Meeting Report

Third Canadian Cancer Treatment Hackathon

New Drug Review and Reimbursement Process

May 8, 2023

Virtual Meeting

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Executive Summary

Colorectal Cancer Canada (CCC) held its third *Canadian Cancer Treatment Hackathon* on May 8th, 2023, with an objective to ideate and design a completely new process that enables new, promising medicines to reach Canadian patients faster.

The Hackathon was comprised of fifteen participants from a variety of backgrounds, such as patient groups, health technology assessment leaders, policy experts, industry leaders, economic experts, and clinicians. These individuals assumed the role of a new 'Super Minister' and together developed ideas on an improved process that provides for early patient access to promising new medicines in a timely and equitable way.

The following key themes evolved from ideas generated during the Hackathon:

Table 1. Hackathon 3 Themes

Theme	Ideas
Payer integration and consistency	- Integrate private and public payers under one umbrella. - Establish a unified approach to minimize overlap and ensure consistency among payers.
Process and decision-making	- Improve decision-making processes and avoid potential harm to patients. - Improve collaboration between manufacturers, stakeholders, and regulatory bodies. - Enhance coordination and communication among provincial and territorial health ministers. - Address disparities and ensure consistent access to treatments and medications across provinces and territories. - Increase political will and align economic development with healthcare strategies.
Health Technology Assessment (HTA) and value-based decision-making	- Incorporate HTA and value-based decision-making approaches in informing reimbursement and funding decisions. - Enhance collaboration between HTA agencies and decision-makers to streamline the assessment and decision-making processes. - Encourage manufacturers to provide additional evidence and data for better evaluation and decision-making. - Address concerns related to negative outcomes for products

	with Phase 3 data. - Address concerns regarding medication delisting based on real-world evidence.
Patient-centric approach	- Place patient needs at the center of the process and prioritize patient-centered care. - Ensure a mission statement that focuses on meeting the needs of patients.
Transparency and accountability	- Establish standardized metrics and promote transparency in decision-making processes. - Enhance visibility into decision-making processes and ensure equitable access to treatments across provinces and territories. - Implement independent third-party oversight of transparency and accountability. - Address payer concerns regarding funding and reimbursement decisions. - Shift focus from supporting drug programs to prioritizing patient-centered care.
Innovative agreement models / managed access programs	- Elevate access to cancer therapeutics through streamlined funding mechanisms and innovative approaches. - Develop post-marketing real-world evidence programs to evaluate the effectiveness of therapies. - Capitalize on the lessons and strategies from the COVID-19 pandemic for healthcare improvement. - Establish a multi-jurisdictional or multi-stakeholder task force for comprehensive medication reviews. Establish a multi-jurisdictional (including out of county reviews by other HTA agencies) and multi-stakeholder task force including the patient voice for comprehensive medication reviews. - Expedite medication reviews by prioritizing faster assessments for previously assessed indications.

Table 1 above summarizes the key themes and ideas that emerged from this Hackathon, covering various aspects such as funding mechanisms, real-world evidence, medication withdrawal, intersectoral collaboration, health equity, patient perspectives, HTA processes, oversight, government intervention, mindset shift, inter-provincial coordination, independent oversight, political attention, transparency, and streamlined access pathways. These ideas aim to optimize access to new medicines.

1.0 Introduction

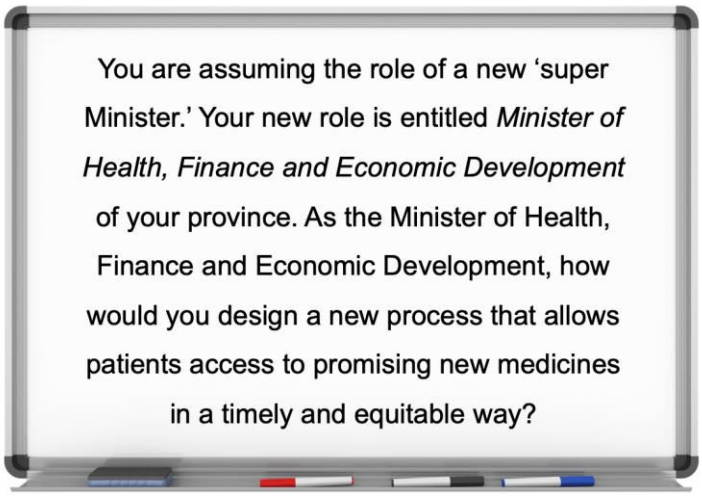
Canadians with public drug coverage continue to have restricted and/or delayed access to new therapies due to the multi-layered sequential review processes, which inform public drug plans' decisions on whether to provide access and reimbursement to new medicines.

On May 8, 2023, Colorectal Cancer Canada (CCC) held its third *Canadian Cancer Treatment Hackathon,* which aimed to ideate and design a completely new process that enables new, promising medicines to reach Canadian patients faster.

Assuming the role of a new "Super Minister" entitled Minister of Health, Finance and Economic Development of the different provinces and territories in Canada, the Hackathon participants from different stakeholder groups were asked to design a new process that allows patients access to promising new medicines in a timely and equitable way, as outlined in the mission statement in Figure 1.

Figure 1. Hackathon 3 Mission Statement

New Drug Review and Reimbursement Process



Participants brainstormed in breakout sessions and shared their ideas in a plenary session (Appendix A – Third Hackathon Agenda).

Overall, Hackathon 3 aimed to address critical questions surrounding:

- enhancing collaboration between stakeholder groups;
- access to medicines in Canada, focusing on optimizing the system; and
- finding innovative solutions to expedite the approval and availability of life-altering treatments.

To encourage inclusive and open dialogue, the Hackathon was conducted under ***Chatham House Rule***, its guiding spirit is to share the information received, but not to reveal the identity of who said it.

1.1 Background

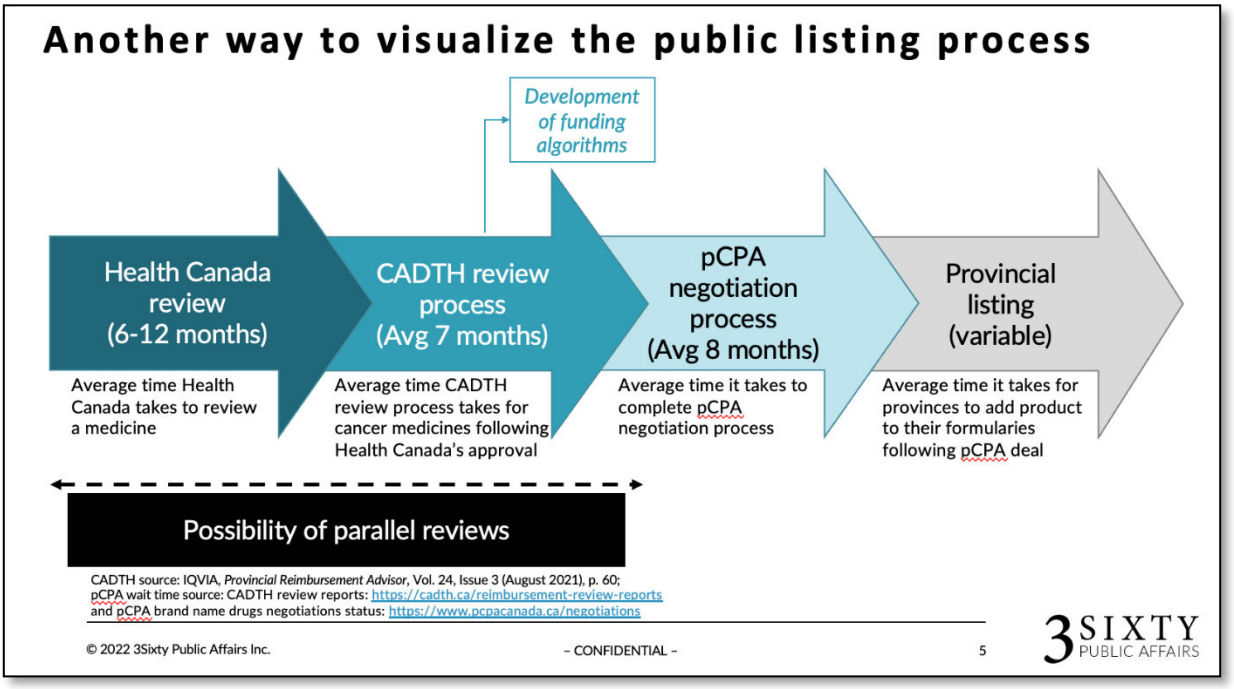
In the quest to enhance medication access in Canada, particularly for cancer treatment, Hackathon 3 brought together experts and stakeholders to discuss the pressing issues surrounding the healthcare landscape. Accordingly, Hackathon 3 provided a platform to explore the challenges, developments, and potential solutions surrounding medication accessibility within the country's healthcare system.

One persistent challenge is the lack of new medicines available in Canada as numerous medications fail to undergo the necessary processes for commercial use approval with Health Canada. A significant factor contributing to the complexity of access to new medicines is the ongoing Patented Medicine Prices Review Board (PMPRB) reform. Uncertainties surrounding compliant pricing and assessment of clinical and cost-effectiveness recommendations for specific patient populations and lines of therapy, particularly in the context of cancer treatment, add further layers of complexity to the landscape.

The intricate treatment algorithms that guide cancer care dictate the utilization of medications at different stages of treatment and take into account considerations for subsequent lines of therapy. A letter of intent within Pan-Canadian Pharmaceutical Alliance (pCPA) negotiations does not guarantee medication listing, but it has demonstrated substantial cost-saving benefits based on experiences in Quebec and Ontario. It is also worth noting that provincial listings often involve varying timelines for funding decisions, posing challenges to patients' timely access to essential treatments. Private payers have historically provided faster access to reimbursed medicines, benefiting a substantial portion of the Canadian population with access to private insurance plans.

However, emerging restrictions on these plans raise concerns about the continuity of such favorable access.

Figure 2. Public Listing Process Visualization



As illustrated in Figure 2**,** another way to visualize the public listing process is the side-by-side review process which can be time-consuming. The funding algorithm issue arises in the context of the Canadian Agency for Drugs and Technologies in Health (CADTH) process, which can sometimes occur in parallel rather than sequentially. One idea that was proposed during Hackathon 1 was to explore the possibility of pre-negotiations, allowing negotiations to take place while the CADTH review is underway.

Figure 3. Yearly Trend of Number of Medicine Launches (NAS) in Canada and Globally (2007-2021)[1]

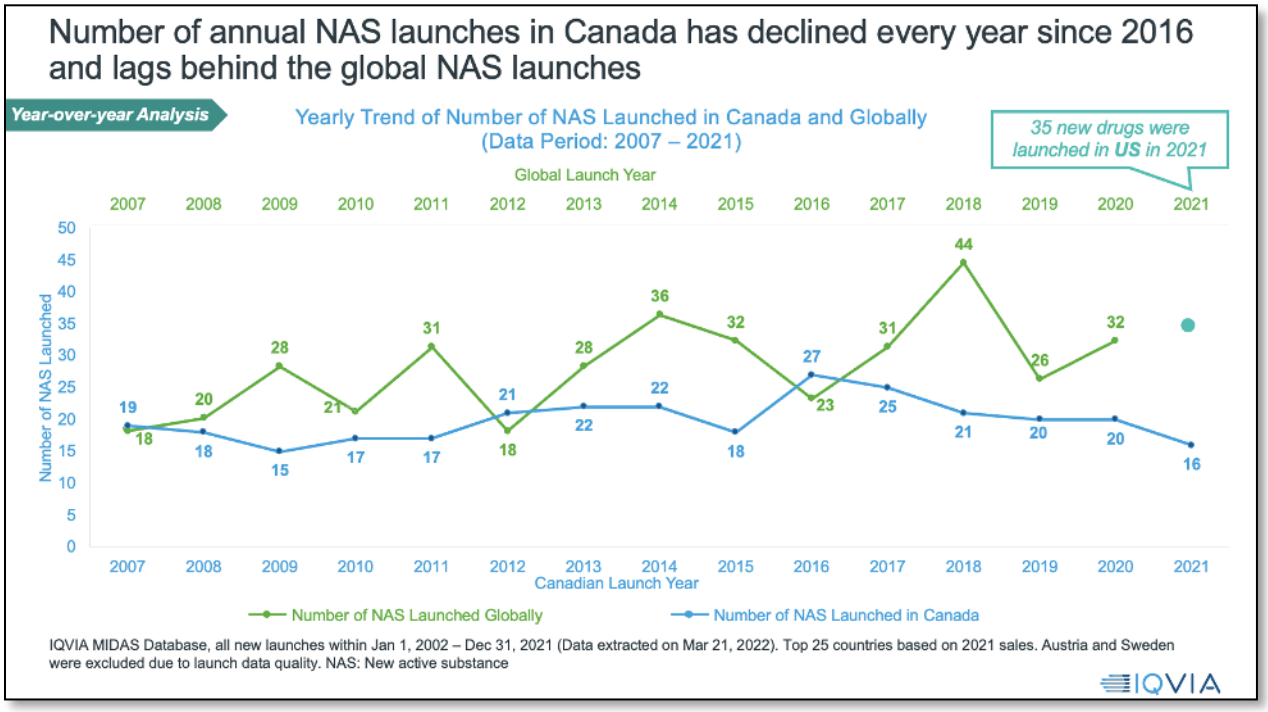


Figure 3 demonstrates the disparity between the number of new medications launched in Canada and those launched in other major jurisdictions worldwide. The need for improvement in medication accessibility is apparent, prompting the exploration of potential solutions.

1.2 Highlights from Hackathon 1:

Hackathon 1 highlighted the need to optimize the current system and identified actionable opportunities to streamline the process to access new medicines.

- One key idea that gained significant support was the implementation of a global solution where data could be reviewed simultaneously, reducing the need for redundant regulatory reviews. This approach aimed to streamline the process and expedite access.
- Another suggestion that emerged from Hackathon 1 was the international sharing of Health Technology Assessments (HTA) reviews (Project Orbis). By leveraging the experiences and evaluations conducted by other countries, Canada could potentially expedite its own HTA process and avoid duplicative assessments. This collaborative approach would require effective partnerships and information exchange to benefit from the insights and conclusions reached by other jurisdictions.
- The third idea was to integrate negotiation and funding decisions with the HTA review process. Traditionally, these activities occur sequentially, leading to delays in access for patients. However, by negotiating the funding simultaneously, it was anticipated that timely

access to medications could be achieved without compromising the thorough evaluation of clinical and economic factors.

1.3 Highlights from Hackathon 2:

Building upon the insights gained from Hackathon 1, Hackathon 2 expanded the discussion by examining international approaches to medication access in different countries. The participants delved into the systems and policies implemented in other HTA jurisdictions; specifically: England, Wales, France, Germany, Italy, and Australia, aiming to learn from their experiences and identify potential strategies that could be adapted to the Canadian context.

In England and Wales, early access drug funds, managed entry agreements, and frameworks for real-world evidence (RWE) were found to be effective in facilitating timely access to promising therapies. France employs a selective approach through its Early Access Program, considering clear criteria for faster pathways when viable alternatives are limited. Germany faces challenges related to cost, certainty, and sustainability within its mandatory sickness fund system. Italy emphasizes patient registries and value-based assessments, dedicating a national fund to equitable access. Australia focuses on data sharing, transparency, priority reviews during HTA, provisional approval processes, and increasing patient involvement.

2.0 Key discussions from the three groups that participated in Hackathon 3.

2.1 Enhancing Payer Integration, Access Pathways, and Patient-Centricity in the Review and Approval Process of New Medicines

The discussions by the first group focused on crucial aspects of the healthcare system, aiming to improve the process of payer integration, access pathways, evaluation of differentiation for cancer and rare disease medicines, patient-centricity, and the establishment of a defined time to reimbursement. The discussions resulted in key insights and recommendations, shaping the path toward more efficient and patient-oriented healthcare practices.

Group 1's deliberations are summarized into categories based on the key points and themes that emerged during their discussion.

A. Payer Integration and Consistency:

There was a consensus among the participants that a process should be created to integrate both private and public payers under one umbrella. The aim is to establish a unified approach that minimizes overlap and ensures consistency among payers. While it was acknowledged that negotiation methods may differ, the focus was on developing processes that are consistent for all payers involved. This approach would enhance efficiency and streamline operations within the healthcare system.

B. Accelerated Access Pathway:

The group emphasized the importance of creating an accelerated access pathway for reimbursement. This pathway would offer an opportunity for patients to receive timely reimbursement, subject to reconsideration. To facilitate the development of such a pathway, the suggestion was made to look at the existing German model as a starting point for comparison. This comparative analysis could provide valuable insights and help adapt the model to suit the specific needs and context of the jurisdiction being discussed.

C. Differentiation for Cancer and Rare Disease Medicines:

The majority of participants expressed support for introducing differentiation in the evaluation process for cancer medicines and rare disease medicines. The idea was to establish a different threshold or criteria for evaluating these specific medications. The objective behind this approach was to potentially grant earlier access to these treatments based on certain predefined criteria. Although there were some points of disagreement on this topic, the majority believed that differentiating the evaluation process would be beneficial for cancer and rare disease patients.

D. Patient-Centric Mission Statement:

The group agreed that the healthcare system should begin with a mission statement that places patient needs at the center of the process. It was recognized that while having a defined process is important, the ultimate focus should always be on meeting the needs of patients. In situations where there is a conflict between patient needs and the established process, the consensus was that patient needs should take precedence. This patient-centric approach ensures that the review and reimbursement process operates with a primary goal of delivering effective and timely treatment to those who need it.

E. Defined Reimbursement Timeline:

Participants stressed the necessity of setting a clear timeline for reimbursement. The objective is to establish specific timeframes within which reimbursement should be processed and disbursed. To enforce compliance with these timelines, the group proposed the inclusion of incentives and/or penalties. By incentivizing adherence to the defined timeline and imposing penalties for non-compliance, the aim is to ensure timely reimbursement for healthcare providers and foster accountability within the system.

The discussions held by the first group revealed a profound recognition of the challenges within the healthcare system and a shared commitment to driving meaningful change. The group's recommendations underscore the importance of payer integration and consistency, immediate access pathways, differentiated evaluation for critical medications, patient-centricity, and defined reimbursement timelines. These insights reflect a collective vision for a healthcare system that prioritizes patient needs, streamlines processes, and fosters accountability. By embracing these recommendations, the healthcare system can evolve into a more efficient, equitable, and patient-oriented paradigm, ultimately improving the overall quality of care provided.

2.2 Strengthening Governance, Collaboration, and Patient-Centricity in Healthcare Decision Making

The discussions held by the second group delved into oversight, accountability, access pathways, collaboration, and process improvements. These discussions aimed to address key questions surrounding patient-centric budget discussions, the role of oversight bodies, the distinction between "listing" and "access," inter-provincial coordination, the need for transparency and accountability, and the potential for independent third-party oversight.

A. Oversight and Accountability:

Oversight and accountability are crucial to ensure that budget discussions remain patient-focused. Germany's multi-stakeholder advisory body, which includes Gemeinsamer Bundesausschuss[2] (GBA), social insurers, hospitals, and working groups, serves as an effective example. The inclusion of various stakeholders, even dentists, showcases the comprehensive nature of this governance tool. Allocating additional resources to the system is necessary, considering that only 11% of medications are currently being removed from the market.

B. Government Intervention and Decision-Making:

Concerns arise when products are allowed to remain on the market with negative outcomes in Phase 3 data. Reliance on the system to pull NOCs even when the data is negative puts government and HTA organizations in a negative light. Addressing this issue is essential to improve decision-making processes and avoid potential harm to patients.

C. Shifting Mindset: Listing vs. Access:

A mindset shift is necessary, focusing on facilitating access rather than solely listing interventions. Embracing a sequential approach and considering all interventions that could be displaced or changed throughout each patient's journey, as well as at the population level, is essential for efficient healthcare delivery. This reframing helps ensure that decisions are guided by the goal of providing timely and comprehensive access to treatments.

D. Collaboration for Managed Entry Products (MEP):

Collaboration is necessary to enable access to MEP products. Reviewing what access looks like and aligning early with clear timelines and transparency can provide more certainty in the process. Establishing effective collaboration between relevant stakeholders can facilitate smoother access pathways.

E. Inter-Provincial/Territorial Coordination and Communication:

Improved coordination and communication among provincial health ministers are needed to foster a more unified, efficient, and patient-centric review and reimbursement process. Addressing disparities and ensuring consistent access to treatments and medications across different provinces and territories should be prioritized.

F. Independent Third-Party Oversight:

Considering the implementation of independent third-party oversight, potentially at a level other than federal, can enhance the regulatory process. Such oversight should have the authority to monitor and regulate the system effectively, ensuring transparency and accountability.

G. Political Attention and Adaptation:

Increased political attention and will are required to drive necessary changes in the new medicines review and reimbursement process. Drawing lessons from successful adaptations during the

COVID-19 pandemic, such as rolling reviews and ongoing data analysis, can provide valuable insights and models for improving existing processes.

H. Transparency and Accountability:

Establishing standardized metrics and promoting transparency are crucial to ensure accountability within the healthcare system. Currently, transparency levels vary among provinces and territories, making it essential to enhance visibility into the decision-making processes. Shifting the focus from supporting drug programs to prioritizing patient-centric care is necessary.

I. Addressing Payer Concerns:

Mitigating payer concerns regarding funding, reimbursement decisions, and the potential need to withdraw products from the market is crucial. Implementing managed entry and assessments at a later date can offer more flexibility and adaptive approaches to funding decisions. Learning from the UK, where only 15% of MEPs demonstrate no clinical value, can provide insights into improving decision-making processes.

J. Streamlined Access Following Positive Recommendations:

Ensuring immediate access following positive clinical recommendations by CADTH can streamline the process, allowing patients to benefit from approved treatments without unnecessary delays. This approach enhances efficiency and effectiveness in healthcare delivery.

The deliberations of Group 2 have provided valuable insights and recommendations to fulfill the role of the Minister for Health in expediting access to medicines for patients. The proposed ideas, such as independent third-party oversight and learning from the lessons of the COVID-19 pandemic, offer potential pathways to accelerate the process while ensuring transparency and accountability. Group 2's deliberations highlight the importance of political will, collaboration, and patient-centric decision-making in shaping a landscape that swiftly delivers innovative treatments to those who need them.

2.3 Enhancing Access, Evaluation, and Governance for Cancer Therapeutics

The deliberations in the third group uncovered valuable insights into optimizing access to life-saving cancer therapeutics and enhancing the overall new medicine review and reimbursement process. By

exploring post-marketing real-world evidence programs, medication withdrawal considerations, leveraging the lessons learned from the COVID-19 pandemic, and addressing the challenges associated with medication listing, the group engaged in thought-provoking discussions on the intersection of innovation, economic development, and patient-centered care.

A. Elevating Access to Cancer Therapeutics:

The idea was to create an elevator-like system that would provide faster and streamlined access to life-saving cancer therapeutics. This approach aimed to evolve the current funding mechanisms and explore innovative ways to bring these therapies into Canada through clinical trials and research, fostering economic development and innovation in the healthcare sector.

B. Post-Marketing Real-World Evidence (RWE) Programs:

Emphasis was placed on developing post-marketing real-world evidence (RWE) programs to evaluate the effectiveness of therapies once they are available on the market. The affordability challenges associated with drug programs and cancer agencies were acknowledged. Leveraging real-world evidence would enable informed decision-making regarding the reimbursement and funding of cancer medications.

C. Pulling Medications from the Market and Central Payment System:

Inspired by the German healthcare system, the concept of pulling medications from the market and implementing a central payment system for innovative technologies was discussed. This approach would involve the jurisdiction taking responsibility for providing initial access to these therapies, aiming to enhance efficiency and cost-effectiveness within the healthcare system.

D. Leveraging the COVID-19 Experience:

The unique opportunity presented by the COVID-19 pandemic to learn from successful strategies and apply them to other aspects of the healthcare sector was recognized. The idea of establishing a fund similar to the UK's National Health Service (NHS) was discussed to mitigate risks for the provinces and territories, ensuring continued access to innovative treatments. Also, the possibility of new clinical trial designs can allow for earlier access to treatments, similar to what was accomplished with the COVID-19 vaccines – focusing on adaptive trials and rolling reviews was highlighted. The focus was on capitalizing on the political will and economic development strategies that emerged during the pandemic.

E. Low Percentage of Listed Medications:

A study published in the Canadian Health Policy journal, revealed a low percentage of cancer medications (11%) are making it to Canada and getting publicly listed[3], which raised questions about the clinical value of the remaining medicines. The proposal was to establish a multi-jurisdictional or multi-stakeholder task force to comprehensively review medications. This task force would ensure equal opportunities for evaluation and listing, addressing concerns about fair consideration.

F. Debulking the System:

To expedite the medication review process, the suggestion was made to prioritize faster reviews for medications that have already undergone assessment for one indication. Pembrolizumab (Keytruda) was cited as an example, highlighting the knowledge gained through previous evaluations. The proposal was to adopt a sequential approach, giving priority to clinical assessment before economic evaluation, with the aim of facilitating faster access to treatments.

G. Political Will and Economic Development:

The importance of political will in driving necessary changes within the healthcare system was stressed. The momentum and strategies employed during the COVID-19 pandemic were considered valuable, with a focus on maintaining and leveraging this progress. The role of the Minister of Finance and Economic Development in responding to constituent demands for reimbursement conditions was highlighted, recognizing the need to align economic development with new medicines review and reimbursement strategies.

H. Real-World Evidence and Medication Withdrawal:

In the event that real-world evidence does not yield positive outcomes, discussions revolved around the potential need to withdraw medications from the market based on clinical considerations.

Through a focus on evidence-based decision-making, political will, and strategic alignment of economic and healthcare objectives, the group underscored the importance of forging collaborative pathways that prioritize patient outcomes.

2.4 Additional Points Discussed: Designing a New Process for Timely and Equitable Patient Access to New Medicines

The key problem identified is the long waiting times for patients to receive access to new innovative therapies, particularly in areas of high unmet need. The discussions highlighted the importance of involving key stakeholders, including Health Canada, pan-Canadian Pharmaceutical Alliance

(pCPA), CADTH, Institut national d'excellence en santé et en services sociaux (INESSS), industry representatives, patients, and clinicians, at various stages of assessing new medicines. Vital steps identified for the assessment process include determining safety and clinical efficacy, addressing gaps in data for economic evaluation, implementing innovative payment models, collecting relevant data points, ensuring transparency, and maintaining accountability to timelines. The participants emphasized the need for a coordinated effort among all stakeholders to streamline the process and facilitate timely access to new medicines for patients. The following table summarizes the key questions and consolidated responses received from participants of Hackathon 3.

Table 2. Key Questions and Responses from Hackathon 3 Participants

Questions	Consolidated responses
What is the issue we are trying to address?	Patients experience significant delays in accessing innovative therapies within the public healthcare system, particularly in cases of high unmet medical need where early treatment is crucial. The lack of a unified understanding among the three ministries (Health, Finance, and Economic Development) and a sequential and rigid approach to processes across jurisdictions pose challenges. Additionally, the rapid pace of scientific advancements outpaces the rate of process changes.
As the Minister of Health, Finance, and Economic Development, how would you design a new process that allows patients access to promising new medicines in a timely and equitable way?	Access to medication would be granted once safety and clinical efficacy have been established, with a predetermined price that can be adjusted through negotiations.
What key steps do you think are vital to assessing new medicines and why are they important?	Key steps include: - Health Canada determining the safety and clinical efficacy of therapies, potentially learning from approaches implemented in other countries. - Collaboration between Health Canada, CADTH/INESSS, pCPA, patients, clinicians, payers, and

	industry to identify data gaps, ensure economic evaluation, implement innovative payment models, collect relevant data, maintain transparency, and be accountable to timelines.
Who are the key stakeholders needed to be involved in each of the steps?	Key stakeholders include Health Canada, CADTH/INESSS, pCPA, industry representatives, patients, payers, and clinicians.
Who should be accountable for the process of reviewing and approving a new medicine to ensure timely access to patients?	The approval process and decisions rest with regulatory bodies and payers, but all stakeholders must work collaboratively to facilitate a more efficient and timely process.

3.0 Conclusion:

The discussions surrounding timely access to innovative therapies within Canada's healthcare system revealed an urgent need for comprehensive reforms. The challenges stemming from long wait times and a lack of coordination among key ministries call for a holistic understanding and adaptive processes to keep pace with scientific advancements. It became evident that accountability for efficient review and approval processes rests upon collaborative efforts among stakeholders. The emphasis on open dialogue, inclusion of private payers, and striking a balance between patient needs and process requirements highlights a collective commitment to improving the system. Drawing inspiration from Germany's approach and leveraging the expertise of organizations like CADTH/INESSS, Canada can forge a path toward a more agile and patient-centric healthcare landscape. By fostering dialogue, integrating diverse perspectives, and implementing streamlined processes, Canada can unlock the potential for timely access to life-saving therapies, ultimately enhancing the well-being of its citizens.

Appendix A – Third Hackathon Agenda

10:30 am	Welcome Remarks	Barry Stein, Colorectal Cancer Canada
10:40 am	Overview of the medicine review and reimbursement process in Canada Key highlights from Hackathons 1 and 2 Roundtable introductions and review format	Bill Dempster, 3Sixty Public Affairs
10:55 am	Breakout groups - Individuals present their ideas to the group - Group members come up with one new medicine review and reimbursement process based on ideas from individual presentations	All
11:25 am	Presentations to the broader group - Each group will present their new medicine review and reimbursement process to the broader group	Facilitated by Bill Dempster, 3Sixty Public Affairs
11:55 am	Wrap up and next steps	Facilitated by Bill Dempster, 3Sixty Public Affairs
12:00 pm	Session adjourns	

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1. Life Sciences Ontario. Is Canada losing its status as a priority medicine launch country?. 2022. Accessed June 10, 2023. https://lifesciencesontario.ca/wp-content/uploads/2022/06/ENGLISH.pdf

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3. Skinner BJ. New cancer drugs in Canada 2012 to 2021: an economic analysis of cost, benefit, availability, and public insurance coverage. *Can Health Policy*. 2023;2023(4). Accessed June 9, 2023. https://www.canadianhealthpolicy.com/product/new-cancer-drugs-in-canada-2012-to-2021-an-economic-analysis-of-cost-benefit-availability-and-public-insurance-coverage/