Better Pharmacare for Patients: Evaluating Policy Options

A Report from the Pharmacare Working Group

The Pharmacare Working Group is comprised of representatives from the Canadian Pharmacists Association and patient group representatives from the Best Medicines Coalition and the Health Charities Coalition of Canada.

June 2018

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Executive Summary

It is generally agreed that improved drug coverage is necessary and possible in Canada. However, while Canadians support reform, there is no clear consensus on what broad model or specific policy options might best serve the needs of our citizens. Pharmacare itself is defined differently by stakeholders, governments and the public. Within this report, we use "pharmacare" to describe policy and program options that are aimed at improving the way pharmaceutical care is governed, managed and delivered in Canada.

Patient care has seen great progress in recent decades with improved management of many medical conditions, thanks in part to the use of prescription medicines. We anticipate that as science continues to advance, and personalized treatments become available to address unmet needs, these net benefits will multiply. While pharmaceutical policy reform has often been focused on reducing medication costs for public payers, it is important to remember that preventing disease, reducing morbidity and mortality, and improving patient experiences should be at the centre of any plan. These outcomes would in turn lead to reduced costs in other areas of the health care system.

From a patient's perspective, the objective of any pharmacare system should be to remove obstacles to ensure that everyone has coverage of necessary medications, regardless of their age, disease, financial situation and place of residence. This includes coverage of a range of treatment options, allowing for individualized care in the event that patients cannot tolerate a drug or find particular medicines ineffective.

As the primary users of the system, patients and their health care providers must be involved in assessing the impact that each policy option could have on access to necessary prescription medicines, including the ramifications for individual patient populations, payers, and the health care system overall. In consideration of these issues, members of the Pharmacare Working Group (the Working Group), comprised of representatives from the Canadian Pharmacists Association, and patient group representatives from the Best Medicines Coalition and the Health Charities Coalition of Canada, agree that any pan-Canadian pharmacare model or policy must satisfy the following five principles:

1. Equity
2. Timeliness of access
3. Appropriateness of therapy
4. Affordability
5. Sustainability

To advance the pharmacare debate in Canada, the Working Group applied these principles to assess five highly debated pharmaceutical policy options. We have grounded this assessment in the core belief that all reforms must ultimately contribute to better patient care and better health outcomes. To identify potential patient-centred outcomes, we reviewed the following policy options:

1. Single national formulary
2. Essential medicines list
3. Catastrophic drug coverage
4. Price controls
5. Models to achieve universal coverage

We hope these insights offer policy makers and health care stakeholders a more informed lens through which to evaluate pharmaceutical reform. We believe that drug policy frameworks must incorporate the best evidence available, including evidence generated by the patient experience, and that the process and conclusions must be transparent, consistent and fair.

About the Pharmacare Working Group

Canadian Pharmacists Association (CPhA)

The pharmacy profession and health care in general are changing, creating new opportunities for pharmacists to focus on providing better patient care. Since 1907 our national, non-profit organization has charted the course through many developments in pharmacy, and continues to be the national voice of Canadian pharmacists.

CANADIAN PHARMACISTS ASSOCIATION
ASSOCIATION DES PHARMACIENS DU CANADA

Best Medicines Coalition (BMC)

The Best Medicines Coalition is a national alliance of patient organizations with a shared goal of equitable and consistent access for all Canadians to safe and effective medicines that improve patient outcomes. The Best Medicines Coalition's areas of interest include drug approval, assessment, and reimbursement issues, as well as patient safety and supply concerns. As an important aspect of its work, BMC strives to ensure that Canadian patients have a voice and are meaningful participants in health policy development, specifically regarding pharmaceutical care.

BEST MEDICINES COALITION

Health Charities Coalition of Canada (HCCC)

The Health Charities Coalition of Canada (HCCC) is a member-based organization comprised of national health charities which represent the voice of patients at all levels of the health continuum. The health charities that HCCC represents strengthen the voice of Canadians, patients and caregivers, and work with others to enhance health policy and increase investment in health research. Access to medicines is an important issue for our members and the Canadians that they serve.

Health Charities Coalition of Canada
Coalition canadienne des organismes de bienfaisance en santé

Project Outline

PROBLEM STATEMENT

Pharmaceutical care in Canada is fragmented, failing to provide equitable and consistent care for all Canadians and sometimes resulting in compromised health outcomes and significant costs to individual patients and society as a whole. Provinces, territories, the federal government, as well as employers and individuals (through direct payment or private insurance providers), fund drug therapies for distinct and often overlapping segments of the population. While many Canadians have coverage for their medications, some experience difficulties obtaining timely access to the right drug therapy. Patient groups and health care providers recognize that we need to address significant barriers to medication access as part of ensuring a sustainable health care system.

OBJECTIVE

We will inform national prescription drug strategy and reform proposals by using patient-centric principles to assess policy options that aim to improve access to prescription medicines.

POSITION STATEMENT

All Canadians, regardless of age, disease, financial situation and place of residence, should have equitable and timely access to proven and safe prescribed medications, as well as to the devices and supports necessary to take their medications effectively without financial hardship.

METHODOLOGY

Through a review of each Working Group member organization's pharmacare position materials as well as extensive discussions about existing gaps and barriers, we identified five key principles essential to improving pharmaceutical care. We considered currently proposed policy options against these principles for their effects on patient outcomes, access to medicines, and the health care system as a whole.

Introduction

Canada's pharmaceutical care structure is fragmented, with geography, age, employment, socio-economic status and disease type all playing a role in determining when and at what cost Canadians can access the prescription medications they need.

While the majority of Canadians have some form of drug coverage under the current mix of private and public insurance, approximately 22% of prescription drug costs are paid for out-of-pocket,[1] and estimates suggest that one in ten Canadians cannot afford their prescriptions.[2,3] This cost-related non-adherence to therapy may affect those who are uninsured as well as those who are underinsured.[4] Further, a recent report has estimated that 4.1 million or 11% of Canadians who are eligible for public coverage are, in fact, not covered because they are not enrolled in the public drug programs for which they are eligible.[5]

Each individual experience with illness – from developing symptoms, to screening, diagnosis, determining a treatment plan, and through the entire course of treatment – is a unique story. Health care professionals often find themselves conflicted between providing the best personalized medication therapy and working within the drug plan parameters set by governments and private payers, or by the financial constraints of their patients. As drug experts who regularly help patients navigate their drug plans, pharmacists see firsthand the frequent barriers their patients face in accessing their prescribed drug therapy.

The close relationship and shared vision for a better future has created the opportunity for the pharmacist and patient communities to collaborate on this discussion paper. We have identified five key patient-centred principles:

Equity: *Every Canadian should have equitable and consistent access to necessary prescription medications.*

Timeliness of access: *Canadians should be able to access the medicines they need in a timely manner.*

Appropriateness of therapy: *All Canadians should have access to high quality medications that are appropriate to their individual needs.*

Affordability: *All Canadians should be able to afford their medications at the point of care.*

Sustainability: *All Canadians should benefit from a pharmacare system that ensures ongoing health system sustainability.*

A number of policy options to contain drug costs and improve access to medications are currently under consideration. This discussion paper identifies some of these options and assesses each through the lens of the five patient-centred principles.

Prescription Drugs in Canada: Identifying barriers to access

In 1964, when Canada proposed a national, publicly-funded health care system,[6] policy makers chose to defer coverage for prescription medications, except for those administered in hospitals. This coverage remains outside the medically necessary services provided under the *Canada Health Act*.

Since that time, there have been great advancements in the diversity and effectiveness of pharmaceuticals. Health care has shifted away from the hospital and most prescriptions are now filled at the community pharmacy. The total costs of medicines have also increased substantially, in part because of our aging population and the introduction of new patented and specialized biologic precision drug therapies. These changes have left some patients and families struggling to pay for their drugs. For example, drugs for rare diseases, which can cost over $500,000 per year, are likely unaffordable for anyone without substantial drug coverage.

There are three primary barriers to accessing medications:

- Coverage gaps for uninsured and underinsured
- Timeliness of approvals and coverage processes
- Drug availability

COVERAGE GAPS FOR UNINSURED AND UNDERINSURED

Currently, public drug programs fall into three broad categories: social insurance models, income-based models, and those targeting specific populations. Within these structures there are further distinctions in administering these plans and how they address certain disease types. For example, while all jurisdictions provide coverage for seniors and those on social assistance, coverage even for these specific populations varies between provinces and can include cost sharing measures that require patients to pay premiums, coinsurance and deductibles, which are not means tested. Private plans may also include some form of cost sharing measures, such as caps on coverage. In some cases, these measures can create a significant financial burden on patients.

In addition to the provincial/territorial plans, the federal government manages programs for Inuit and First Nations, the military, inmates of federal penitentiaries, veterans, and the RCMP, and it contributes to employee benefits for the federal civil service. There is also a range in the coverage provided by Workers' Compensation Boards and in protecting patients against catastrophic drug costs.[7]

Although each jurisdiction provides some form of drug coverage, the public plan formularies vary across the country, along with the eligibility criteria for access to those drugs. Eligibility criteria for public plans may include age and socio-economic factors, but drugs prescribed to patients also must be included on the plan's formulary.

Patients who are ineligible for public plans must either pay for drugs out-of-pocket or they may be eligible for coverage under a private plan, which are primarily sponsored by employers. Private plans provide drug coverage for up to 25 million Canadians, which is almost 70% of the population.[8] However, even with access to a public or private drug insurance plan, patients sometimes face prohibitive out-of-pocket drug costs.

TIMELINESS OF APPROVALS AND COVERAGE PROCESSES

The extended period of time from drug approval to coverage, necessitated by prolonged review and decision-making processes by various regulatory, negotiation and reimbursement bodies of new and innovative medicines continues to be a challenge for patients and a significant barrier to drug access and optimal care. Canada's regulatory, negotiation and reimbursement bodies include the following:

- Health Canada, through the Health Products and Food Branch (HPFB)
- Canadian Agency for Drugs and Technologies in Health (CADTH), which includes the Common Drug Review (CDR) and the pan-Canadian Oncology Drug Review (pCODR)
- Quebec's *Institut national d'excellence en santé et en services sociaux* (INESSS)
- Patented Medicine Prices Review Board (PMPRB)
- pan-Canadian Pharmaceutical Alliance (pCPA)
- Federal/provincial/territorial public drug programs (general formularies and exceptional access programs)
- Non-Insured Health Benefits program (for Indigenous peoples through the Department of Indigenous Services Canada)
- Provincial Workers' Compensation Boards
- Private plan review and approval procedures

In fact, Canada has one of the longest wait times for coverage of new drugs. It takes an average of 449 days from initial national marketing approval to public launch and reimbursement of new drugs, which positions Canada 15th out of 20 comparator OECD countries.[9]

There is also considerable variation in approval processes with regard to exceptional access programs. These programs enable access to drugs not funded through the public formularies, where no listed alternative is available. Generally, to become eligible for exceptional access to a particular drug, a patient's prescribing practitioner must submit an application on the patient's behalf to the exceptional access program, complete with medical information and clinical rationale for the request. This process, along with lengthy backlogs, can excessively delay patient access to medications. For example, the overall length of time to approve applications in Ontario for two of the most requested biologic drugs averaged seven to eight weeks.[10]

BARRIERS TO ACCESS FOR INDIGENOUS PATIENTS

Gaps in coverage and delays in access to drugs are exacerbated for Indigenous Peoples through the Non-Insured Health Benefits (NIHB) program, which insures Status First Nations and Inuit people not covered by provincial, territorial or private insurance plans. A major problem is that the NIHB, along with some provinces/territories, positions themselves as payer of last resort. Therefore, many Indigenous patients are left waiting while provincial/territorial programs and the NIHB dispute and delay their responsibility for drug coverage.[11]

Further access inequities for NIHB patients involve formulary listing disparities and inconsistent claims processes. For example, some common and life-saving medications that are available to patients under provincial/territorial drug programs are not generally available to patients under the NIHB and require pre-approval from Indigenous Services Canada. Additionally, the process to approve Indigenous patients for medications that are not on the NIHB's auto-approve list is significantly more cumbersome than similar processes under provincial/territorial plans. The NIHB process involves long forms and an NIHB committee decision, which can take weeks, while provincial/territorial drug program approval processes are automated and take only a few minutes.[12]

DRUG AVAILABILITY

As drug plans continue to drive down prices of both brand medications and generics through negotiations and listing arrangements, the unintended consequence can be a decrease in medication availability and supply in Canada. Various other factors also contribute to temporary and ongoing supply issues. Community pharmacists routinely experience drug shortages when manufacturers and distributors are unable to meet the demand.[13] Even when patients have sufficient drug insurance, they can face periodic or long-term shortages of their medications. Not surprisingly, these have a significant impact on patients.

Patient-centred principles

Flowing from the three key barriers to access are five core principles that should guide all pharmacare policy decisions.

EQUITY

Every Canadian should have equitable and consistent coverage for medically necessary prescription medications.

- Canada's patchwork of drug coverage means that Canadians do not have equitable access to prescription medications.
- Canadians should not be forced to make critical decisions about their health based on the availability of drug coverage in their jurisdiction.

While most Canadians have access to some form of public or private drug insurance, too many Canadians do not. For those who do, the level of coverage may vary considerably based on age, disease, financial situation and place of residence. This creates inequity among patients. Since most private plans cover more medications than public plans, a further layer of inequity is created. The table below demonstrates the varying coverage between drug plans both within and across the provinces.

Number of drugs with claims reimbursed in 2015 by Health Canada unique identifiers: Drug Identification Numbers (DINs)[14]

	NL	NS	NB	QC	ON	MB	SK	AB	BC
Unique DINs covered across both public & private plans	4,229	4,359	4,567	7,452	5,095	4,771	4,067	4,123	5,243
Unique DINs covered only by public plans	410	294	270	340	240	679	233	46	554
Total DINs covered by public plans	4,639	4,653	4,837	7,792	5,335	5,450	4,300	4,169	5,797
Unique DINs covered only by private plans	1,446	1,533	1,739	1,975	3,970	1,094	1,464	2,695	1,528
Total DINs covered by private plans	5,675	5,892	6,306	9,427	9,065	5,865	5,531	6,828	6,771
Difference in DIN coverage through public and private plans	1,036	1,239	1,469	1,635	3,730	415	1,231	2,659	974

* No data available for PEI

TIMELINESS OF ACCESS

Canadians should be able to access the medicines they need in a timely manner, without extended wait times.

- Canada's process for reviewing, approving and providing coverage for prescription medications is complex and lengthy, and can delay access to necessary time-sensitive care.
- Shortages in drug supplies can affect the timeliness of access to medications.

Patients often experience delays in accessing the care that they need, and these delays can occur at several points on a patient's treatment journey. This can result in poorer health outcomes, secondary effects requiring further treatment, and can lead to unnecessary hospital stays. Patients can also experience stress and anguish when they are suddenly faced with the uncertainty of a delay in accessing treatment.

APPROPRIATENESS OF THERAPY

All Canadians should have access to the medications that are most appropriate for their individual needs.

- Patients, in consultation with their health care provider, should have access to a comprehensive range of medicines to achieve optimal care and outcomes.
- The ongoing use of medications must be monitored and reviewed to ensure that patients continue to obtain the best possible outcomes and that health resources are used efficiently and appropriately.

All health care professionals, i.e. physicians, pharmacists and nurses, along with patients, play a role in ensuring the appropriate use of prescription drugs through prescribing, dispensing, monitoring and adherence practices. The costs associated with inappropriate prescribing are particularly evident among seniors older than 65 years of age. The estimated total costs to public drug plans for filling inappropriate prescriptions for these Canadians total $419 million annually and contribute to significant medication waste.[15] While inappropriate prescribing is a complex issue with a number of causal factors, one example related to drug coverage is when a patient is prescribed a less effective medication for their condition because the drug they require is not available on the patient's drug plan formulary.

AFFORDABILITY

All Canadians should be able to afford their medications at the point of care.

- Many Canadians, even those with coverage through drug plans, have difficulty affording the medications that they need.
- Affordability must also consider costs to drug programs and to systems.

In Canada, governments fund only 43% of prescription drugs, with the private sector covering the remaining 57%, of which 35% is through private insurers and 22% is through patient out-of-pocket expenditures.[16] High out-of-pocket costs arise when patients do not have any insurance or not enough coverage on account of exclusions, cost-sharing, or plan limits.

Unfortunately, higher out-of-pocket costs are often associated with lower household incomes and either minimal or no drug insurance coverage. In fact, Statistics Canada found that, on average, households in the bottom before-tax income quintile (lowest 20 per cent) allocate over 1 per cent of their annual spending to out-of-pocket drug expenses. This represents four times the spending of households in the highest before-tax income quintile (0.24 per cent).[17] The economic burden associated with out-of-pocket costs has continued to grow in recent years, especially among low-income families.

Even Canadians who have private drug coverage may face challenges. For example, an individual with 80% coverage and drug costs of $100,000 annually, such as for some rare disease or oncology treatments, could be forced to pay unsustainable out-of-pocket amounts.

It is possible that as employers are faced with the prospect of rising drug benefit costs they may mitigate their risk by moving away from unlimited benefits, which can be detrimental to coverage of necessary treatments.

SUSTAINABILITY

All Canadians should benefit from a pharmacare system that ensures the ongoing sustainability of the health system.

- Reforms must focus resources on addressing cost pressures and supporting long-term sustainability for Canadians now and into the future.

- Various measures can contribute to sustainability, including selectively increasing drug budgets to realize savings elsewhere, promoting appropriate prescribing and adherence and allowing for a mix of public and private drug programs.

At a time when drug plans are looking to improve value for money amid various cost pressures, a key consideration is the long-standing sustainability of not just drug programs but the broader health system. In 2017, prescription drug spending was forecast to make up 14% of health expenditure in Canada, or approximately $34 billion.[18] One key driver of growth in drug spending is the development of specialized drugs. Express Scripts Canada (ESC) reported that:

- Specialty drugs accounted for only 2% of claims in 2016, but they made up 30% of total prescription costs.

- Just 14% of plan members accounted for 72% of total plan spending.

In 2011, members with annual claims of more than $10,000 represented 18.1% of total spending; by 2016, that number was 28.8%.[19] In 2015, ESC estimated that specialty drugs would account for 42% of prescription drug costs by 2020.[20]

Given strained health resources, the option of providing a continuing role for private insurance and thereby focusing the allocation of public resources is one consideration. A system which includes an appropriate mix of comprehensive public and private drug programs could contain public costs and contribute to sustainability.

Appropriate prescribing and adherence to treatment are key tactics in reducing broader health system costs. For example, patients who cannot adhere to their medications may experience reduced functioning at work, rely on family care providers, increased physician visits, increased medication use, need emergency departments and in-patient services, and have increased mortality risk.[21] These consequences ultimately create added pressure on the strained health care system and increase total costs. Pharmaceutical reform must, therefore, focus on achieving cost savings across the system, utilizing health care resources and practitioners effectively and efficiently, improving health outcomes and reducing lost productivity in the workforce.

Assessing Policy Options: Informing the Way Forward

Numerous formal reviews have explored Canada's pharmaceutical care challenges and have called for broad reform, including:

- National Forum on Health, 1997
- Royal Commission on the Future of Health Care, 2002
- Senate Report on the Health of Canadians – The Federal Role, 2002
- National Pharmaceutical Strategy, 2004

More recently, in 2015, the federal Liberal Party's election platform promised a renewed Health Accord, including a commitment to reassess transfer payments to the provinces and to enact pharmaceutical reform.[22] In January 2016, the Standing Committee on Health began a comprehensive study on the development of a national pharmacare plan, and reported in April 2018. In 2017, provincial/territorial health ministers began developing options to improve access and affordability of prescription medications for all Canadians.[23] In February 2018, the federal government announced the creation of an Advisory Council on the Implementation of National Pharmacare to conduct further research and recommend options to move this important policy forward.[24] On the provincial/territorial level, there continues to be a patchwork of initiatives being implemented across the country to address gaps in drug access. For example, on January 1, 2018 Ontario introduced its OHIP+: Children and Youth Pharmacare Program, broadening universal coverage for a segment of its population.

As a means to reduce drug costs in Canada, we have seen an increase in joint efforts such as the pan-Canadian Pharmaceutical Alliance (pCPA), which was originally organized by nine provinces and now includes Quebec and the federal government. The pCPA negotiates lower drug prices with drug manufacturers on behalf of public plans, and introduced major generic drug price reductions on April 1, 2018.[25] The federal government has also announced draft revisions to drug pricing regulations for the Patented Medicine Prices Review Board that would affect the maximum price of new patented drugs. Additionally, the possibility of providing federal leadership on a single national formulary or an essential medicines list is being considered.

In light of these and other potential developments, the Working Group has evaluated five key drug policy options:

1. **Single National Formulary:** A single formulary for use by all public (and possibly private) plans, replacing all existing formularies.
2. **Essential Medicines List:** A universal publicly-funded program that would cover a limited list of frequently prescribed medicines based on disease prevalence, evidence of clinical efficacy, safety and cost-effectiveness.
3. **Catastrophic Drug Coverage:** A universal public program designed to provide coverage for patients with high out-of-pocket drug costs relative to their income.

4. **Price Controls:** Measures to control drug pricing through regulation or negotiations, e.g., changes to the policies, guidelines and procedures or cooperation among payers to leverage buying power and eliminate duplication by jointly negotiating the price of brand and generic drugs.
5. **Fully Public or Mixed Models to Achieve Universal Coverage:** Comprehensive universal drug coverage for all Canadians through an entirely public system or mix of private and public plans.

The following analyses apply a patient-focused lens to these five policy options using our five principles: equity, timeliness, appropriateness, affordability and sustainability.

SINGLE NATIONAL FORMULARY

A single national formulary is a list of medications covered by all public (and possibly private) plans, replacing existing formularies or serving as a minimum standard.

While there is significant overlap in listed medications among public[26] and private formularies, there are many differences that can result in considerable inequities depending on their age, disease, financial situation and place of residence. A national formulary would provide a single, consistent list of medications for public drug plans and might also include private drug plans, creating a consistent universal base that individuals could then supplement through additional coverage.

While this option allows for enhanced consistency across the country and improves equity, any formulary has the potential to limit or delay the availability of new or innovative treatment options, as well as patient and prescriber choice. A further limitation of a national formulary is that, in itself, it does not assist those who are not eligible. The following observations should therefore be considered:

- A national public formulary must not revert to the lowest common denominator. It should not remove coverage already available to any Canadian. Therefore, it should meet or exceed the coverage available under the most comprehensive provincial plan (Quebec).
- A national formulary should improve patient access to both generic and innovative new drugs.
- An effective single national formulary must be based on principles of optimal patient care and as such be comprehensive and provide treatment options to recognize the genetic diversity of Canadians and the importance of patient choice in achieving optimal health outcomes. As part of efforts to manage drug expenditures, and based on the assumption that all patients will have the same response to a drug, choice within a therapeutic class on a formulary can be limited. One Canadian study demonstrated that forcing patients to a single drug in a specific therapeutic class (Proton Pump Inhibitors) resulted in increased health system costs.[27] Formularies must therefore avoid overly restrictive eligibility criteria, including step therapy and line-setting, and reflect the need for individualized care. Patients whose health is stable on a particular medication should not lose access to that effective therapy.

- Negotiations for the listing of any new medications should be based on the best possible evidence and patient needs, not based primarily on the ability to negotiate a specific price.

Although new medications would still be subject to review and negotiation timelines, a single formulary could also have a positive impact on timeliness of access by reducing duplication in drug approval processes and the costs associated with these reviews.

ESSENTIAL MEDICINES LIST

An essential medicines list usually refers to a universal publicly-funded program that would cover a limited list of frequently prescribed primary care medicines based on disease prevalence, evidence of clinical efficacy, safety and cost-effectiveness.[28] It is important not to conflate this limited concept with that of a national formulary. A national formulary would provide a baseline for all public and private plans and apply to those who are eligible under these plans, whereas an essential medicines list usually refers to a limited set of drugs covered universally, i.e. for all Canadians, and strictly through public funding.

While this list of medications would generally improve equity, it raises considerable concerns and challenges for patients who require access to medications not contained on the essential medicines list. What is an essential medicine to some may not be considered essential to others within our diverse population.

In addition to the considerations raised in the assessment of a national formulary, which would also apply to an essential medicines list, we have identified the following concerns:

- Some patients will see a decrease in out-of-pocket spending for some prescription drugs, but other patients who require medications that are not included on the list will not benefit.
- It is inherently difficult to define such a list and identify which medications are considered essential and which ones are not.
- It is important that an essential medicines list allow for additional supplemental coverage through other public and private plans.

CATASTROPHIC DRUG COVERAGE

Catastrophic drug coverage refers to a universal public program designed to provide coverage for individuals who are experiencing high out-of-pocket drug costs relative to their income. Currently, all provinces and territories offer some form of catastrophic drug plan based on varying definitions of high drug costs relative to income.[29] A national program would provide access to a consistent program across Canada, resulting in increased equity. However, patients may still face affordability barriers, depending upon program criteria. The following observations should be considered:

- Based on income and affordability, program criteria should exempt certain patients from immediately paying the full cost of their medications out-of-pocket, and then waiting for reimbursement. This could result in patients foregoing treatment due to high upfront costs.

- Catastrophic drug programs should be electronically adjudicated to ensure immediate eligibility checks and minimize the administrative burden on patients and prescribers.
- It may be difficult for all provinces/territories to agree on a threshold that constitutes "undue financial hardship."

PRICE CONTROLS

Since 2010, governments have made considerable progress in reducing the cost of drugs, primarily through the pan-Canadian Pharmaceutical Alliance (pCPA). The pCPA has completed negotiations for over 200 new patented drugs and reduced the price of almost 70 generic drugs effective April 1, 2018. Savings of up to $3 billion are projected over the next five years.[30] The federal government is also considering updated regulations regarding the Patented Medicine Prices Review Board (PMPRB) in order to lower the maximum allowable price for new patented drugs.

On the surface, it may appear that reduced drug costs would improve the affordability and overall sustainability of health care and drug spending in Canada. However, price reduction measures could also lead to diminished access to medications. The following observations should be considered:

- A less favourable market could lead to the reduced or delayed introduction of new and innovative therapies.
- Failure to negotiate a specific price could cause drug plans to stop covering certain drugs.
- Single supplier contracts could reduce competition. This creates risks and exacerbates the potential for drug shortages.
- Due to the complex nature of the drug supply chain, reductions in drug costs could affect manufacturers, distributors, pharmacies and other health care facilities, which may in turn affect patient access to medications.
- Any measures must also acknowledge the needs of patients who pay out-of-pocket for medications. These patients should also benefit from lower negotiated prices.

FULLY PUBLIC OR MIXED MODELS TO ACHIEVE UNIVERSAL COVERAGE

Canada is the only OECD member country with a universal health insurance system that does not also include coverage for medications. Universal coverage could be achieved in two ways:

1. Through an entirely public single payer model, either nationally or in collaboration with the provinces and territories.
2. Through a social insurance model that includes both public and private coverage and builds upon Canada's existing drug plans.

Either design must consider how and by which parties this coverage would be funded as well as the implications of each model for patients.

Single Payer Public Coverage:

Universal public coverage would replace Canada's current system of mixed public and private insurance and be funded and/or administered by either the federal or provincial/territorial governments.

If the adopted model includes a comprehensive formulary, like those offered under private plans, patients who currently lack coverage would see significant improvement in access, regardless of age, disease, financial situation or place of residence. However, the following observations should be considered:

- To implement a universal public system and contain public expenditures, governments may have to limit the availability of certain medications, which would reduce the level of drug coverage available to patients who currently have comprehensive coverage through private plans.
- If only an essential medicines list is universal, many Canadians could experience a loss in coverage, including those who are currently covered under private and public plans.
- Patients who are prescribed drugs outside of the national formulary (e.g., oncology, chronic disease, or rare diseases) would have to wait for special approval processes.
- The significant cost shift from the private sector to the public purse could mean fewer investments in other areas of the health system requiring improvement, including home care, surgical wait times, access to diagnostics and mental health programs.

Public/Private Coverage:

Universal coverage could be achieved by building upon provincial/territorial/federal programs and leveraging existing private plans, which currently provide coverage for 25 million Canadians through supplementary health insurance.[31]

A mixed coverage system would avoid a complete overhaul of the system, thus limiting disruption to patients' existing access to medications. This system would also reduce public costs to replace coverage already offered through private plans, with which the vast majority of Canadians are currently satisfied.[32] Further, mixed payers could foster continued drug plan innovation through regulated competition. However, the following observations should be considered:

- A mixed system would likely result in some level of inequity between Canadians, but this can be mitigated by a comprehensive, mandatory national formulary, with supplemental coverage at additional cost.
- Subsidies would be required for low income Canadians to purchase supplemental private insurance. Any cost-sharing initiatives should be tied to income.
- Any system requires effective governance and management, but mixed funding could result in higher costs than a fully public universal plan.

Conclusion

Canada is at a tipping point regarding drug access as too many Canadians are not receiving optimal care. Patients are sometimes unable to afford to fill their prescriptions; they must endure extended wait times for access to medications; or they do not have access to the right medication for their needs. Outcomes are compromised with significant implications for patients, caregivers, public and private payers, the health care system and our society as a whole.

It is time for all Canadians – regardless of age, disease, financial situation and place of residence – to have equitable and timely access to a comprehensive formulary of proven and safe medically necessary prescription drugs without financial hardship.

Significant pharmaceutical policy reform to address key barriers to access is necessary and important. Several policy options now in discussion or development may bring value to the system while also having the potential to improve patient care. Our deliberations in applying patient-centric principles to key policy options have led to important insights, which we hope will inform future policy and program considerations.

Key learning from the evaluation includes:

1. **Single National Formulary:** While this option could create a more equitable level of coverage for Canadians and could help streamline listing processes, it would not benefit patients who require medications outside those listed in the formulary nor those who are ineligible for public or private drug insurance. While a single national formulary has some merit, it is not a stand-alone solution.

2. **Essential Medicines List:** This option could improve access to medicines for some Canadians who currently lack coverage for primary care drugs, but it would exclude those who rely on the many therapies not on the list.

3. **Catastrophic Drug Coverage:** Improved and consistent access would support patients who face extraordinarily high prescription costs relative to their income. The minimum cost threshold must be set at a reasonable level and it must minimize upfront, out-of-pocket costs which may act as a barrier to drug access and adherence.

4. **Price Controls:** Regulatory changes to control drug prices are intended to improve the overall sustainability of the system and could improve affordability for patients. However, this approach risks limiting therapeutic options if low prices are a barrier for manufacturers to ensure timely new drug introductions in Canada.

5. **Models to Achieve Universal Coverage:** Universal coverage can be implemented in different ways and could provide more equitable access to prescription drugs.

    a) **Single Payer Public Coverage:** If a completely public system results in coverage for a more limited list of medications, many patients will suffer. All governments must avoid implementing the lowest common denominator and strive for patient-centred outcomes.

    b) **Public/Private Coverage:** A mixed-funding social insurance system would build on the strengths of the existing system and levels of coverage. It could, however, continue to create inequities and lead to higher costs. It would be important to mitigate these risks.

NEXT STEPS: MOVING FORWARD

Our organizations will continue to discuss these policy options and alternative models with all stakeholders and policy makers with the goal of ensuring that all reforms ultimately contribute to better patient care and outcomes.

Moving forward, we call for careful consideration of the following:

- Important principles – equity, timeliness of access, appropriateness of therapy, affordability and sustainability – must guide pharmacare policy, program design and administration.
- There must be ongoing, comprehensive and meaningful engagement with patients and health care professionals as options are explored and implemented. Incorporating these perspectives and experiences is integral to developing solutions that are effective and sustainable.
- Pharmaceutical reforms must guarantee that no Canadian is left behind. The needs of every patient must be recognized, including those with unique needs. Equally important, all patients must have access to a comprehensive range of medicines including those that are most appropriate to their individual needs.
- Drug policy alternatives must address all potential benefits and repercussions within drug programs and health systems broadly. The affordability of any given policy option must be carefully considered within the context of providing the best possible care to patients now and in the future.

Appendix A: Pharmacare Working Group Members

The Canadian Pharmacists Association, Best Medicines Coalition and Health Charities Coalition of Canada would like to thank the members of the Pharmacare Working Group for their time and thoughtful contributions to this review and analysis. Their expertise and enthusiasm were instrumental in the development of this document.

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