Introduction

Since the establishment of the Canadian Medicare system, we have been discussing the concept of universal Pharmacare for Canada. However, no federal government to date has made a valid attempt at implementing such a program. Upon the release of the Hoskins report, “A Prescription for Canada: Achieving Pharmacare for All”¹ in June 2019, the conversation has once again been reignited, with a growing national support for reforming access to prescription medicines in this country ².

Canadians spend approximately $34 billion on prescription medicines annually, representing 15.7% of the $253.5 billion annual health care spending in 2018.³ Growth in prescription medicine spending outpaces Hospital and Physician spending⁴, and will continue to grow as the population grows, ages and the rate of chronic disease continues to rise.⁵ The growth of these chronic diseases require management through use of prescription medicines.

Canada’s fragmented drug coverage system, which is a patchwork of public and private insurance plans, leaves 1 in 5⁶ Canadians foregoing taking their prescription medicines because of cost considerations. Canadians are also paying the third highest price for drugs per person in the OECD, behind USA and Switzerland ⁷, so there is room for improvement. Implementing Pharmacare for all and ensuring all Canadians have universal access to essential medicines, would be a key pillar in fulfilling our journey to Universal Health Coverage.

The newly elected federal Government promised to address this inequity in our healthcare system through a national Pharmacare program. In this article we outline what we foresee as the 4 main areas that will need to be examined, each being its own array of issues, obstacles and considerations, if a national Pharmacare program is to be successful. We will explore each of these topics in greater depth in our future series of articles to be released over the coming months.

³ CIHI (1975-2018), National Healthcare Expenditure Database.
⁴ Ibid: #3
⁵ Government of Canada, Canadian Chronic Disease Indicators - https://health-infobase.canada.ca/codi/
⁶ Angus Reid Institute (June 6, 2016), “Canadian Public Opinion Regarding a National Pharmacare Program” written submission to HESA.
⁷ Ibid: #1
Establishing a national Pharmacare system would result in a significant change to the current landscape of accessing medicines for Canadians.

How drugs and prescription medications typically travel through the Canadian healthcare system is mapped out in Figure 1 below.

**Figure 1: Journey of a Pill in Canada:**

- **Drug Coverage**
  - Some Canadians may have drug costs covered through insurance or provincial drug programs.

- **Hospital and Pharmacies**
  - Distributors and wholesalers supply the drugs to hospitals, healthcare facilities, and pharmacies.

- **Manufacturing of Drugs**
  - Manufacturers licensed by Health Canada procure raw materials from suppliers (active ingredients, chemical based, excipients, etc.) to make the drug.

- **Drug Price Set**
  - Drug Prices Set through negotiations with provinces if will be covered by provincial drug programs. Otherwise patented drugs prices are set by the manufacturer based on total manufacturing costs.

- **Drug Approval Process**
  - Manufacturer submits a New Drug Submission.

- **Pharmaceutical Molecule R&D and Drug Discovery**
  - This step includes: Initial drug research, Pre-clinical trials, and Clinical trials.

- **Health Canada Review**
  - Review and approval for Canadian market examined as per Food and Drug Act.

- **Health Canada Approval**
  - Health Canada authorizes the drug for the Canadian market and issues Notice of Compliance (NOC) and Drug Identification Number (DIN).

- **Distributors and wholesalers**
  - All manufactured drugs flow through wholesalers, distributors, importers that are licensed by health Canada.

- **Manufacturer Purchase Contracts**
  - Licensed manufacturers receive purchase orders from: Regional Health Authorities, contractor, group purchasing organizations, wholesalers, distributors, importers, F/P/T.

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The most significant changes we expect with the introduction of a national Pharmacare program as recommended by the Hoskins Report would be:

- **Introducing** a National Formulary and Essential Medicines List (EML) which would be a carefully chosen list of essential medicines covering most major conditions and representing about half of all prescriptions.

- The establishment of a new Canadian Drug Agency (CDA), which would cause the wind down of provincial insurance coverage for medicines on the EML.

- The consolidation of procurement activities resulting in reduced pricing for these medicines on the EML.

- The shifting role of private insurance to provide supplemental coverage for medicines outside of the EML and brand name products.

These changes, if implemented appropriately, should reduce administrative costs and increase buying power for drug negotiation and procurement and result in more affordable drug prices for Canadians. Achieving this will mean navigating a gauntlet of private sector stakeholders and negotiating an agreement across all the provinces and territories, which will certainly not be an easy feat.

**What will a national Pharmacare system cost?**

The expected cost of the nation Pharmacare system will be highly dependent on four key factors:

1. **Coverage** – who will have access to and what medicines will be included in the EML?

2. **Price** – how much the weight of a single national bargaining power affect the drug cost negotiations with drug manufacturers?

3. **Demand** – the utilization of medicines on the EML.

4. **Cost Sharing** – the effectiveness of any cost-sharing mechanisms introduced, such as those proposed by the Federal Advisory Council of co-pays of $2 for essential medicines, $5 for other medicines capped at $100 per household annually, etc.

The Federal Advisory Council estimates that the cost of Prescription Medicines by 2027, the time by which a national Pharmacare program would be fully implemented, would be $46.8 billion compared with spending of $51.6 billion on the current system and which does not meet the needs of large portions of the population.

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8 Ibid: 81 (these figures are net of confidential rebates)
Pharmacare for All – A Big Idea

Incremental public cost of national pharmacare in 2027 (net of confidential rebates)

The savings or cost differential, are largely a result of reduced administration, greater use of generic/biosimilar medicines, and achievement of better drug prices and rebates. In theory, it achieves these through a larger and stronger purchasing power. The increased cost to public spending would be $15.8 billion, apart from savings aforementioned from reduced drug prices, they must capture some of this additional financing through the $23 billion in reduced private plan and out-of-pocket coverage.

The costs related to non-adherence with treatment regimens are currently having and will continue to have significant downstream effects on our health care system which commonly result in increased emergency room visits, hospitalizations and premature deaths. We expect estimates of these broader health systems savings to be over $1 billion annually\(^9\), but could represent just the tip of the iceberg as the study only examined non-compliance with 3 chronic conditions. Reducing the barrier of cost for prescription medicines presents an opportunity for broader health system savings and efficiencies. Beyond impacting the health system, the cost of non-adherence to prescribed medicines also has negative economic consequences including increased worker absenteeism, reduced productivity and reduced life expectancy.

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\(^9\) Ibid #1

Source: Council’s calculations using data from IQVIA Solutions Canada, CIHI, PMPRB and Health Canada.
Introducing an EML is a key recommendation of the Hoskins report, which will aim to close the gap and increase accessibility for prescription drugs across the country. The organization assigned to creating the EML will need to consider what medications it will cover, the formulary and how to value new pharmaceuticals that come to market. These factors will be heavily linked to the overall success of a national Pharmacare program.

An essential medicine, by definition is a medication that addresses the health care requirements of local citizens, and bought in an adequate amounts to address the needs of the population. While many countries look to the World Health Organization for guidance there are also many other countries worldwide that have cataloged their respective formularies of essential medicines. It is important that Canada develop its own EML that considers the priorities of Canadians and the medical conditions that Canadians face.

Government covers medications delivered in hospitals but a Canadian formulary must target medications prescribed in the outpatient setting. The Hoskins report further asserts that a Canadian EML should attempt to service most major health conditions, such as diabetes and hypertension, besides including approximately 50% of the most currently prescribed medications in Canada. The EML has the potential to have a serious financial impact on Canada and its economy, with a broad and/or expensive list and its potential cost being more than the government has projected. Conversely a list that is too narrow could lead to higher healthcare expenditures by inadequately treating or preventing certain diseases.

There are several other reasons, other than financial, why “getting the list right” is imperative. The EML should be able to service a diverse population, with varying options required for different ages and ethnicities. For

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example, the pediatric population will require different drug options than the elderly, and appropriate outcomes will need to be chosen to measure a medication’s therapeutic value. From a clinical lens, non-medical switching of medication, where a patient must change their current drug to one included on an EML, might induce side effects or sub therapeutic outcomes, which would end up increasing the overall burden on the healthcare system. Last, the risk of over-prescription of medications exists. Over-prescription can be just as dangerous as under-prescription, resulting in polypharmacy, side effects, drug interactions and antimicrobial resistance.

Transparency will be a key factor to the success of a national Pharmacare program and thus it will be crucial for the Canadian government to create a formula to determine which therapeutic options they include on the EML. Empirically, this means a governmental agency will have to place a value on pharmaceutical options, weighing the benefits to local populations and considering the cost of healthcare outcomes.

**Consideration of Rare Diseases**

Procurement strategies and the development of a formulary designed to treat rare diseases will be a separate process as recommended by the Hoskins report. And it is very important to engage patient groups and clinicians throughout this process. The government has showed it plans to use a performance-based funding agreement for its procurement strategy and will need to consider the benchmarks that it will utilize to measure performance, the timelines associated with these benchmarks, and a value-based pricing model to continue the support of R&D in this sector. There needs to be careful consideration to the performance-based funding formulae used for the procurement of drugs for rare diseases.

**How will an EML affect drug innovation in the Canadian market?**

For continued progression and innovation in health care, both the EML and a rare disease formulary must consider the importance of R&D in the pharmaceutical sector. The pharmaceutical industry has historically focused on blockbuster drugs, but more recently is increasingly focused on rare diseases. That said, only 5% of rare diseases currently have treatment options. As the R&D to sales ratio for multinational pharmaceutical companies has been decreasing over the last several years, one has to wonder if further downward pricing pressure from negotiations has the potential to negatively impact and/or stifle innovation in the Canadian pharmaceutical market. Thus, it is vital to signal to the law makers and program leads the importance and value of innovation, especially regarding new chemical entities, by having a pre-determined formula that includes R&D as a consideration.

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The Intergovernmental Dimensions of Pharmacare – How to Work Together?

The intergovernmental dimension of Pharmacare is fraught with challenges and has enjoyed little progress since the establishment of the Canadian Medicare system in 1962. The constitutional distribution of powers between the federal and provincial governments coupled with the financial relationship between different orders of government will be critical, and likely very challenging, elements to the successful implementation of the national Pharmacare program. Adding to these challenges is the fact that provincial governments are already active in the drug coverage space, and supported by entrenched stakeholder networks, such as private insurers. The current model leads to considerable variation across provinces in drug benefit programs in areas such as eligibility and degrees of coverage.

So what could the national role be in this context? Two potential governance models come to mind. First, the federal government could be the funder of provincial programs with variation in the delivery model (but with a common minimal standard). Second, the federal government could be both the funder and deliverer. There are a variety of issues to be considered when looking at both of these options.
Not all provinces will have equal need for federal funding

While all provinces provide some form of publically funded drug coverage, it varies across provinces. The Canada Health Transfer and the Canada Social Transfer provide per-capita based federal funding to provinces to support specific policy areas such as provincial health care programs. That said, there is significant variability in the current allocation of federal funds and overall spend on these programs and the amount of support each province provides to individuals living within that province. This discrepancy stems from the variation of models used and the establishment of different enrollment requirements for coverage. For example, in Ontario, less than 10 percent of the non-senior population are active beneficiaries of the provincial drug program. We compare this to almost 60 percent in Saskatchewan. A federal Pharmacare policy that “fills in the gaps” of current public spend, may need to subsidize certain provinces more than others.

Certain provinces allocate a significant proportion of their budget to provincial drug programs, while others do not. A federal program that assumes that provincial contribution to drug coverage programs today will equal provincial contribution to a federal plan is not realistic. For example, Quebec, which spends significantly on their provincial drug program, may divert these funds to a federal program that benefits individuals nationally, while other provinces contribute relatively lower amounts. Adjusted expectations with clearly stated criteria and consideration of social-demographic factors are needed, or some funding will come from elsewhere.

It will probably require sophisticated intergovernmental machinery to implement a system that works for Canadians.

We have to protect those already on public programs

About 1 in 4 Canadians receive some degree of coverage from a publicly funded drug program. However, this ratio varies across provinces. Various provinces use various models for public drug programs across Canada - commonly, high-cost conditions, needs-based populations such as seniors and low-income individuals, and individuals not covered by private plans receive some degree of provincial funding for their pharmaceutical needs. The majority of Canadians receiving these benefits living in low-income and rural areas as well as those with high drug cost represent less than 3 percent of beneficiaries but account for more than a third of spend.

Large formularies may not be sustainable. Mostly, drug classes are common across all twelve public drug programs in Canada, however constituents that currently receive public drug funding enjoy relatively large formularies that sometimes include specialty and high cost medications. It is not likely that a national formulary, such as an EML, could sustain the breadth of drugs covered by provincial plans.

This begs the question for many Canadians, does a federal drug coverage plan mean I will lose my coverage? A complete transformation of the current pharmaceutical program in Canada is expected to benefit many, but may disadvantage some. It does not guarantee those covered under a provincial formulary will have the same degree of coverage under a federal formulary.

Portability across Canada is critical

Canadians have a right to their insured health services regardless of which province or territory they are delivered in. Every year in Canada, over 250,000 people relocate from one province to another. A federal drug program and, more-broadly, a health care system that is truly person-centered, must enable Canadians to access their prescriptions and drug coverage programs wherever they live in the country. For many Canadians, ability to access drugs affordably is critical. This need for systemic agility will require a digitally enabled real-time approach to information sharing between provinces.

15 Mowat Centre (September 6, 2018), “Prescribing Federalism: Key Takeaways” - https://munkschool.utoronto.ca/mowatcentre/prescribing-federalism-key-takeaways/
17 Ibid: #1
18 Ibid: #1
Working with the Private Sector

Canada’s existing drug procurement policies represent a delicate balance between the public and private sectors. The Patented Medicines Review Board (PMPRB) manages drug prices in Canada. The PMPRB sets the maximum allowable price for any drugs in Canada that have received approval from Health Canada. However, the real cost of the drugs to patients depends on the patient’s insurance status.

A majority of Canadians receive prescription drug coverage through public coverage or private insurance. Drug prices and coverage for individuals covered through public sources\(^\text{21}\) are negotiated by the pan-Canadian Pharmaceutical Alliance (pCPA), while drug coverage for those covered through private insurance is determined by the annual or lifetime cap set by the insurance providers. Public and private drug plans covered approximately 83% of the total prescription costs in Canada in 2017. It therefore leaves individuals not covered under either of those categories to determine what they can afford.\(^\text{22}\) According to the Hoskins report, around 7.5 million, or 1 in 5, Canadians do not have prescription drug insurance or have inadequate insurance to cover their medication needs and will bear the burden of these out-of-pocket costs.

One of the key recommendations of the Hoskins report is the need to revamp the procurement process for pharmaceuticals at a national level to lower the costs generated by the existing fractured and fragmented approach. This is an important success factor in implementing a national program as lowering costs is a key justification for the potentially massive system transformation required to deliver the proposed national Pharmacare plan. They can achieve this transformation with cooperation from two key stakeholders in the private sector: drug manufacturers and insurance companies.

**Leveraging Canadian Buyer Power**

Drug manufacturers selling products in Canada are limited by the price ceilings

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\(^{21}\) This includes drugs sourced through the public drug plans in the 13 provinces and territories, Non-Insured Health Benefits, Correctional Services of Canada and Veterans Affairs Canada.

\(^{22}\) Ibid: #1.
or by the prices negotiated by the pCPA on behalf of public drug plans (which accounts for just over half of the Canadian population). As a result, there is clearly room for improvement in leveraging the full weight of a national Canadian buying power. If implemented correctly, the proposed CDA could be poised to take advantage of this buyer power on behalf of all Canadians and deliver lower drug costs.

A mitigating factor will be that Canada is a relatively small market, representing only 2% of global spending on pharmaceuticals. Downward pricing pressure could make Canada less attractive to global pharmaceutical companies, potentially limiting Canadians’ access to life-saving drugs. A Canadian Pharmacare program will need to draw inspiration and learn lessons from countries such as New Zealand and Denmark and maximize usage of Canada’s existing Special Access Program. We expect that the proposed CDA would need to be creative in its negotiations by bundling negotiations for multiple products from the same manufacturer or negotiating with multiple manufacturers for the same class of drugs.

**Ensuring Adequate Supply for Canadians**

Canada’s proximity to the United States presents a challenge for a Canadian Pharmacare program. Since the United States pays the highest average cost of prescription drugs in the world, Americans with easy access to the Canadian border often cross over to access cheaper Canadian drugs. Any further lowering of Canadian drug prices could put pressure on Canadian supply. Ensuring that a national Pharmacare program can support supply for Canadians is critical.

**A Role for Private Insurance**

The Pharmacare plan could dramatically impact the role of the private insurance companies in the Canadian market. Canadian insurance companies have argued in favour of mandating employee coverage through private plans and providing public coverage for all remaining Canadians, allowing the government to focus its efforts on getting the new national formulary and common pricing right from the start. If private plans are meeting the needs of some Canadians, there may be a reason to retain some aspects of the current system. However, one challenge to sticking with the status quo is that individuals covered by private plans are likely to be younger and healthier than the overall population, isolating high-needs Canadians such as the poor, elderly or chronically-ill on public plan. This could strain the system and result in a greater burden on Canadian tax dollars.

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**Conclusion**

A national Pharmacare program for Canada is a Big Idea which addresses some of the major issues in our health system related to equity, access and financial sustainability. While the implementation of such a program will be highly complex, it is important to understand what the expected benefits of such a program would be beyond the pocket book savings for Canadians.

A national Pharmacare program is likely to make prescription drugs more affordable for Canadians. However, this does not solve the issue of access. Patients will still need to see a clinician before accessing a prescription for their healthcare needs. The government, at all levels, must continue to address Canadians’ access to clinicians and the current barriers in place. A renewed focus on the importance of timely and accessible primary care must go hand in hand with a national Pharmacare program.

We will explore the above issues in more depth over a series of articles being released in the coming months.