CANADIAN CANCER SURVIVOR NETWORK RÉSEAU CANADIEN DES SURVIVANTS DU CANCER

A Pharmacare Vision Based on the Healthcare Needs of Patients

Canada is the only country in the world with a publicly funded healthcare system that does not include access to prescription medicines. Access to prescription medicines and/or therapies – Pharmacare for short – affects all Canadians.

There are two main issues that Pharmacare must address: the uninsured (coverage gap issue) and the underinsured (formulary-based issue).

Public drug plans are only available for specific populations. Those that are not eligible for these plans do not have coverage at all unless they are provided by their employer (if they are employed) or purchased through a private insurance company. With the exception of Ontario, children to those aged 64 years old do not have any form of unconditional coverage.

Often private drug plans have premiums that are increasingly more costly with yearly maximums decreasing and formularies that become restrictive or unavailable, especially when an employer discovers that its employee(s) have a chronic illness or rare disease.

For Canadians who are underinsured, the lack of access to medically necessary therapies has resulted in out-of-pocket expenses and non-adherence to prescription medicines. Canadians are either skipping their doses, reducing them, or not taking them at all. Statistics report that about one in ten Canadians are not filling their prescriptions due to cost, equating to nearly one in four Canadian households.[1]

Patients and consumers see that the current healthcare system does not provide them timely, equitable, safe and effective access to medically necessary therapies. At the same time, Pharmacare must not be a program that merely satisfies the lowest common denominator because this does not guarantee access to prescription medicines. The lowest common denominator, in this case, refers to coverage of baseline prescription medicines for the majority population.

Accessible and affordable drug formularies must address the actual medical needs of patients, especially those with chronic illnesses or diseases, including cancer, and people with rare diseases. Currently, these patients are prescribed treatments that are often costly, unaffordable or unavailable.

[1] Steven G. Morgan et. al, "Pharmacare 2020: The Future of Drug Coverage in Canada," *The Pharmaceutical Policy Research Collaboration*, University of British Columbia, 15 July 2015 at 7.

Pillars for an accessible, fair and equitable program for Pharmacare and healthcare are already envisioned in federal legislation. Of particular importance, the *Canada Health Act* [R.S.C., 1985, C. c-6] states that the federal government of Canada must ensure:

- That the future improvements in health will require the cooperative partnership of governments, health professionals, voluntary organizations and individual Canadians
- That continued access to quality healthcare *without financial or other barriers will be critical* to maintaining and improving the health and well-being of Canadians[2]

National Pharmacare has been pursued by Canadian governments since the 1960s, and it is long overdue.

We urge that the federal government of Canada, along with the provincial and territorial governments, commit to their constitutional responsibilities for healthcare and include a Pharmacare program that properly addresses the needs of Canadians.

The Canadian Cancer Survivor Network (CCSN) is pleased to submit this policy paper to the Advisory Council on the Implementation of Pharmacare.

This submission provides a list of the key components and recommendations for a national Pharmacare program. These recommendations are organized by the following principles: **Accessibility**, **Timely**, **Safe and Effective**, **Equitable Financing**, **Invest**, **Collaboration, Accountability of Governments**, and **Consistency**.

[2] *Canada Health Act*, RSC 1985, c C-6, Preamble.

ABOUT THE CANADIAN CANCER SURVIVOR NETWORK

The Canadian Cancer Survivor Network (CCSN) is a charitable organization of cancer patients, survivors, caregivers, families, friends, community partners and sponsors who work together to take action to promote the very best standard of care, support, follow-up and quality of life for patients and survivors.

CCSN strives to ensure that patients and survivors can easily access tools to understand decision-making processes for positive change on issues critical to optimal patient care. We provide patients and survivors support to make a difference through working with others to take action on those issues. Lastly, we contribute to strengthening current knowledge of patients and survivors about cancer diagnosis, treatment, options and outcomes and to provide pathways in collaboration as means to ending disparities in patient care and treatment. For more information, please visit our website at www.survivornet.ca.

Key Components of a Pharmacare Program

- All people residing in Canada have timely, consistent, equal and equitable access to safe and effective therapies, including treatments and medications, as well as the information, diagnostics, care and support that they need, without conditions.
- Every person is to have equal opportunity to access therapies regardless of barriers related to the social determinants of health.[3]
- The plan for Pharmacare must be pursued with a mixed model approach: a national formulary that addresses essential medicines of those uninsured (for children to 64 years old) and a nationwide enhancement and consistency of coverage and eligibility for the underinsured, especially patients with cancer, chronic diseases and rare diseases.
- A fair Pharmacare program will consist of a coverage plan that goes beyond a formulary that meets the lowest common denominator.
- Patients should be recognized and included in every level of decision-making processes as they are key stakeholders in healthcare. In addition, Pharmacare must be guided by principles that are patient-focused.

[3] "Social Determinants of Health," Public Health Agency of Canada, accessible at http://cbpp-pcpe.phac-aspc.gc.ca/public-health-topics/social-determinants-of-health/.

Recommendations

ACCESSIBILITY

a) Protect and improve existing individual access to therapies at or above their current level. Essential to this recommendation is safeguarding access to medically necessary therapies for uninsured and underinsured residents of Canada regardless of ability to pay or place of residency.

Pharmacare must strive to build on the foundation of healthcare mechanisms and systems already in place. The plan continues to provide, and improves upon, what people are currently receiving for medically necessary care. Through this development process, it delivers the key components of Pharmacare.

b) A Pharmacare program views access as based on the values of universality, equality and without conditions.

Improving access is informed by social justice principles. This means upholding equal opportunity to access and benefit from all social determinants of health. It also recognizes respect for people who access the health system, including their support team.

According to the *Canada Health Act*, s. 3 states that the "primary objective of Canadian health care policy" is to "protect, promote and restore the physical and mental well-being of residents of Canada and to facilitate reasonable access to health services without financial or other barriers."[4]

Of particular importance, the *Act* also specifies that healthcare insurance plans in provinces and territories (P/Ts) must meet the criteria of universality, portability and accessibility.[5]

c) Recognize the discrete needs of people with life threatening and serious debilitating illnesses that significantly impact quality of life.

A Pharmacare plan makes an express distinction of the healthcare needs and accessibility challenges of patients with chronic diseases, including cancer, and rare diseases. Patients in these populations often face unaffordable yet medically necessary therapies. For instance, many of the new cancer therapies are administered out of hospital in pill form and are therefore not covered by public drug plans in some provinces.

Currently, public insurance for cancer oral drugs across Canada are uneven. Despite the necessity of these medicines in the treatment of cancer patients, they are not covered by eastern

[4] *Supra* note 2 at s 3.
[5] *Ibid* at ss 10, 11 and 12.

provincial governments. Oral cancer drugs are covered from Manitoba to British Columbia, but not from Ontario eastward. Cancer oral drugs are often costly and needed on a regular basis. Patients who cannot afford these drugs face the dilemma of whether to move to another province in order to have access to their medically necessary treatments. Healthcare must be accessible without conditions of residency to promote the well-being of Canadians.

In order to properly address healthcare for rare diseases, the Government of Canada must undertake the creation of a national framework for rare diseases. This will include consultations with the public and further opportunities to participate.

TIMELY

a) **That the Minister of Health, along with the Government of Canada, take a leadership role in reducing delays in access to new therapies by actively engaging health technology assessments (HTAs) and P/Ts about the necessity of timeliness and availability of prescription therapies for patients and consumers. Patients are dying waiting for drugs to be approved. This is unacceptable for a country that prides itself in human rights.**

Canada is lagging in the approval process of medical therapies, especially in comparison to the United States. Studies show that Canada's inefficiencies and protracted regulatory and reimbursement approval processes on the federal and provincial level has resulted to denying over 5,000 patients the means to alleviate the conditions of their serious diseases.[6] Oncology drugs are reviewed and approved at much slower times than other drugs even though there are designated mechanisms established for their review. The approval process also needs to capture the increasing challenges that biologics and precision and personalized medicines bring as they are coming down the pipeline.

The availability of medical therapies in P/Ts is inconsistent across the country, resulting in therapies being covered at different times in different provinces, with some provinces not covering them at all. As a result, patients do not have guaranteed access to life-saving drugs. Some patients die waiting for drugs to be approved. Many could have achieved a significantly better quality of life had they received access to these medicines earlier.

Delays in the approval process send a stark remark about how Canada, a country that likes to think of itself as a champion of human rights, actually values patients' lives.

b) **In conjunction with the leadership role of the Minister of Health and the Government of Canada, the provincial and territorial Ministerial Offices on Health must work together to develop a mutual recognition process of medical therapies for approval in their jurisdictions. Developing this consensus lessens the delays for the approval and reimbursement of new therapies.**

Under the current regulatory and reimbursement approval process in Canada, it is up to the P/Ts to decide whether they accept the recommendations of HTAs for certain drugs and therapies.

As mentioned above, some therapies are available in some provinces of the country but not in others, resulting to a healthcare system that promotes treatment and survivorship based on residency and ability to pay.

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[6] See Nigel S.B. Rawson, "Potential Impact of Delayed Access to Five Oncology Drugs in Canada," *Centre for Health Policy Studies,* Vancouver: Fraser Institute, November 2013; Ali Shajarizadeh and Aidan Hollis, "Delays in the Submission of New Drugs in Canada," *CMAJ,* 187(1), 2015.

It is critical that a Pharmacare program ensure access to necessary medicines at the right time, regardless of residency and with minimal financial burdens. Governments and stakeholders must work together to achieve optimal care and enhance treatment and survivorship for patients.

c) Increase efficiency, communication and transparency among key stakeholders from the bottom up. Make aligned review processes wherever applicable and appropriate.

The Minister of Health, Health Canada and HTAs must promote lines of communication with P/Ts to increase efficiency, transparency and communication of the healthcare needs of patients.

Regional Health Authorities (RHAs) can consult with stakeholders in front-line delivery, such as hospitals, hospital pharmacies, and patients, in developing in-hospital and outpatient formulary decisions.

RHAs have the ability to transfer patient and health care practitioner (HCP) knowledge of healthcare services and availability to P/T Health Ministries. Of key importance in this knowledge transfer is the reporting of unmet needs by patients, such as access to life-saving therapies. This will aid P/Ts in their efforts to develop mutual recognition of drugs recommended from the federal regulatory review processes.

RHAs across the country should keep open lines of communication between one another to ensure that access to life-saving drugs is available throughout Canada.

SAFE AND EFFECTIVE

a) Accept, assess and value qualitative and quantitative real world evidence in determining therapeutic value.

Assessments are informed decision-making processes that integrate best practice and available evidence into health systems and health policy. In addition, these recommendations are undergirded by the principles of accountability and transparency for all health systems processes and health policy.

b) Promote safety and efficiency through increasing patient access to medical records, regardless of ability to pay.

That the Government of Canada engages with relevant stakeholders on the importance of patient access to medical records. Patients experience administrative and financial barriers in accessing their medical records. This is exacerbated by the fact that patients often see several healthcare professionals for multiple medical issues. However, increasing patient access not only makes health systems more efficient, but patients are able to be better informed about their care.

Access to medical records is also necessary because insurance companies can demand copies of these files to support a patient's application for reimbursement for certain therapies. However, as a result of a Supreme Court decision in 1992[7], the law allows physicians and hospitals to charge patients a fee for providing copies of medical records.

These fees are not always affordable. Some hospitals charge patients an upwards of $2,532 for a copy of their medical records. Other clinics have a fee for simply putting in the request for a copy.[8]

In addition, P/Ts differ in their regulations about access to medical records. The Federal Minister of Health must consult with stakeholders in the healthcare system to develop national standards for patient access to medical records.

Health systems also need to be prepared to address the increasing number of electronic technologies available in the Canadian market that allows patients and physicians to access and update medical records together in real-time. Healthcare professionals who do not keep electronic records are doing their patients a disservice.

[7] *McInerney v MacDonald,* [1992] 2 SCR 138, at 159 [*McInerney*].
[8] Lisa Priest, "Why you have to pay for your own medical records," *The Globe and Mail,* 30 April 2018, accessible at: https://www.theglobeandmail.com/life/health-and-fitness/ask-a-health-expert/why-you-have-to-pay-for-your-own-medical-records/article598924/.

c) Adopt a Pharmacare system that functions on prescribing practices that are informed, safe and effective. Raise awareness and educate stakeholders wherever necessary.

There is a knowledge gap among HCPs, patients and consumers due to the increasing complexity of pharmaceuticals, especially with regards to innovative medicines. Informed, safe and effective prescribing practices consist of developing clear lines of communication among HCPs, pharmacists and patients about their medical histories. With over 13,000 drugs in the Canadian market and a growing number of Canadians with multiple chronic diseases that require several daily medications, safe and appropriate prescribing practices are necessary.[9]

However, medical practitioners lack the knowledge and skills necessary to address the complexity of innovative treatments. For physicians, only nine to 50 hours of medical school are devoted to Clinical Pharmacology.[10] Educational and awareness initiatives must be developed in order to address the new and emerging landscape of medical therapies entering the Canadian market.

In addition, the inability of HCPs to address the growing list of medicines also leave patients' prescriptions unaccounted for. Some patients are filling prescriptions that are out of date and no longer needed. Doctors and/or pharmacists need to regularly evaluate patients' prescription records. Doing so avoids the creation of waste in the healthcare system, thereby opening ways to put savings back into the healthcare budget.

[9] Standing Committee on Health, 42nd Parliament, 1st Session, *Pharmacare Now: Prescription Medicine Coverage for All Canadians* (2018), at 57.
[10] *Ibid.*

EQUITABLE FINANCING

a) Analyze the value of a drug or treatment for a Pharmacare system to include savings in other parts of the healthcare budget and broader socio-economic impact.

Develop value-based drug pricing contracts, including systems for sharing data and other relevant information. Expand HTA processes to measure the value of all components of the healthcare budget. HTA bodies are able to analyze the value of a drug in broader terms of overall cost to the healthcare system and society as a whole.

Pharmaceutical system savings must be reinvested back into the Pharmacare budget to provide increased access to therapies.

b) That the Government of Canada increase their funding to P/Ts through the Canada Health Transfers to accommodate for the public insurance of prescription medicines dispensed outside of hospitals.

The federal government should increase its share in cost for healthcare through the federal transfer payments, namely the Canada Health Transfers (CHT). This recommendation is reflected in the Preamble of the *Canada Health Act*, which states that the Parliament of Canada assists provinces in meeting the costs involved in the development of health services.

There has been chronic underfunding by the federal government for CHTs with P/Ts. Healthcare costs between the federal government and P/Ts were based on the federal statute passed in 1957 called the *Hospital Insurance and Diagnostic Services Act.*[11] Under this statute, F/P/Ts agreed on a division of healthcare costs by 50/50. Since then, federal government shares have dropped to below 20%. By reducing CHT, the federal government has diminished their moral authority over healthcare.

Reducing federal funding lowers the ability of P/Ts to meet the demands of their residents. At the same time, the decrease in funding for public services makes way for an increase in private healthcare businesses due to the inability of governments to meet the healthcare demands of the public. Private healthcare businesses divert needed resources such as doctors and nurses from the public system.

More importantly, there is no mechanism in place to track where the money is spent. CHTs are transferred to the P/Ts' general revenues rather than their health ministries. Therefore, the federal government and P/Ts must work together to develop a performance measurement process to ensure that finances are allocated to healthcare priorities.

[11] Government of Canada, *Canada's Health Care System* (2011), at Timeline.

Addressing issues within the cost-sharing responsibilities of governments ensures that P/Ts have the capability and support of the federal government in meeting healthcare needs of their residents.

A Pharmacare program is merely bandaging root problems if a Pharmacare program does not address the issues present in a poorly funded healthcare infrastructure. Furthermore, provincial and territorial governments need federal financial support in order to address the costs of Pharmacare and provide it under a publicly funded system.

c) **A Pharmacare program functions as first-payer coverage for residents of Canada who have no form of insurance. For patients and consumers who have insurance coverage through private plans, a Pharmacare program functions as second-payer coverage.**

While there are no "best practices" for Pharmacare, the path to implementing a program needs to consider lessons from current models of coverage.

In this recommendation, a Pharmacare program ensures that the uninsured have fair and equitable access to public plans. Designating Pharmacare as second-payer coverage for Canadians who have private insurance ensures that patients have coverage for treatment above and beyond what their insurance pays, and increases efficiency and savings.

INVEST

a) Promote and invest in innovative research and medicines.

Canada is home to many internationally renowned research agencies and institutions. However, due to inefficiencies in the system, much of this innovative work is not entering the market. A Pharmacare program needs to reward excellence in science by ensuring the results of research produced in Canada enters the Canadian market.

b) Increase funding for chronic diseases, including cancer, and rare diseases.

With increasing cancer rates due to an aging and growing population, the Government of Canada must ensure that there is sufficient funding designated for cancer, chronic diseases and rare diseases.

COLLABORATION

a) **The plan has a patient-centred notion of values, with patients playing a role in HTA processes and in defining values.**

This recommendation highlights the principle of inclusivity of key stakeholders in decision-making processes, in which patients, consumers, HCPs and indigenous communities take part.

People who access the health system must have meaningful and ethical engagement, including engagement in health systems planning, decision making, implementation, knowledge transfer and exchange, monitoring and evaluation, and systems redesign. A Pharmacare program strives to collaborate among healthcare stakeholders and all levels of government, with recognition of the healthcare priorities of each province and territory and of patients.

b) **Enhance capacity building and mentorship networks.**

Provincial and territorial governments work with the Government of Canada in the creation of binding healthcare agreements. As a part of this, P/Ts should periodically assess their respective jurisdictions and identify areas for improvement, healthcare issues, and concerns of patients. This review process entails working together with key stakeholders, including patients.

There are drug shortage strategies and tools in place that can be used to inform decision-making processes on consumer needs of medicines and drug trends.

Key players in the front line delivery of drugs are also well informed and have existing reporting infrastructures and expertise on pharmaceutical trends. Many hospitals and some community pharmacies are involved in this reporting.

a) **Engage in informed, inclusive and meaningful consultations with key stakeholders on the terms of a national formulary and nationwide enhancement and consistency of coverage and eligibility for cancer, rare diseases, and chronic diseases.**

That the Government of Canada, along with the governments of P/Ts and the Advisory Council, consult with key stakeholders, particularly patients and consumers, on the creation of a national formulary. This is extremely important in order to avoid producing a national formulary that only meets the lowest common denominator. A formulary that meets the lowest common denominator does not address the root problems of inaccessibility and non-adherence of Canadians with prescription medications/therapies.

Of particular importance in this recommendation is the inclusion and strengthening of engagement processes and mechanisms for the most vulnerable populations such as that of lower income, persons with disabilities including mental illnesses, racialized communities, rural communities and indigenous communities.

ACCOUNTABILITY OF GOVERNMENTS

a) That the Government of Canada and provincial and territorial governments abide to cost-sharing responsibilities and bilateral agreements through the creation of a performance measurement process.

The Government of Canada, along with the governments of P/Ts, have agreed on the Shared Health Priorities and healthcare goals for cost-sharing responsibilities (i.e. CHTs). These governments must also work to create an evaluative process to ensure that finances are properly allocated to their assigned mandates and that P/Ts meet the targeted goals written in bilateral agreements.

CCSN recommends that the Government of Canada amend the *Canada Health Act* to strengthen commitment to the conditions agreed upon in bilateral health agreements between the federal government and P/Ts. The *Act* must ensure that these bilateral agreements are binding on both parties or that a mechanism is established to ensure accountability of the P/Ts. This would entail amending the Conditions for Cash Contributions of the *Act*.

According to the *Federal-Provincial Fiscal Arrangements Act*, cash contributions are conditional upon promoting universality, access and quality healthcare.[12]

This recommendation highlights the evaluation system already present under Performance Measurement of the A Common Statement on Principles on Shared Health Priorities.[13]

b) That the annual reports of healthcare goals of the P/Ts be accessible to the public.

Evaluations of P/Ts must be made public via the production of a report provided annually to Canadians. This, in turn, promotes ongoing reviews of the timeliness, efficiency and guarantee to access to medically necessary therapies that Pharmacare should embody.

[12] *Federal-Provincial Fiscal Arrangements Act*, RSC 1985 c F-8, Part V.1 ss 24(a) and 24(b).
[13] Health Canada, "A Common Statement of Principles on Shared Health Priorities," *Government of Canada*, 2017, available at: https://www.canada.ca/en/health-canada/corporate/transparency/health-agreements/principles-shared-health-priorities.html.

CONSISTENCY

a) Amend the *Canada Health Act* to include prescription drugs generated by HCPs and dispensed outside of hospitals in accordance with a national formulary.

Drugs administered in hospitals are fully funded by the public healthcare system. A Pharmacare program that works to increase access to prescription medicines without conditions is strengthened by amending the *Canada Health Act* to include prescription drugs that are dispensed outside of hospitals.

b) That the *Canada Health Act* and the *Federal-Provincial Fiscal Arrangements Act* be amended to require annual reports.

According to s. 23 of the *Canada Health Act*, annual reports by the Minister of Health are mandatory.[14] However, s. 25.8 of the *Federal-Provincial Fiscal Arrangements Act* states that a report by P/T Ministers of Health is only at an optional responsibility to the Parliament of Canada.[15]

In order to promote accountability, efficiency and communication, the Minister of Health and the P/T Ministers of Health must work together in the production of annual reports, which are subsequently made available to the public.

[14] *Supra* note 2.
[15] *Supra* note 12.

Definitions

Access

Therapies must be available for all people residing in Canada in terms of supply and accessibility, without conditions.

Equal

This refers to access regardless of where people reside and their income status, with a special focus on vulnerable populations and indigenous communities.

Equitable

The social determinants of health refer to “equity” in the health system or fairness in terms of social justice.

Therapies

An inclusive term for treatments and medications, including medical devices.

Safe and effective

A more accurate term for evidence-based therapies.

Abbreviations

CHT	Canada Health Transfers
HCP	Health care practitioners
HTA	Health technology assessment
P/T	Provinces and territories
RHA	Regional health authorities