



BLUESKY PROJECT

Reimagining Canada's Approval and Reimbursement System for Innovative Medicines

February 2022

INNOVATIVE
MEDICINES
CANADA



MÉDICAMENTS
NOVATEURS
CANADA

EXECUTIVE SUMMARY

Every new medicine in Canada must satisfy multiple requirements to be accessible for individual patients and the Canadian healthcare system as a whole. These requirements are spread across a range of agencies and jurisdictions, each with differing mandates, regulatory frameworks, and accountabilities. Timing and eventual outcomes for a given new medicine are too often variable and uncertain. There is a growing sense among many stakeholders that Canada can – and should – improve the process for all.

As the voice of the innovative pharmaceutical industry in Canada, Innovative Medicines Canada (IMC) has taken the initiative to think through the possibilities for evolving the current Canadian system to improve its efficiency and predictability for all stakeholders.

Specifically, IMC supports a model grounded in a modern, ambitious vision for what a best-in-class review and reimbursement system should feature. For IMC, the entire process must be reshaped to better serve patient interests in an aligned, integrated manner at all stages of review (including post-approval). The system must feature much greater predictability, accountability, and agility to incorporate emerging science. The end goal must be much more equitable access to medicines.

IMC supports a system which incorporates the right tools and practices to realize the system vision. Much more work is required to facilitate rapid access to urgent, priority medicines where required. Canada's infrastructure for performance-based agreements and other novel reimbursement arrangements is incomplete and uneven. The process itself must be adapted to the reality of many new technologies – Health Technology Assessments (HTAs), for example, may not be appropriate or useful at time of market entry for every single product (as is currently the case). Stakeholder voices must not just be solicited, but rather fully integrated across the review process and overall product lifecycle to inform best decision-making for all parties.

Realizing this vision and introducing new tools will require extensive consultation and dialogue to ensure durable adoption and to meet the objectives of any shared vision. A new system for Canada must be underpinned by identifying tangible opportunities for process improvements and efficiencies. Equally, any proposals considered for Canada must be informed by the experiences in other leading jurisdictions – not for Canada to adopt without assessment but rather to understand the respective challenges and opportunities already experienced around the world on many of these key questions or ideas.

Looking to the future, IMC is keenly interested in convening the appropriate policy conversations with all relevant stakeholders in an open and inclusive fashion. There are often many different paths to reaching the same objective – but it is only through the consultative process that the best solution for Canada can be established. There is no time to waste – with science and medicine increasingly offering promising new therapeutic possibilities, Canada must position itself as a leading jurisdiction for new product launches while offering a clear and sustainable review and public reimbursement system for the benefit of all parties.

INTRODUCTION

Canada's system for the regulatory approval, health technology assessment, pricing and public reimbursement of new medicines and vaccines is complicated and subject to ongoing evolution. Multiple agencies with – at times – overlapping mandates have emerged across various levels of government jurisdiction. Health system stakeholders are increasingly at risk of misunderstanding the overall policy intent, such as it may exist.

More urgently, Canada's global position as an advanced economy capable of attracting timely launches of new innovative therapies is facing both internal and external challenges. While other jurisdictions are exploring and adopting novel approaches to how new medicines are assessed and integrated into patient care pathways with the goal of sharing risks and benefits among all stakeholders, the Canadian system has been characterized by misaligned policies, inefficiencies, and variable procedures and timelines for reimbursement. Too many treatments are taking far too long to be available for the patients who can benefit from them. Canada has not kept pace with global best practices with respect to facilitating early patient access, real-world data capture and utilization, and novel agreement models.

Greater urgency and common purpose are required to reimagine what Canada's overall system can and should be. This document sets out some initial thinking from the membership of IMC. It has been developed as an important early step for the wider multistakeholder collaboration and political leadership that will be the necessary preconditions of lasting and effective policy change.

ABOUT INNOVATIVE MEDICINES CANADA

IMC is the national voice of Canada's innovative pharmaceutical industry. We represent companies, ranging from established organizations to fledgling startups, all of whom are dedicated to improving the lives of Canadians. IMC advocates for policies that enable the discovery, development and commercialization of innovative medicines and vaccines.

A SHARED CANADIAN VISION FOR APPROVAL AND PUBLIC REIMBURSEMENT OF NEW MEDICINES

Canada's current system has evolved as an aggregate of decades of discreet decisions taken by various governments, agencies and stakeholders. If a common objective was ever set out, it has not been the subject of open debate and public consensus. Rather, adjustments to the overall process have been adopted over time absent any clear articulation of their ultimate impact on the shared health system that all Canadians want and depend on.

Taking the opportunity to step back and reconceive what a modernized, best-in-class approval and public reimbursement system is, is important for multiple reasons. Spending the required time to align on a shared vision at the outset generates an agreed point of reference to consider, evolve or introduce any specific elements in the overall system. It allows all stakeholders to ask the critical question: does this particular policy or process advance the vision we support? Are there opportunities to learn from other jurisdictions? Can we identify and remove duplicative activities and drive greater consistency and predictability for all parties? An updated system vision is also the basis on which to focus future activities, particularly by narrowing focus on those policy and process areas which will require further work and choices.

IMC supports a system vision of the future which starts and ends with the patient. The terminology of "patient-centred" is commonly applied in a range of different contexts of medicine and may not always be used with sufficient precision. For this context, the ultimate purpose of Canada's system of reviewing and enabling access to new medicines must meet the current and future health requirements of Canadians at a sustainable and world-class standard.

This vision has several more specific implications:

1. A genuinely patient-centric system must sustain robust and equitable reimbursement coverage for all Canadians, irrespective of geography, ethnicity, gender, employment status. The aspiration should be a system which provides a high-level of coverage across all disease states, in a constant state of evolution as

medical science offers promising and safe innovative treatment options. This aspect of the vision does not imply a single source of coverage, but rather a dynamic, diverse coverage universe that can accommodate different patient preferences while ensuring a high level of equity across Canadian society.

- 2.** MC supports a vision of a future system which incorporates predictability, timeliness, and overall agility as core components of its mandate and operations. Canadians expect and deserve a system which can move as fast as any in the world in integrating new innovations. As a practical matter, any new medicine cannot be launched in every jurisdiction simultaneously. However, on the global stage, a more predictable and collaborative system will allow Canada to remain at the forefront of attracting early launches to respond to health challenges and improve health outcomes as quickly as possible.
- 3.** Canada's system must aspire to function in a more integrated manner. Too often, different policies from different agencies or levels of government are uncoordinated. This does not result in compromise, consensus outcomes but rather a general level of dissatisfaction and lack of progress on all fronts. If one aspect of the system upstream – market authorization, for example – incorporates a key element, this should be reflected downstream in any subsequent activities by other agencies. In place of defending the siloed, established processes, all parts of the system should be challenged to adapt and align to a larger vision in service of the common end-user: the Canadian patient.
- 4.** Finally, a vision for the future must embrace an approach to value that is sustainable and balanced. Budgets are not infinite and should not be allocated without due consideration. For the industry responsible for bringing innovative medicines to the Canadian market, there must be an up-front recognition that the full value of that innovation can only be realized if we can establish its value to society while ensuring it is made available to patients in a sensible manner. We cannot allow the tensions between purchaser and supplier to prevent dialogue, shared urgency, and creative approaches to measuring value and sharing risks over both the short and long-terms.

This initial vision represents a key opportunity to revitalize the larger conversation for all system stakeholders around the system Canadians

need. It is the start – not the end – of the needed conversations ahead. The intent here is to establish key areas that should be contemplated, refined and incorporated into a future model of reviewing and reimbursing new innovative medicines.

IMC's membership has set out some additional considerations – key elements of a future system to support the initial vision – for additional context and dialogue.

FUTURE SYSTEM ELEMENTS: GIVING SHAPE TO THE VISION

While any vision depends on broad, aspirational language as a platform to define consensus, eventually the system must work to define its constituent elements and core activities as pillars of operation. Essentially, the vision must be granted shape and direction in order to be realized. IMC's membership has initiated the process of delving deeper into those aspects which offer the chance to animate the aspirational vision.

Specifically, six (6) broad areas of attention have emerged as key elements in realizing the consensus vision:

- 1. Rapid Access**
- 2. Performance-Based Agreements (Innovative Reimbursement Solutions)**
- 3. Agile Health Technology Assessment (HTA)**
- 4. Enhanced Stakeholder Input**
- 5. Disease-Based Approaches**
- 6. Competitive Incentives**

1. Rapid Access

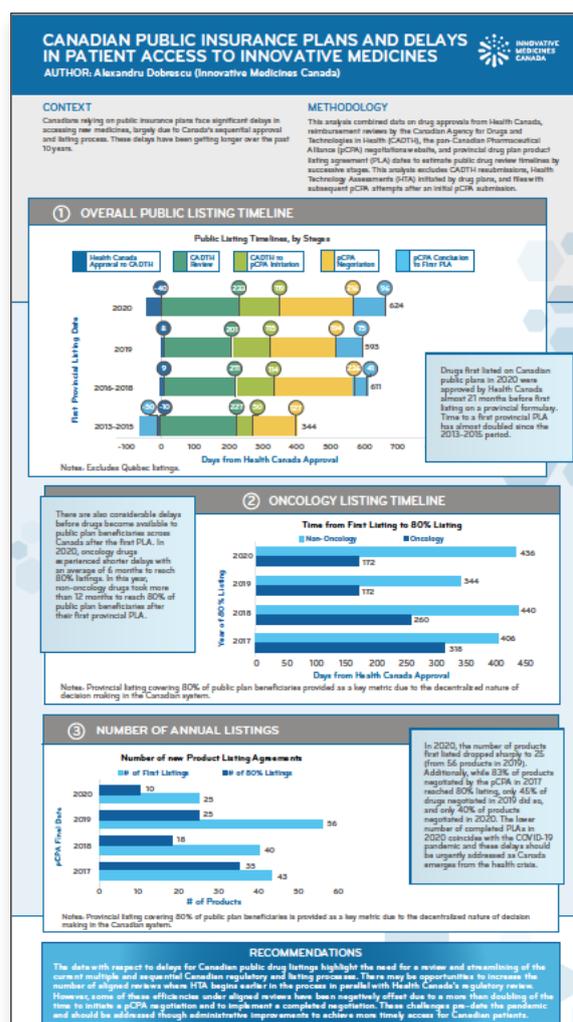
Many Canadian patients are waiting too long for access to new treatments, even when approved by Health Canada and reviewed by other agencies for pricing compliance and cost-effectiveness. The current

system processes remain uncoordinated, unpredictable, and prone to delays or uneven decision-making across the country. As recent analysis demonstrates, there is substantial room for improvements in this regard.¹

While not every new therapy arriving to the marketplace is first-in-class or addressing a clear unmet medical need, there are multiple examples of exasperated patients, families, and clinical teams desperate to deploy certain therapeutics on an urgent basis.

Any future reimbursement system must build in the necessary flexibilities and efficiencies to identify and accommodate these highly urgent situations with a much greater sense of predictability and purpose. The goal should be the opportunity for access before or at regulatory approval, assuming the appropriate criteria are addressed and supervised. Interim availability and funding models should be explored and scoped with clear inclusion and transition criteria to the larger reimbursement system. There is the possibility to advance the availability of treatments by months or even years in some cases – with consequent positive health outcomes for patients.

To be clear, not every new medicine will be appropriate for accelerated approval and listing. But as it stands currently, the example of new medicines granted Priority Review at Health Canada is highly illustrative of the challenge. Once approved, these medicines may not receive any separate treatment or adjustments in the lengthy process of review and negotiation prior to being made available to patients. One part of the process makes an accommodation which is not



¹See "Canadian Public Insurance Plans And Delays To Patient Access To New Innovative Medicines" (A. Dobrescu, IMC, CADTH Symposium, November 2021) <http://innovativemedicines.ca/resource/les-regimes-dassurance-publics-canadiens-et-les-retards-dans-lacces-des-patients-aux-medicaments-novateurs/>

reflected at subsequent stages. This can and must change if Canada is to truly realize a patient-centred reimbursement system for new medicines.

2. Performance-Based Agreements²

As biomedical sciences progress, new treatment platforms and mechanisms of action are presenting exciting new therapeutic options to address many disease states. For many of these conditions, the emerging evidence is compelling while not conforming to traditional disease population models.

For example, as our understanding of genomics grows, many emerging treatment options can now target ever-more patients and populations based on genetic or other biomarkers. In other cases, it may be challenging or even unethical to conduct traditional double-blinded, placebo-controlled confirmatory clinical trials due to any number of issues including disease profiles and relative severity, intended patient population profiles (e.g., pediatrics, pregnant women) and other similar challenges.

It is becoming increasingly clear that many of the questions or uncertainties about the expected benefit of certain treatments are unlikely to be resolved to the satisfaction of many system stakeholders prior to market approval and use in the “real world.” It is no longer viewed as tenable to defer wider (yet supervised) use of a new therapy in favour of attempting further and potentially inconclusive clinical trials over many months and years.

There are also inevitable financial questions surrounding many new medical innovations, especially those with non-traditional evidence packages. Payers are understandably torn between their desire to enable



²For further reading, see “Innovative Agreements Framework” (Innovative Medicines Canada, October 2021) <http://innovativemedicines.ca/wp-content/uploads/2021/11/IAFramework-Industry-Oct-2021.pdf>

access to potentially beneficial therapies for their patient populations against finite and typically pressurized medicine budgets and concerns about relative opportunity costs and maximizing population health as a whole.

There is an opportunity to establish new frameworks for different types of reimbursement solutions to address both clinical and fiscal considerations. Often described as “pay-for-performance” or “managed entry”, all parties can identify and commit to activities, timelines and relevant terms and conditions to monitor key aspects of a particular medicine’s place in therapy and clinical performance over time. Novel agreements can also be structured to allow for staggered payments, adjustable rebates or other mechanisms to balance the needs and priorities of each party.

Importantly, the notion of adjusting based on a shared set of decision factors is the foundation of all parties realizing appropriate value from the investment in the new medicine. Based on what occurs in practice, clinical and financial parameters can be adjusted with the active involvement of not just manufacturers and payers but also clinical experts and patients.

3. Agile HTA

Canada’s system of HTA has matured over a number of years. Conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH) for all public jurisdictions with the exception of Quebec, and by *l’Institut national d’excellence en santé et services sociaux* (INESSS) for Quebec, HTA review is a mandatory requirement for public reimbursement in all but the most exceptional instances. HTA aims to conduct a rigorous, evidence-based comparative review of a given new therapy’s clinical and cost-effectiveness. While HTA bodies are able to conduct larger class reviews for multiple agents already on-market, the majority of efforts are focused on conducting reviews at time of market entry. Almost all new medicines are subject to the same review expectations and standards.

For the reasons discussed above, this focus at the time of market entry may not always be appropriate for a given therapy based on the realities of the available evidence. Rather than leaving the general process and requirements in place without adjustment, there is a different approach to conducting HTAs which is more dynamic, recognizing that evidence can and will evolve over time. For some medicines, conducting an HTA at time of market entry may be incomplete, premature, or may not be capable of providing useful, actionable recommendations for clinicians, payers and other system stakeholders. These issues should not stand as a barrier to timely patient access supported by monitoring and real-world evidence (RWE) collection and analysis. In fact, a shared commitment to generating and utilizing RWE over time can allow for

clear benefits to all parties, addressing questions and areas of uncertainty while promoting a more efficient and proportionate process overall.

4. Enhanced Stakeholder Input

The interest and value of inviting and incorporating the perspective of health system stakeholders in decision-making is increasingly expected and regarded as best global practice. There is no substitute for the lived experience and informed perspective of patients, caregivers or clinical experts. These stakeholders have an invaluable role to play in ensuring relevant information is available to decision-makers, including on priorities, disease impacts, treatment preferences, and other considerations.

In Canada, some steps have been taken by various agencies to solicit feedback or integrate the perspectives of stakeholders in reviews and the overall reimbursement process. There are many theoretical approaches which have established models and approaches to implement.³ But this has not always been as uniform, rigorous or extensive as in other jurisdictions. There is a clear opportunity to take this critical consideration to the next level as a societal imperative.

If decision-making is to evolve as more dynamic and flexible, then so too must the process of seeking and integrating the necessary input from impacted stakeholders. Expanding and regularizing this work has the added benefit of strengthening the health system. By promoting a greater understanding of medical needs, available treatments and the perspectives and priorities of each stakeholder, the eventual decisions which emerge are inevitably much more understood and actionable. Our health system benefits from not just the decision itself but a much richer understanding of why a given decision was taken, supported by the reassurance that those expert perspectives were incorporated into the process in a meaningful way.

5. Disease-Based Approaches⁴

The current configuration of health delivery – and the financial structures to support it – are grounded in established administrative practices.

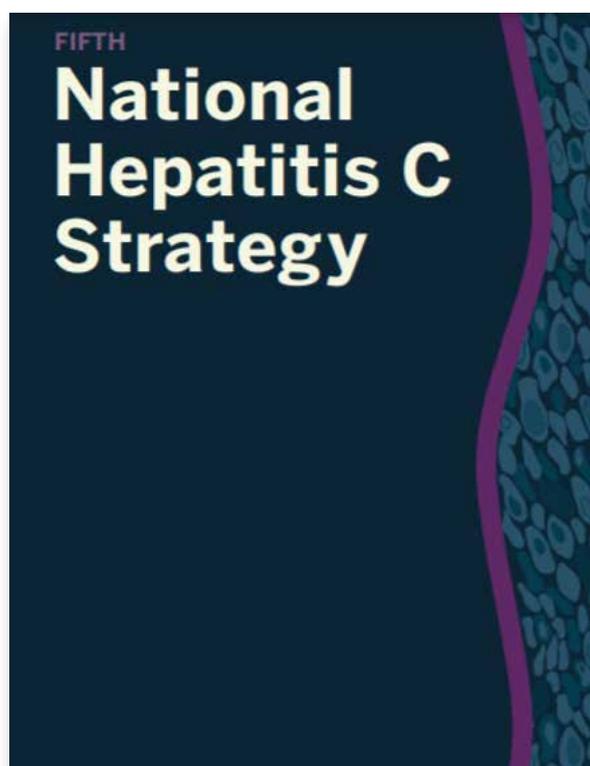
³ For example, Multi-Criteria Decision Analysis (MCDA). [Multi-criteria decision analysis for health technology assessment: addressing methodological challenges to improve the state of the art | SpringerLink](#)

⁴ For further reading, see [20210326_IMC_Drug_Rare_Disease_Consultation_FINAL.pdf \(innovativemedicines.ca\)](#)

Jurisdictions conceive programs, seek and receive annual budgets, and measure performance according to well accepted rules and guidelines. Importantly, specific budgets are allocated against specific programs for specific purposes, whether it be hospitals and health authorities, public health, physician compensation schedules, or pharmaceuticals coverage. With certain exceptions, budgets are built and managed against individual activities and not the broader policy goal. Incentives may not be properly integrated across the system or may even be outright misaligned.

While targeting the funding and measurement of the outcome, and not the activity or “thing” being paid for, sounds like common sense, it has proven far more challenging to model and implement. In the Canadian context, efforts have been made to reconfigure budgets in certain instances, but this has yet to achieve permanent critical mass – policy “escape velocity.” Some jurisdictions have also attempted to organize more coherent care models – notably in oncology through the various Cancer Agencies – but even within these distinct models there can be a tendency to fall back on narrow budget siloes for each discrete program or activity area.

There are recent examples of attempts to address other disease states worth further consideration. For example, Australia has pursued a national program of Hepatitis C eradication since March 2016.⁵ Importantly, this policy was enabled by the availability of multiple, highly effective innovative therapeutics. But as a comprehensive, integrated approach, the Australia policy also incorporated incremental funding increases, unrestricted access to therapeutics grounded in expenditure limits, and expansion of the role of healthcare providers, notably pharmacists, to implement the strategy.



⁵See for example: [Elimination of Hepatitis C Virus in Australia: Laying the Foundation - PubMed \(nih.gov\)](#)

Active conversations continue in Canada for many challenging disease states which could be suitable candidates for this type of holistic, unified approach to treatment incorporating a range of services into more coordinated, seamless care models. By aligning the various elements of care delivery under a single framework, the intent would be to capture and evaluate the results and overall value to the patient and society. Adjustments in budgets should only be evaluated in the context of results – increases in some aspects of service delivery may be warranted when directly linked to clear outcomes.

6. Competitive Incentives⁶

The ability of Canada to attract new biopharmaceutical investments, including early launches of new innovative medicines and vaccines, depends on predictable and competitive market conditions. This aspect incorporates multiple legal, regulatory, and commercial inputs which, in aggregate, make up Canada’s relative international position.⁷

MAKING CANADA AN INTERNATIONAL LIFE SCIENCES LEADER
 Canada's innovative pharmaceutical industry is committed to collaborating with federal and provincial governments to build a thriving life sciences sector, one which will protect Canadian patients' access to the newest, most innovative medicines, that will attract investment to Canada, foster innovation, and contribute to a more robust domestic manufacturing capacity. Achieving this goal will require two things:

- 1 A COMMITMENT TO WORK TOGETHER**
 The collaboration that has taken place over the last year – between industry, governments, researchers, and patients – has fueled the discovery, development, approval, and delivery of vaccines and treatments in near record time. That model of collaboration must now become the standard for how we move forward.
- 2 A COMPREHENSIVE STRATEGY**
 The report from Canada's Health and Biosciences Economic Strategy Table recognized that building a thriving life sciences sector requires us to have an "whole-of-government" approach, an approach that considers not just what bio-manufacturing strategies are needed, but one that considers Canada's policy and regulatory environment in a holistic way.

This document outlines the industry's recommendations for a comprehensive and integrated approach to building a thriving life sciences sector in Canada.

THE OPPORTUNITY
 The COVID-19 pandemic has graphically demonstrated the need for a better life sciences environment in Canada. The innovative biopharmaceutical industry can make important contributions to Canada's health and life sciences environment:

- Access to capital;
- Expertise in R&D, commercialization and manufacturing;
- Partnerships with universities, colleges, life sciences clusters, VCs, CDMOs and start ups;
- Assistance with post-pandemic health system challenges; and
- Long term vision and perspective.

While the industry is only one component of the life sciences sector, the experience of other leading life sciences jurisdictions demonstrates the contributions it can make to national health and wealth.

CANADIAN STRENGTHS
 Canada has important life sciences strengths and assets that can be better leveraged, including:

- Universities and Colleges with recognized medical, and biomedical and software and computer engineering faculties;
- Public healthcare system infrastructure;
- Emerging innovation clusters in regenerative medicine, oncology, infectious diseases, metabolic diseases, neurodegeneration, genomics and personalized medicine; and
- World leader in key sectors such as AI and stem cell therapy/regenerative medicine.

Canada's strengths are recognized internationally, and a collaborative effort can fully unleash its life sciences potential.

Offering consistently favourable operating conditions in a globally competitive environment is important. As a relatively small national market, Canada should not make any assumptions on its future ability to capture the complete value from the pharmaceutical sector. Recognizing that other jurisdictions are continually assessing and evolving their relative frameworks and global positions, Canada can and must take a far more active, “hands-on” role in anticipating emerging scientific developments

and ensuring that its complex system is adequately equipped – not just to receive research investments, partnerships, and new commercial launches,

⁶For further reading, see *Making Canada an International Life Sciences Leader* http://innovativemedicines.ca/wp-content/uploads/2021/05/20210330_Making_Canada_International_Life_Sciences_Leader_EN_Final.pdf

⁷For further reading, see *20210312_ISED_Biomanufacturing_IMC_response.pdf* (innovativemedicines.ca)

but to embrace and incentivize those high-value activities on the global stage. This work cannot be static but must be monitored and improved upon at frequent intervals.

Part of this process must also be a commitment to work from a sound evidence base and avoid false economies. There has been a perception in the past that Canada was unable to maintain or actively cultivate pro-innovation policies out of concerns for their implications for value seeking and financial sustainability. This is misplaced thinking that inhibits Canada's long-term competitiveness. Fundamental elements of the private sector's ability to assume risks over months and years include a clear and consistently applied intellectual property regime, timely and transparent review and assessment processes, modern and agile regulatory frameworks, and an ability to access and compete in the marketplace in a predictable manner.

None of these elements restrict the ability of budget-holders to conduct reviews or negotiate reimbursement arrangements, including novel agreements, with the innovative industry. Quite the opposite: with a strong, predictable, and world-class operating environment, Canada enhances its ability to engage with the private and public sector and drive mutually beneficial agreements and overall sustainability in the service of its citizens' health.

MOVING FORWARD: KEY ENABLERS AND TOOLS

Translating the idealized access to medicines system for Canada will inevitably require time and the meaningful participation across and between various stakeholders. No one single organization can achieve change on this scale without the involvement and contributions of others.

Looking ahead to the future, there are a number of practical steps that Canada can start pursuing now to prepare the ground and provide a much more secure opportunity to properly define and reach its policy goals for patients.

Enabler 1: Drive A More Efficient Process

Future aspirations and bold objectives are important anchors to reimagining the Canadian access system. At the same time, recognizing the reality of the current set of agencies, procedures and timelines and driving tangible, incremental improvements will directly benefit patients while strengthening the ability of all parties to collaborate on larger, longer-term changes.

Opportunities have already been identified within each current process element to advance efficiencies while still respecting the mandates and purposes of each activity area. Key opportunities include:

- At the regulatory level, including expanding priority review criteria, increasing the use of conditional approvals, further advancing international regulatory collaborations, scaling the rolling review process, adopting other agile regulatory tools, and committing to more active and ongoing communications with sponsors;
- At the Health Technology Assessment (HTA) level, including implementing a common submission portal, advancing work-sharing between agencies, making additional investments in capacity and patient expertise, and exploring “rolling” HTAs to mirror key regulatory initiatives;
- At the joint price negotiations level, including enhancing staff capacity and resourcing, improving the process timing, performance standards and metrics reporting transparency, establishing a best practices approach for both manufacturers and jurisdictions, standardizing the roles and timing of jurisdictional interventions, and adapting an appropriate appeal process and dispute resolution approach;
- At the jurisdictional level, including expanding fiscal and budget cycles, better leveraging existing datasets for value demonstration purposes, simplifying formulary management practices and update procedures, and additional work-sharing between jurisdictions including to support joint negotiations.

At the same time, opportunities to promote efficiencies and greater alignment across multiple process steps must be identified and captured.

Enabler 2: Best Global Practices

Canada is not alone in aiming to provide high-quality, timely access to innovative treatments for its citizens in a sustainable manner. Most new innovations will be introduced to multiple markets at different times, so the same questions and issues faced by Canada are actually shared challenges at the international level. At the same time, as noted elsewhere, other jurisdictions are adopting new policies and evolving existing processes in real-time. Canada must be adaptable, agile and open to seeking out best practices around the world and understanding their respective advantages, drawbacks and potential applicability to the Canadian system.⁸ One characteristic of many global policies of interest⁹ is that they often occur against the context of updated national policy strategies for the broader life sciences industry. Sincere attempts are made to operationalize an agreed policy vision by finding new ways of working and experimenting with interim or pilot studies to determine wider feasibility. We need to encourage much more of this work in Canada.



As a practical next step, further research is required to identify and validate recent developments in Canada's peer jurisdictions. Possible starting points for this work include UK, Scotland, France, Denmark, and Germany. Of equal importance, Canada must take a more mature and nuanced approach to tracking and evaluating policies and practices as applied in the United States. As the largest global market for innovation and source of research activity, there is a significant body of evidence and experience with fostering innovation at all stages within the healthcare system for the benefit of patients.

⁸IMC recently commented on the work of one important multinational initiative, the Access Consortium: <https://globalforum.diaglobal.org/issue/january-2022/access-consortium-work-sharing-initiative-an-industry-perspective/>

⁹See for example, [the UK's Life Sciences Vision Policy Paper](#)

Enabler 3: Transparent Performance Standards & Reporting

One of the perennial challenges in pursuing policy development for innovative medicines and vaccines is an incomplete or selective picture of what is taking place at different points in the process. Certainly, improvements have been made over the years in establishing, resourcing and ultimately meeting performance targets with relative consistency at the regulatory and HTA levels. But this is not always the case downstream at the negotiation and ultimate reimbursement stages.

It will always be difficult to discuss solutions to problems or challenges which may not be apparent to all stakeholders. Shared accountability for patients demands a much more rigorous and transparent approach to setting activity targets and ensuring those are monitored and reported upon in the public domain.

In the same manner as the regulatory and HTA process currently work against clearly defined targets, the entire system must evolve to operate in a comparably predictable and consistent manner. It is not about performance for its own sake but rather treating targets and accountability and a fundamental pillar of ongoing policy engagement and system improvement.

Performance is an important – but not the only – indicator of whether Canada is achieving its objectives with respect to patient access to new medicines. When combined with continued improvements to procedures and operations and regular benchmarking against best-in-class or emerging international practices, Canada can only then fully realize its objectives of maximizing health outcomes for patients in a modern, efficient, and inclusive manner.

CONCLUSION

No review and reimbursement system for new medicines is perfect. But irrespective of jurisdiction, there should be a firm commitment from all system stakeholders to regular dialogue to track performance, monitor outcomes, identify concerns or questions and be open to changing

processes as warranted, on a regular basis. Canada has never really sought or adopted a commonly accepted vision for the kind of system for new medicines that meets its societal aspirations. IMC believes that a renewed, inclusive, and aligned vision is a necessary foundation of change – but insufficient on its own to making the required adjustments to the established complex process.

The time for greater public conversation on this challenge is now. IMC is prepared to engage with all key external partners – governments, agencies, patient and caregiver organizations, the medical and scientific community, the medicines supply chain, payers, and any others – to validate and solidify the vision, to drive consensus on the needed system elements for the future, and to rally support for short term changes that unlock greater efficiencies and improvements as a precursor to the future.

