thought leadership in this space, championing the sector's potential through events, reports, and rallying support across government, industry, and academia. This work is deeply aligned with the Board's broader mission to build a globally competitive, resilient economy anchored in innovation and inclusive growth.

Toronto-Waterloo Corridor Definition
Throughout the series, the area described as the Toronto-Waterloo corridor or 'the region' refers, unless otherwise specified, to the Toronto Census Metropolitan Area (CMA), Oshawa CMA, Kitchener-Cambridge-Waterloo CMA, Hamilton CMA, and Guelph CMA. Together, these areas encompass a functionally integrated, urban economic region that the Board defines as the Innovation Corridor. In cases where data collection and comparison are not possible for the region, smaller geographic units will be used, including the Greater Toronto Area and/or the City of Toronto.

Stakeholders Consulted
Insights in this report are informed by extensive engagement with stakeholders across the Toronto-Waterloo life sciences ecosystem, including multinational corporations, home-grown companies, post-secondary institutions, and industry associations. Contributions took various forms: some stakeholders offered direct input through individual consultations, while others shared their experience as speakers and panelists at the Board's latest life sciences events, including the following:

- **Life Sciences Symposium:** Can Toronto be the Next Boston?
- **Life Sciences Breakfast Series:** Medical Isotopes Revolution; Attracting Capital Investment and Anchor Companies; and Toronto's Regenerative Medicine Frontier

The authors are grateful for the invaluable insights, inputs, and resources shared by a wide variety of stakeholders, including:

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Action plan and four playbooks to transform the life sciences sector

For too long, efforts to bolster the life sciences sector have been cautious and piecemeal—falling short in the scale and coordination required to build a world-leading life sciences ecosystem here in Toronto. This action plan lays out a path forward, recognizing that meaningful progress demands bold and simultaneous movement across four key pillars: capital, infrastructure, talent, and a fast path to market.

Building on this action plan, we developed four complementary playbooks that dive deeper into how each proposed action can address the sector's major challenges:

PLAYBOOK 1

Unlocking Capital

Life sciences companies in Ontario face barriers raising capital. Companies argue that the challenges boil down to a low risk tolerance amongst Canadian investors for the life sciences sector, given uncertainties with clinical trials and long product development cycles. Conversely, investors active in the sector often note that the challenge lies less in the availability of capital than in the state of readiness of companies for investment.

In the absence of opportunities to raise capital, firms increasingly look abroad for funding, taking with them the economic benefits of high-growth, high-potential companies (job creation, intellectual property, and export development capabilities).

To unlock the capital needed for a growing sector, we must do three things:

1. **Strengthen the domestic investment ecosystem**
2. **Develop growth-focused programs to accelerate startups' development journey**
3. **De-risk investments through government incentives**

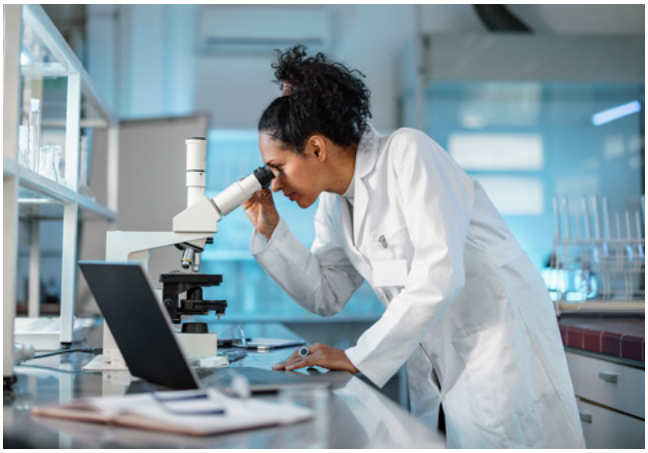
PLAYBOOK 2

Accelerating Wet Lab Construction

Ontario's life sciences sector faces a critical shortage of wet lab space, meeting only 52% of the estimated two million sq. ft. demand causing innovative companies to stall growth or relocate. Wet lab facilities, essential for biotech and pharmaceutical research, cost up to five times more than standard office spaces, and developers typically require 60% pre-leasing with long-term commitments, an unrealistic ask for most startups.

To accelerate wet lab construction, we must do five things:

1. **Increase construction incentives**
2. **Provide rental guarantees**
3. **Establish public-private partnerships**
4. **Expedite permitting and adjust land use policies**
5. **Better connect demand with supply**



PLAYBOOK 3

Strengthening Talent Pipelines

Ontario's life sciences sector faces critical workforce gaps, including a shortage of C-suite executives, experienced market-ready scientists, and bio-manufacturing workers, with only 25% of bio-manufacturing positions projected to be filled in the next five years. Despite a 36% increase in life sciences graduates from 2017 to 2022, the region struggles to retain talent due to lower average wages and fewer job opportunities compared to key competitors such as Boston and San Francisco.

To close the talent gap, we must do three things:

1. **Leverage short-term executive expertise and advisory**
2. **Expand support for talent development and retention programs**
3. **Encourage entrepreneurship**

PLAYBOOK 4

Streamlining the Path to Market

Accessing the Canadian life sciences market is challenging for life sciences companies given its fragmented regulatory, reimbursement, and procurement frameworks. While regulatory and reimbursement systems are complex to navigate, procurement policies focus on cost savings rather than value-added through innovation. For pharmaceuticals, this results in an average timeline of 2.5 years from global authorization to public reimbursement, compared to just eight months in the United States. For medical devices and other medical products, it means fewer opportunities to be commercialized, deterring the adoption of innovative technologies in the healthcare system.

To accelerate companies' paths to market, we must do four things:

1. **Adopt international standards**
2. **Ensure transparency on pricing practices**
3. **Harmonize reimbursement processes**
4. **Adopt a value-based approach to procurement**

Meaningful progress demands bold and simultaneous action across four key pillars: capital, infrastructure, talent and a fast path to market.

Realizing the economic power of life sciences

Ontario's life sciences sector is a powerhouse of innovation, home to 3,500 firms contributing $15 billion in GDP, and supporting 88,000 jobs with $10 billion in wages. Yet, Ontario's potential remains underutilized. Despite generating $86 billion in revenue and exporting $13 billion in cutting-edge innovations worldwide, systemic barriers push promising companies to ecosystems like California, whose mature market generated $472 billion in economic output.

Our Edge

The Toronto-Waterloo Corridor has the ingredients to lead in life sciences, including:

- Home to Canada's #1 life sciences research hub
- Five of Canada's top research hospitals
- 11 globally recognized universities and internationally renowned colleges
- A top 10 North American ranking in the Global Startup Ecosystem Index
- Home to the highest concentration of AI talent
- Over 720 university-spawned startups
- Robust pipeline of graduates in engineering, physical and biological sciences, mathematics, and AI
- #1 in active clinical trials per capita among all G7 nations
- Vast network of foreign and homegrown, high-potential companies

Ontario's life sciences sector at a glance

3,500 firms

$15B in GDP

$86B in revenue

88,000 jobs

$10B in wages

$13B in exports

Source: TRBOT Calculations. For more information, check The Winning Formula: An Action Plan to Unleash the Life Sciences Sector. Pages 25-29.

Understanding Canada's fragmented life sciences regulation and reimbursement pathways

In Canada, companies seeking to bring life sciences products to market face a fragmented regulatory environment shaped by overlapping responsibilities across federal and provincial governments as well as independent regulatory bodies. While the federal government oversees the approval and pricing of drugs and health technologies, provinces and territories fund and manage their reimbursement and procurement systems.

Unlike access to healthcare, prescription drugs are not universally covered in Canada. Generally, Canadians access medicines through one or more of the following options:

- **Public drug plans**
  Each province and territory operates its public drug plans, primarily delivered to seniors, individuals on social assistance, and other specific populations. Government-backed drug coverage—defined by formularies or a list of drugs covered—depends on eligibility criteria, age, income, and medical condition.

  Provinces and territories include drugs in their formularies by considering 1) recommendations by Canada's Drug Agency (CDA), 2) price and coverage negotiation agreements between the manufacturer and the Pan-Canadian Pharmaceutical Alliance (pCPA), and 3) their healthcare priorities and budget (more details on the specific roles of these institutions are provided in the following sections). On average, it takes 16 months before a drug is included in public formularies compared to only four months for private drug plans.

- **Private insurance plans**
  Two-thirds of Canadians have some form of private drug coverage, usually through employer-sponsored benefit plans or individual health insurance policies. Private plans often cover a broader range of medicines and provide faster access to new therapies than public plans. Insurance companies conduct their coverage assessments, focusing on drug efficacy, safety, and costs. Unlike public plans, private insurers are not bound by CDA or pCPA regulations, except for the province of Quebec, which mandates that private plans match the benefits offered in the province's program.

- **Out-of-pocket payments**
  For Canadians without public drug coverage or private insurance, medicines are paid out-of-pocket. Approximately 20 percent of Canadians have inadequate drug coverage or none at all.

The average timeline from global authorization to public reimbursement is 2.5 years in the Canadian market. It takes about eight months to obtain regulatory approval, 119 days to market launch, and another 1.5 years to reach the best-case scenario for public reimbursement. The same process takes only eight months in the United States.[1]

Similarly, healthcare procurement also rests with provinces and territories since they are responsible for managing and delivering healthcare services to their constituents. Each jurisdiction tailors its procurement policies, and many mechanisms are in place for companies to sell to healthcare institutions. These mechanisms include selling through Group Purchasing Organizations (GPOs), Shared Services Organization (SSO), Government-led procurement, direct negotiations, and contracts.

Instead of navigating a single provincial entity, companies engage in one or more of the mechanisms—each with its evaluation criteria, timelines, and budgets. This means that while an innovative device, for example, is widely adopted in one hospital, the same product can face multiple hurdles when trying to be sold to another institution.

Canada takes longer to approve drugs than other countries

Health Canada is the federal department responsible for regulating life sciences products by reviewing and approving prescription and over-the-counter drugs, biologics, vaccines, and medical devices before they can be marketed in Canada. Several studies have concluded that Health Canada takes longer to approve medicines from the time of submission than its counterparts—the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

A study examining approval dates for 33 new oncology drugs introduced between 2003 and 2011 found that not only were fewer drugs approved in Canada (24) compared to the United States (33) and Europe (26), but it also took twice as long for Health Canada to approve the same drugs in the U.S. (356 vs 182 days), and only slightly less than in the European Union (408 days).[2]

Manufacturers have limited access to drug pricing evaluation criteria

Once a drug is approved, there can still be a delay before the start of the reimbursement process. This begins with a price assessment by the Patented Medicine Prices Review Board (PMPRB). The PMPRB determines the price of a new drug based on:

1. The drug's level of therapeutic improvement

2. Prices for medicines in the same therapeutic class

3. International price comparisons with 11 countries (Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom)

The unnecessary complexity, variability, and discretion inherent in the pricing evaluation factors and guidelines have caused tensions between the government and industry. The federal government has proposed amendments to the PMPRB's process to reduce Canada's drug prices, as the average list price for patented medicines is the second highest among 31 OECD countries—only behind the U.S.[3]

However, industry has expressed concerns about the potential severe impact of the proposed changes on its revenue.[4] Currently, the PMPRB is in the process of developing an updated Price Review of Patented Medicines Framework, and new guidelines are expected to be implemented by 2025.[5]

Once the PMPRB has established the Maximum Average Potential Price for a new drug, drug applications for reimbursement undergo two subsequent assessments:

1. A clinical and cost-effectiveness review by Canada's Drug Agency (CDA)

2. A review by the Pan-Canadian Pharmaceutical Alliance (pCPA), evaluating factors such as affordability, current drug coverage alternatives, and therapeutic gaps

Companies submit an offer to the pCPA, which negotiates pricing and reimbursement criteria on behalf of provincial governments' drug plans. The issue lies in companies' limited access to information from CDA and the pCPA, including assessment criteria and pricing negotiation processes.[6]

As explained earlier, final pricing decisions and coverage ultimately rest with public and private drug plans. In Ontario, the Ministry of Health makes the final decision about the inclusion of a new drug in its public formulary, influenced not only by CDA and pCPA recommendations but also by the province's Committee to Evaluate Drugs (CED). The CED conducts additional assessments of the quality, therapeutic value, and cost of drug products—similar to previous regulatory assessments.

The regulatory landscape for medical devices in Canada

After obtaining Health Canada approval, medical device companies must acquire a Medical Device Establishment Licence (MDEL). This licence is mandatory for manufacturers, as well as importers and distributors across all device classes. The application process involves completing the MDEL application and remitting the applicable fees. Adhering to Health Canada's requirements for labeling, advertising standards, and post-market surveillance, is critical to maintaining the MDEL.

Upon securing the MDEL, companies are authorized to distribute their products to healthcare facilities, retailers, and other distributors. Unlike patented medicines, medical device prices are not subject to federal price controls. Manufacturers have the discretion to set their prices, though these are often influenced by negotiations with hospitals, healthcare facilities, and provincial health authorities during procurement processes.

The challenges of selling to Ontario's healthcare system

Selling a medical technology in Canada to healthcare providers requires navigating a decentralized procurement landscape shaped by inconsistent practices and financial constraints. Each province and territory implements its policies, budgets, and funding structures for healthcare institutions to purchase assets needed for patient care.

Hospitals, clinics, and other healthcare providers in Ontario rely on one or more of the following key actors to procure goods and services:

Group purchasing Organization (GPO): GPOs negotiate contracts with suppliers on behalf of a group of member organizations (e.g., hospitals) to secure volume-based discounts, acting as contract administrators. GPOs are often private and/or member-led.

Shared Services Organization (SSO): SSOs focus on not only procurement but also centralized shared services (e.g., finance, IT, and HR) on behalf of affiliated healthcare organizations. These are often established by provincial governments or health authorities to standardize practices and reduce administrative burden.

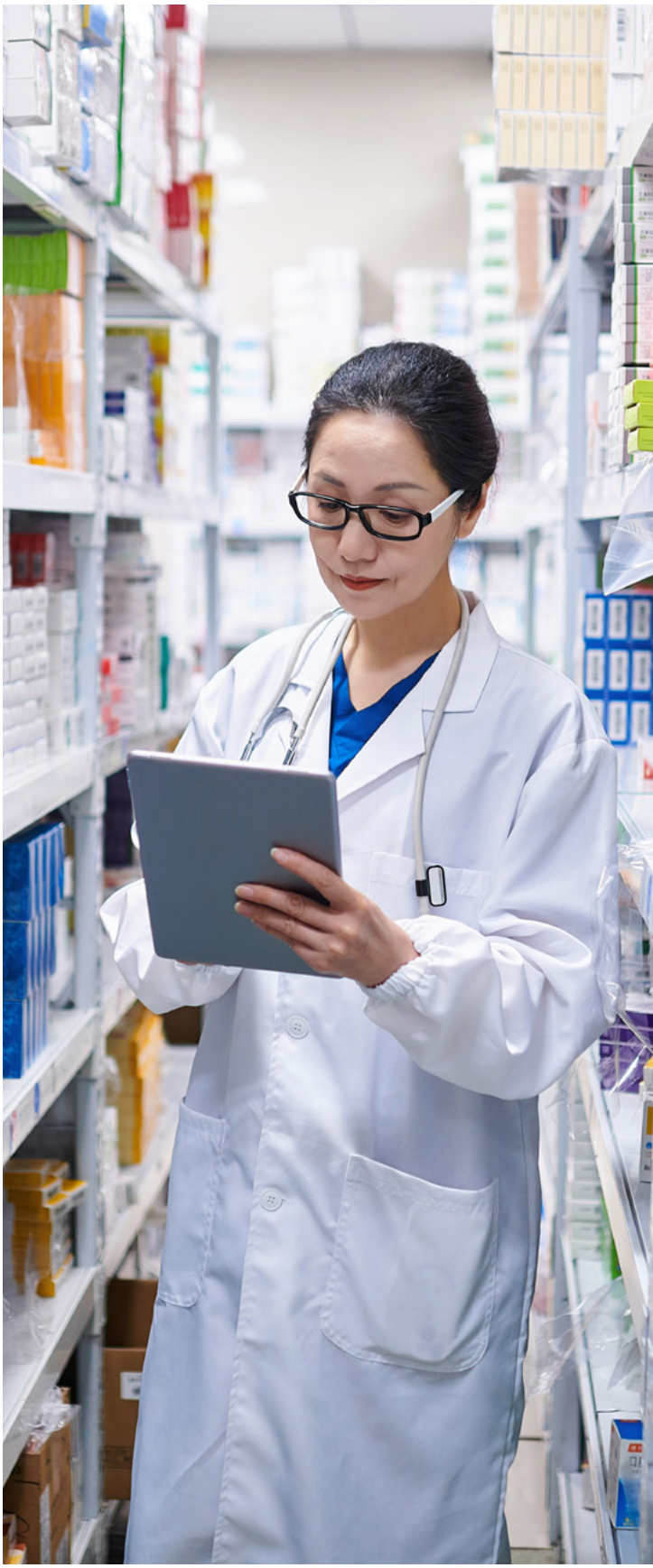
Internal procurement departments: Healthcare institutions can procure independently by posting procurement opportunities in the Ontario Tenders Portal (OTP), the province's official e-tendering system. Through this platform, institutions post Requests for Proposals (RFPs) or Request for Information (RFIs) to invite bids from suppliers. The institution's department handles the full process: drafting tender documents, evaluating submissions, evaluating submissions and awarding contracts.

Ontario's healthcare procurement landscape has long emphasized prioritizing the "cheapest priced" goods and services to demonstrate short-term savings, at the expense of long-term value for the healthcare system. This cost-centric approach, while addressing short-term budgetary limitations, often overlooks broader objectives critical for a patient-centered healthcare system.

By focusing primarily on the lowest upfront costs, the procurement system inadvertently sidelines investments in high-value products that, although initially more expensive, could lead to significant long-term benefits such as improved patient outcomes and overall cost reductions across the healthcare continuum.

Furthermore, the current approach to healthcare procurement in Ontario limits technology adoption. An overly rigid focus on costs can delay or prevent the purchase of cutting-edge goods and services that enhance diagnostic accuracy or treatment efficacy, ultimately affecting the quality of care patients receive. Domestic companies, particularly startups, are discouraged from introducing groundbreaking products when navigating Ontario's time-consuming, burdensome procurement processes.

Even when Ontario-based companies develop groundbreaking solutions, it is more compelling to seek markets elsewhere. Once a product is procured under a specific contract, opportunities often conclude there, with no mechanisms to facilitate broader adoption of products that have demonstrated positive health outcomes or cost savings in other areas. **Understandably, government procurement policies are designed to ensure cost control, but they lead to a paradox where technologies are developed here but benefit patients elsewhere first.**



What's at stake

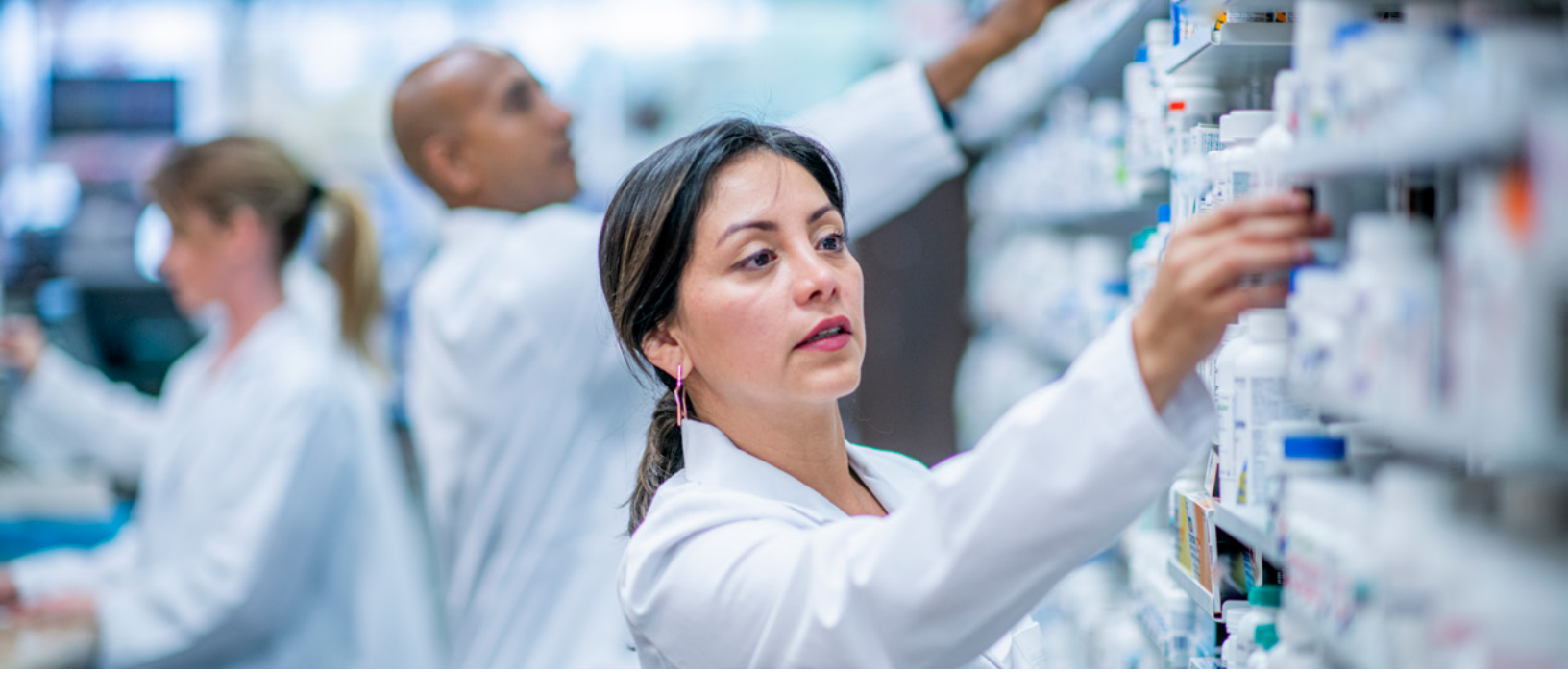
Canada's pathway for life sciences products to market is not competitive. The agencies involved perform a valuable role, however, their sequential nature and duplicative evaluations can mean that a life sciences product approved and available in other countries is still winding through Canada's and Ontario's layered regulatory process. These bottlenecks make it increasingly difficult for Canada to keep pace with global leaders, where innovation adoption and commercialization occur at a much faster rate. If our regulatory environment continues to discourage efficient market entry, the sector faces a risk of falling further behind, with competitiveness suffering the most. Without substantial reform, these challenges are likely to persist, creating ongoing obstacles that prevent Canada from fully realizing its potential in the global life sciences landscape.

Canada has one of the slowest market access processes among OECD countries, an increasingly costly disadvantage for life sciences companies, investors, and patients alike. Delays in getting therapies to market reduce the incentive to launch in Canada, cut into potential returns, and create barriers to timely care. When it takes nearly three times longer to launch a drug here compared to other jurisdictions, the financial case for entering the Canadian market becomes harder to justify. The longer and more complex the approval process, the greater the cost and uncertainty, particularly in a country that accounts for less than 2% of global pharmaceutical sales. **In a global race to attract investment, clinical trials, and new treatments, Canada's pace risks pushing drug launches or future studies to the sidelines.**

In Ontario's publicly funded healthcare system, securing reimbursement is critical for companies looking to scale, as it determines whether a product can be adopted system-wide and integrated into clinical practice. However domestic companies often encounter a cautious funding environment. Health system budgets are tightly controlled and primarily directed toward maintaining existing services, leaving little room for the adoption of new technologies, even those that demonstrate strong clinical value or long-term cost savings.

Ontario-based innovators face limited opportunities to test new products, secure early adopters, and scale their solutions. As a result, many home-grown innovations find initial success in international markets rather than domestically. Take Intellijoint Surgical—a standout Ontario medical technology company—as a case in point. Despite developing its navigation technology in close collaboration with 12 Ontario orthopedic surgeons and securing Health Canada approval back in 2015, the company didn't make its first sale to a Canadian public hospital until 2022.

In the years between, Intellijoint's tools were adopted in over 15,000 surgeries across the U.S., Australia, New Zealand, and Japan. Its eventual breakthrough at Toronto's Humber River Hospital underscored a frustrating reality: even proven Canadian innovations often gain international traction long before accessing the medical market at home, delayed by procurement systems that push companies to look elsewhere.[7]



Four actions to accelerate the path to market

Strengthening Canada's global competitiveness in the life sciences sector begins with modernizing our regulatory landscape. By streamlining and aligning approval pathways, we can eliminate inefficiencies, reduce time to market, and create a more agile, innovation-ready environment: one that supports the commercialization of next-generation health technologies and positions Canada as a destination of choice for life sciences investment.

ACTION 1

Adopt international standards

- **Health Canada should work toward greater alignment with trusted international regulators such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA),** in order to reduce regulatory duplication and streamline market entry. Harmonizing regulatory requirements can lower the cost and administrative burden for companies bringing innovative products to Canada, while preserving Health Canada's authority to uphold safety, efficacy, and quality standards.

- **Health Canada should implement a more agile, non-mandatory review process for products already approved by recognized international agencies**, one that enables faster access for Canadian patients without compromising oversight. This would allow the regulator to prioritize reviews where Canadian-specific evidence is needed, while leveraging trusted international decisions to avoid unnecessary delays. By modernizing its regulatory approach, Health Canada could expedite launches of new therapies in Canada and ensure that patients benefit from timely access to innovative treatments.

ACTION 2

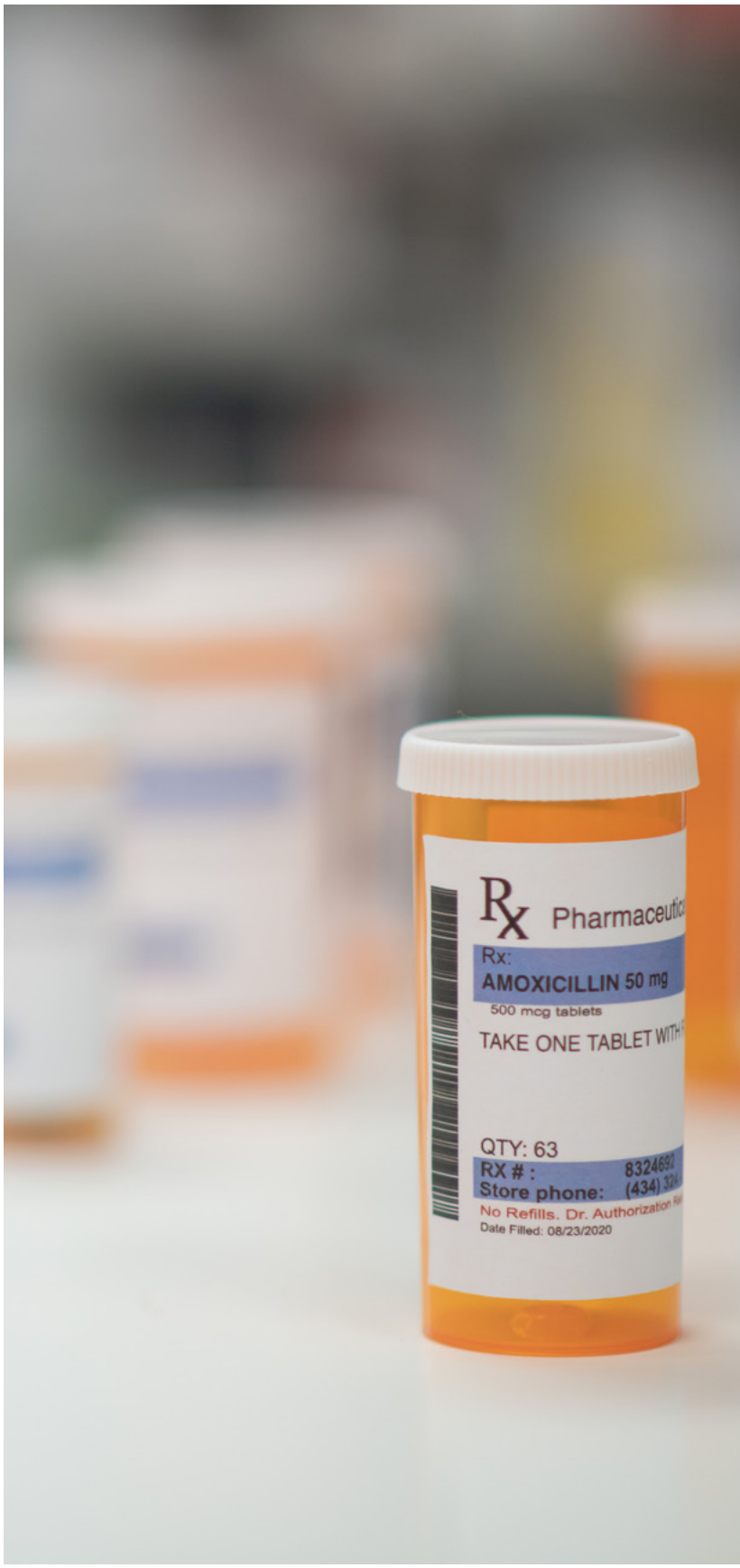
Ensure manufacturers have access to drug pricing evaluation criteria

Canada's Drug Agency (CDA) and pan-Canadian Pharmaceutical Alliance (pCPA) should work toward ensuring more transparent drug pricing negotiations with manufacturers. With a better understanding of information shared between both agencies, companies can anticipate potential challenges and enter negotiations more efficiently, helping to speed up the process without sacrificing quality and accountability.

ACTION 3

Harmonize provincial drug reimbursement frameworks with those of national bodies

- **The Ontario Committee to Evaluate Drugs (CED) should align its methodologies to avoid redundant assessments.** Doing so will strengthen the drug reimbursement process and ensure the timely inclusion of new drugs in Ontario's drug formulary.
- **The CED should adopt a mutual recognition model where it accepts CDA and pCPA's clinical assessments,** focusing its analysis on areas where Ontario has unique needs or concerns (e.g., budget impact or provincial priorities). This approach allows Ontario to maintain jurisdictional control over its drug formulary while reducing time to list and improving access to new therapies.



ACTION 4

Adopt a value-based procurement approach

- **The Provincial government should create a province-wide value-based procurement system that prioritizes health outcomes, economic value and efficiency for all hospitals and healthcare institutions.**

  Suggested guiding factors include:

  1. Alignment with the healthcare needs of the patient population
  2. Lifecycle cost analysis of a technology, including acquisition, maintenance, and disposal expenses
  3. Total cost of care reduction and long-term cost implications of a product or service, and its ability to reduce downstream healthcare expenses such as hospital readmissions
  4. Prioritization of solutions that have demonstrated efficacy through clinical evidence and tangible health benefits

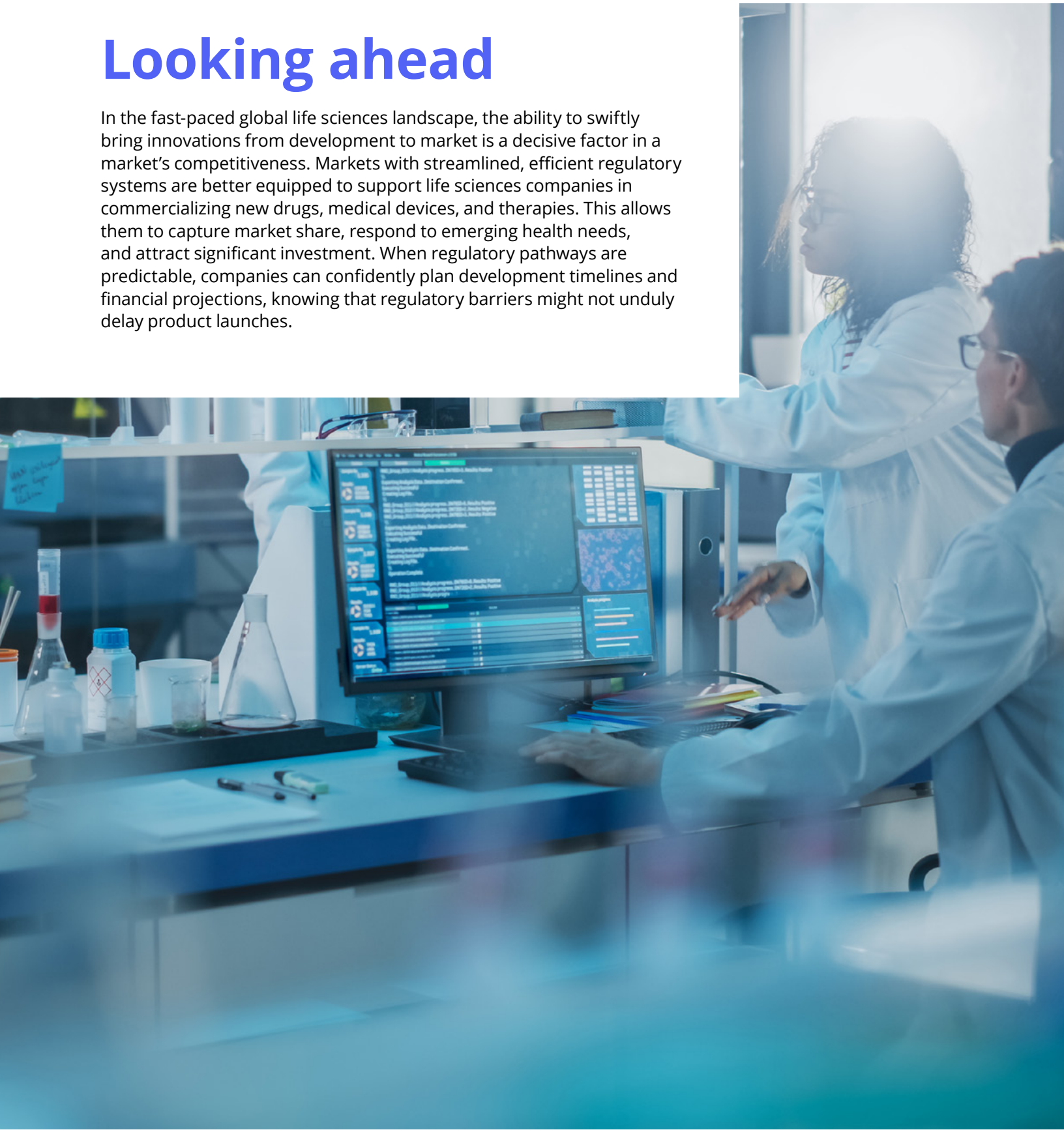
- **The provincial government should create a Provincial Technology Certification Office to assess and certify medical devices for procurement across Ontario.** By granting a province-wide approval certification, an office under the Ministry of Health could reduce the need for redundant review by individual healthcare facilities or networks and shorten the timeline from tender issuance to acquisition.

- **The provincial government should create a directory of market-ready, made-in-Ontario life sciences technologies to support the adoption of local innovation.** This tool would enable hospitals and health networks to easily identify homegrown solutions that have demonstrated readiness and impact. Backed by a province-wide approval or certification system, the directory could serve as a trusted resource for procurement officers seeking effective, Ontario-developed technologies.

- **The provincial government should develop a one-stop procurement concierge program that allows businesses of all sizes to engage in public sector procurement.** Over the next five years, the government of Ontario is expected to design and implement a one-stop procurement concierge program that could provide emerging startups with the critical opportunity to test their products, secure early adopters, and scale their innovations. A brand-new program could be modelled after British Columbia (BC)'s procurement Concierge program, which offers an online "matching" platform that connects suppliers with the procurement needs of hospitals and healthcare facilities.

Looking ahead

In the fast-paced global life sciences landscape, the ability to swiftly bring innovations from development to market is a decisive factor in a market's competitiveness. Markets with streamlined, efficient regulatory systems are better equipped to support life sciences companies in commercializing new drugs, medical devices, and therapies. This allows them to capture market share, respond to emerging health needs, and attract significant investment. When regulatory pathways are predictable, companies can confidently plan development timelines and financial projections, knowing that regulatory barriers might not unduly delay product launches.



Endnotes

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The Toronto Region Board of Trade is one of the largest and most influential chambers of commerce in North America and is a catalyst for the region's economic growth agenda. Backed by more than 11,500 members, we pursue policy change to drive the growth and competitiveness of the Toronto region, and facilitate market opportunities with programs, partnerships and connections to help our members succeed – domestically and internationally.

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