PHARMACARE COSTING IN CANADA

Estimated Costs of Proposed National Pharmacare Programs

W. Neil Palmer, Courtney A. Nelson & N. Dylan Lamb-Palmer

Prepared by PDCI Market Access Inc.
Commissioned by the Canadian Pharmacists Association
March 2016

Contents

Executive Summary

- Existing proposals for national, exclusively public administered pharmacare programs are impractical, disruptive and their potential for cost savings is overstated. Their implementation would:
    - replace the increasingly effective existing jurisdiction-specific and pan-Canadian initiatives which to date have significantly improved access, sustainability, and affordability of prescription drug coverage for Canadian patients;
    - limit the selection and availability of prescription drugs with implications for patient treatment options and outcomes; and
    - significantly increase government expenditures on drugs largely for patients that already have private coverage.
- The evolving "Pan-Canadian" (as opposed to "national") pharmacare approaches are likely to be more effective, feasible and (in some cases) more affordable solutions to ensure all Canadian patients have access to the medicines necessary to maintain and improve their health.
- This study estimates that governments could provide relief to the roughly 10% of Canadians who are not covered, or have inadequate prescription drug coverage, through either private or public drug plans by investing up to $2 billion a year in a pan-Canadian pharmacare solution.
- In this report, PDCI Market Access describes these pharmacare approaches, examines their benefits and tradeoffs and estimates the costs for a number of variations of these approaches, including:
    - **Public-Only** approaches which require all Canadians to become beneficiaries of the single publicly funded program in each jurisdiction that would replace the existing mix of public and private drug insurance; and
    - **Pharmacare for the Uninsured** approaches which maintain the existing mix of public and private drug insurance for those patients who are beneficiaries while providing additional programming to ensure that no Canadian patient is left without prescription drug coverage.
- While all approaches considered are similarly effective in ensuring that all Canadians have access to some form of prescription drug insurance (universal), other benefits and tradeoffs are considered to evaluate their relative appropriateness and desirability for implementation in Canada. These benefits and tradeoffs include:
    - Alignment with the principles of the Canada Health Act;
    - Quantitative costs (to governments, taxpayers and patients);
    - Implications for patients' access to new and existing medicines;
    - Equitability of coverage across the country;
    - Sustainability; and
    - Feasibility of implementation.
- Those approaches that are "Pan-Canadian" in nature are evaluated to be more feasible than national approaches because they maintain provincial and territorial sovereignty over healthcare administration and decision-making as per the Canadian Constitution.
- "Pan-Canadian" approaches are estimated to confer cost-savings or impose only modest cost increases in terms of overall drug expenditures.

- Those "Pan-Canadian" approaches that build upon and maintain the existing public and private drug reimbursement infrastructure are additionally desirable because they represent:
    - Continued quality and quantity of coverage for the majority of Canadians who are existing public and private drug plan beneficiaries. This results in better health outcomes for Canadians and more efficient allocation of healthcare dollars.
    - Minimized risk and costs to governments and taxpayers by maintaining a robust private drug insurance industry to share these risks and costs. This improves long-term sustainability and affordability for both taxpayers and patients.
    - Solutions that will ensure Canada remains a desirable market to which innovative pharmaceutical manufacturers will continue to bring important medical innovations contributing to improved health status for Canadians.
    - Solutions that build upon, rather than abandon, investments made to date on initiatives that have successfully improved universality, comprehensiveness and sustainability of prescription drug coverage across Canada.
    - They incur lower costs to governments and taxpayers than public-only options.
    - More feasible solutions due to the evolutionary approach they propose to improve prescription drug coverage where other revolutionary approaches have failed to take root.

Changes to expenditures for governments and taxpayers, private insurers and patients (compared with 2015 actual expenditures) are summarized in Table 1.

Table 1 - Estimated Costs of Potential "Pan-Canadian" Pharmacare Models ($ millions)

Approach	Variation	Public Expenditures	Private Expenditures	Out-of-Pocket Contributions	Total
2015 Actual Expenditures		**$11,281**	**$10,235**	**$6,752**	**$28,268**
Public-Only Pharmacare Approaches	All Public, No Copay	**+$15,998**	**-$10,235**	**-$6,752**	**-$989**
	Public, $10 Co-Pay	**+$7,908**	**-$10,235**	**+$1,338**	**-$989**
	Public, 20% Co-Pay	**+$10,542**	**-$10,235**	**-$1,296**	**-$989**
	Public, Patient pays Rx fee	**+$9,526**	**-$10,235**	**-$280**	**-$989**
Pharmacare for the Uninsured Approaches	Public "Modified" Québec Model	**+$2,151**	**$0**	**-$2,045**	**+$106**
	Public PEI Generic Drug Plan Model	**+$93**	**$0**	**-$2,013**	**-$1,920**
	Private	**$0**	**+$2,349**	**-$1,999**	**+$350**

Implementing a pan-Canadian program to cover the uninsured would represent an affordable (up to $2.15 billion in added government expenditures) and feasible solution to eliminate existing gaps in prescription drug coverage across the country, while maintaining the quality and quantity of prescription drug coverage that Canadian patients experience today. Harmonizing catastrophic coverage programs across the country (for example, providing programs consistent with Ontario's Trillium Drug Program on a pan-Canadian basis) could provide a basis for establishing and calculating a federal contribution (of approximately $1B) to pharmacare.

Introduction

A January 2016 meeting of Canada's federal, provincial and territorial (F/P/T) ministers of health laid the groundwork for what Canadians can anticipate as their governments' central health policy concerns in the coming years. The *Statement of the F/P/T Ministers of Health* released at the conclusion of the meeting identified the key health policy issues representing the governments' shared priorities and described how the governments in Canada will work together on major health policy initiatives including "enhancing the affordability, accessibility, and appropriate use of prescription drugs". In particular, the plan includes establishment of a F/P/T working group "to explore approaches to improving coverage and access to prescription drugs for Canadians".[1]

Calls for a national pharmacare program have persisted in Canadian public policy circles since the 1960s, but have largely gone unanswered. With F/P/T governments' renewed interest to revisit collaboration opportunities to explore pharmaceutical initiatives such as pharmacare[2,3], several parties have recently proposed pharmacare approaches with the intent of gathering momentum towards breaking the "gridlock"[4] on the national pharmacare discussion.

In light of these recent developments, the Canadian Pharmacists Association (CPhA) has commissioned PDCI Market Access (PDCI) to undertake an update to its 2002 *Cost Impact Study of a National Pharmacare Program for Canada* to provide a meaningful contribution to the forthcoming public policy discourse to explore opportunities aimed at expanding pharmaceutical drug coverage to all Canadians.

This *Pharmacare Costing in Canada* report is the second of a two-part series proposing solutions to improve access to prescription medicines across Canada. The first part, a preliminary report released in January 2016, summarized PDCI's assessment of a National Pharmacare Cost Estimate Study of 2012/13 drug cost dataset published by *Morgan et al* in 2015. PDCI's preliminary report concluded that the Morgan study overstated the potential savings achievable from its proposed universal national pharmacare plan and would cause public expenditures to increase by approximately $6.6 billion, rather than $1 billion as quoted in that study. Furthermore, the National Pharmacare approach that was described in that study would impose significant restrictions on the quantity and quality of prescription drug coverage Canadian patients would have, along with other numerous undesirable consequences. This *Pharmacare Costing in Canada* study identifies alternative approaches by which prescription drug coverage in Canada could similarly be available for all Canadians, fulfill the spirit of key Canada Health Act pillars (including accessibility, comprehensiveness, universality and

portability) and pursue additionally desirable objectives such as equity, sustainability and feasibility of prescription drug coverage programs for all Canadian governments, taxpayers and patients.

The objectives of this study are to describe several approaches that extend prescription drug coverage to all Canadians, examine their relative benefits and tradeoffs for Canadian patients, and provide estimates of their cost impact on Canadian governments, taxpayers and patients. Here, we contrast the benefits and tradeoffs of public-only pharmacare approaches (plans which would replace the existing mix of public and private drug coverage infrastructure currently operating in Canada) with pharmacare for the uninsured approaches (alternatives that build upon and supplement the existing mix of public and private drug plans to expand coverage to Canadians who are currently uninsured). The approaches and variations on these approaches that are examined in this study include:

The objectives of this study are to describe several approaches to extend prescription drug coverage to all Canadians, examine their relative benefits and tradeoffs for Canadians, and to provide estimates of their cost impact on Canadian governments and taxpayers.

1. **Public-Only Pharmacare Approaches:** In these models, publicly funded drug plans for all Canadians would replace the existing mix of public and private drug coverage and include variable out-of-pocket patient contributions:
    a. No-Copay (1st dollar coverage): Completely publicly funded with no contributions, co-pays or prescription fees paid out-of-pocket by individual patients.
    b. Co-Pay Variation 1: Primarily publicly funded with a $10/prescription co-pay paid out-of-pocket by individual patients.
    c. Co-Pay Variation 2: Primarily publicly funded with a 20% co-pay paid out-of-pocket by individual patients.
    d. Co-Pay Variation 3: Primarily publicly funded with only the pharmacist professional fee paid out-of-pocket by individual patients.
2. **Pharmacare for the Uninsured Approaches**: In these models, the status quo remains for all patients who currently are eligible for private and public drug plan coverage, but any patients ineligible for such coverage or otherwise uninsured must access this new plan. Variations on this approach include:
    a. A "Modified" Québec Model assessing the impact if all jurisdictions adopt a compulsory purchase model for their uninsured population similar to the approach taken in Québec since 1997.

b. A PEI Generic Drug Program Model assessing the impact if all jurisdictions were to follow the recently implemented Generic Drug Program in PEI where out-of-pocket cost to patients per prescription of a publicly funded generic drug are capped and the remainder is reimbursed by the public drug plan for all uninsured residents.
c. A Private Model assessing the impact if private plans were required provide coverage for the uninsured population in place of a provincial public plan similar to the Québec RAMQ model.

All models above are quantitatively and qualitatively evaluated against one another. They are also qualitatively compared with the public-only National Pharmacare approach proposed in the 2015 *Morgan et al* National Pharmacare Cost Estimate Study (which was quantitatively assessed in the first part of this two-part study).

Background

PRINCIPLES AND OBJECTIVES

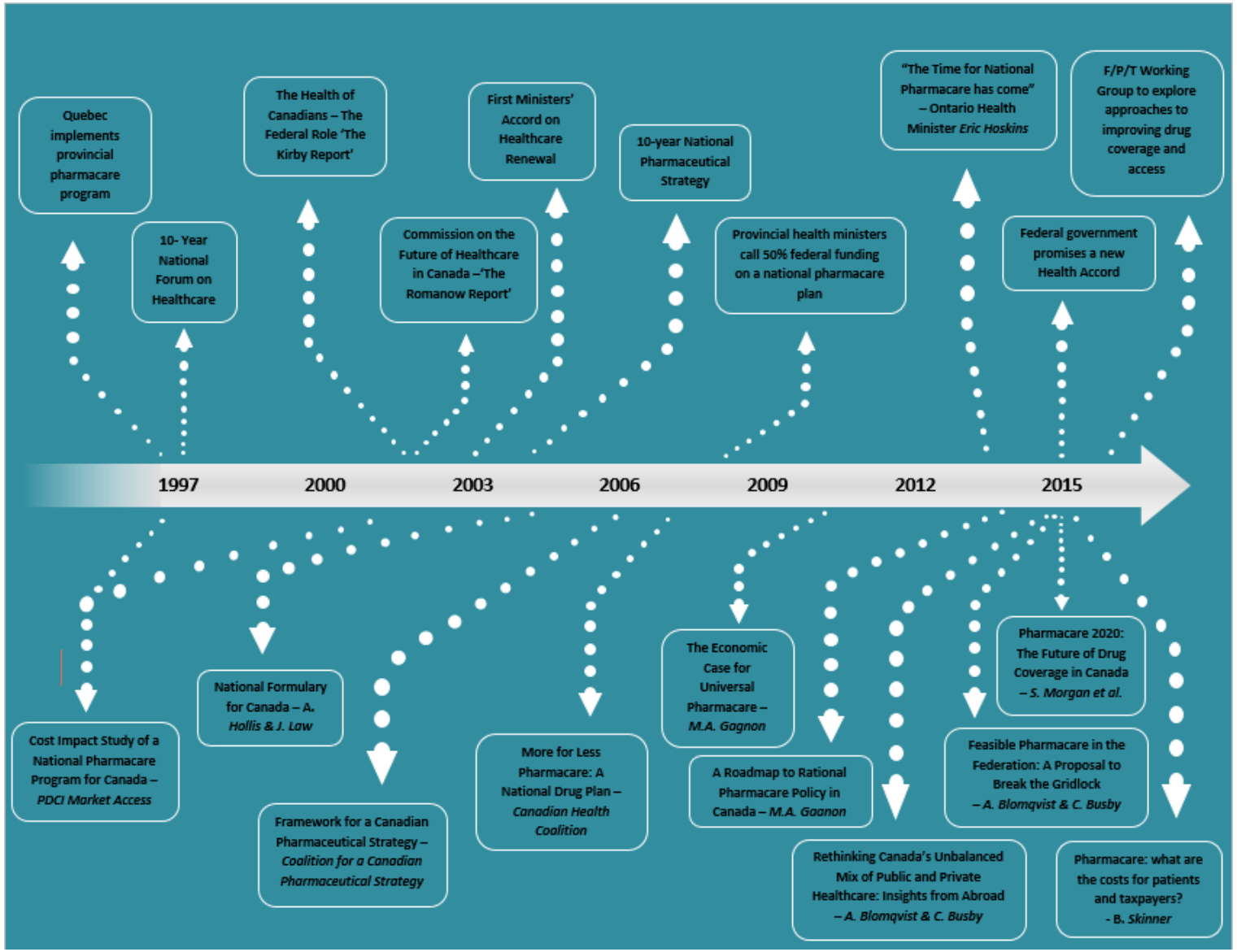
Calls for a national pharmacare program have persisted in Canadian public policy circles since the 1960s. Figure 1 summarizes some of the key political and academic contributions to this public policy discourse over the last 20 years.

Conversations about implementing Canadian pharmacare necessarily include explicit or implicit discussion to define "pharmacare" and identify the principles, values and objectives it should aspire to fulfill. The starting point is often the five pillars of the Canada Health Act (CHA):

- Accessibility
- Comprehensiveness
- Universality
- Portability
- Public Administration

The CHA outlines the conditions under which provincial and territorial healthcare systems must conform to be eligible for federal transfer payments. These conditions outline in general terms the physician, hospital and other medically necessary services that provinces and territories must provide to their residents. Others suggest Canadian pharmacare ought to pursue two additional objectives: equity and sustainability. Equity is largely interpreted as meaning that if a therapy is funded and available in one province it should be funded and available in all provinces notwithstanding the

Figure 1 - Pharmacare in Canada - A Timeline



differences in the underlying provincial healthcare systems. Sustainability refers to the program being optimally structured such that it is fiscally self-sustaining and avoids becoming a burden on taxpayers.

The CHA explicitly recognizes that provinces and territories have exclusive constitutional authority and responsibility for the delivery of healthcare. Consistent with the CHA principles, the provinces have established provincial healthcare systems that are similar in terms of the core healthcare services they deliver, but different in terms of how they deliver and administer these services.

There is, then, no national healthcare system but rather 10 provincial (and 3 territorial) health systems for which the respective governments are the single payer.[5]

Given the evolution of diverse and autonomous provincial healthcare systems, there would be significant challenges in superimposing a "one size fits all" national pharmacare solution on current infrastructure. For example, in the western provinces, cancer agencies play an important role in the funding and administration of cancer drugs. In Nova Scotia multiple sclerosis drugs are coordinated through the Dalhousie Multiple Sclerosis Research Unit (DMSRU), and in British Columbia, HIV drugs are funded through the BC Centre for Excellence in HIV/AIDS (BC-Centre for Excellence) Drug Treatment Program. These programs were established because they represented the best approach for their respective jurisdictions. These are but a few of the examples of special programs that currently exist in each province but likely could not co-exist in a national single formulary program.

Therefore, any discussion of integrating a "national" pharmacare program must necessarily take into account differences among the existing provincial healthcare systems and must instead be "pan-Canadian" in nature.

Any discussion of integrating a "national" pharmacare program must necessarily take into account differences among the existing provincial healthcare systems and must instead be "pan-Canadian" in nature.

Despite their differences, provincial health ministries have collaborated on pharmaceutical initiatives through pan-Canadian mechanisms including the Canadian Agency for Technology and Health (CADTH) and the pan-Canadian Pharmaceutical Alliance (pCPA) established by the Council of the Federation. The objectives of these agencies are to harmonize health technology assessment recommendations, increase access to drug treatment options, and improve consistency of drug coverage across Canada while respecting the individual governments' authority and responsibility for delivery. This is important given the differences in how healthcare is delivered in each province and how pharmaceuticals are integrated into the provincial healthcare system.

The pan-Canadian collaborative approach that has evolved in recent years is actively attaining the desired benefits of national pharmacare – including improving access, equity and sustainability of drug coverage for Canadian patients – without sacrificing local decision-making, which is essential serving the needs and values of the patients in individual jurisdictions.

Proponents of a national pharmacare approach suggest that it would lower prices (through monopsony buying power) and point to "lower" prices in some of the reference countries used by the Patented Medicine Prices Review Board (PMPRB). In fact, the monopsony buying power is already in place through the pan-Canadian Pharmaceutical Alliance for the public sector in the case of branded drugs and for all purchasers (public or private) for generic drugs.

Moreover, relying on international price referencing is problematic as it is subject to currency exchange volatility and differences in approved indications, patient populations and the underlying domestic markets in which the prices were established.

The Patented Medicine Prices Review Board (PMPRB) publishes average foreign-to-Canadian ex-factory price ratios of patented drug products under its jurisdiction in its annual reports. Previous studies have referenced these reports when concluding that Canadians currently pay relatively high drug prices that could be alleviated through a national single-payer with monopsony power. Low foreign-to-Canadian price ratios are then used as a target to illustrate the potential cost savings of their preferred pharmacare plan. The problem with international price comparisons is that changes in currency exchange rates have a strong confounding effect. While the Canadian dollar is weak, foreign drug prices appear relatively high. When the Canadian dollar strengthens, Canadian drug prices appear to rise. The PMPRB addresses this issue for regulating drugs prices by relying on 36 month average exchange rates, not the actual exchange rates. For its Annual Report, the PMPRB uses both the 36 month exchange rates it uses for regulating prices, but also OECD purchasing power parities (PPP) for reporting average international price ratios. PPP rates reflect relative costs of living in the respective countries and remove exchange rate volatility and therefore are much steadier over time.

Using PPP rates, the 2014 PMPRB annual report indicates that Canada paid only the fourth highest drug prices out of the eight comparator countries. Moreover, these ratios have improved in every comparator country over the previous year (between 2% and 44%). Furthermore, these ratios do not capture other elements which further improve Canadian drug pricing, such as:

- Payer rebates included in product listing agreements (PLAs) which are negotiated by the pan-Canadian Pricing Alliance (pCPA) are typically not reported to the PMPRB and are therefore not captured in their annual reports.

- The PMPRB compares only at ex-factory prices and excludes markups and professional fees (i.e. the retail prices actually paid by patients and payers). These factors in certain comparator countries can be significantly higher than those in Canada.

BUILDING BLOCKS FOR A PAN-CANADIAN PHARMACARE APPROACH ALREADY EXIST

Numerous provincial and federal organizations and pan-Canadian initiatives described in this section have already been implemented to improve universality and access for prescription drug coverage across the country. Important advances have been made in absence of any developments on the national pharmacare front and momentum for these initiatives continues to gather.

Catastrophic Drug Coverage

The objective of catastrophic drug insurance is to protect individuals from financial hardship due to medication expenses.[6] Catastrophic plans impose a maximum on out-of-pocket spending for prescription drugs. Most commonly, these plans employ a "geared-to-income" limit such that beneficiaries pay for their drug costs until they reach a predetermined maximum calculated on the basis of their income. After this maximum is reached, the plan pays for the remainder of drug expenses until the coverage year resets. Since medication affordability is central to catastrophic drug coverage, some plans allow individuals to pay their yearly expenditure over several installments (e.g. if their maximum is 4% of income, they could pay 1% in each quarter of the year, preventing potentially prohibitively large one-time expenditures).

The 2003 First Ministers' Accord on Healthcare Renewal declared that all Canadians should have access to catastrophic drug coverage. Today, all jurisdictions have catastrophic plans except for Yukon, the Northwest Territories, and Alberta; however even in these jurisdictions there are mechanisms and alternatives for catastrophic coverage.[i] While the catastrophic plans across the country have similar requirements for eligibility (i.e. beneficiaries must be residents of the province or territory who are not eligible for another F/P/T plan), there are marked differences in the

[i] The Non-Insured Health Benefits (NIHB) program for First Nations and Inuit health is a federal drug benefit program which provides prescription drug coverage for the majority of residents in the Canadian Territories. Alberta has a "non-group" plan that provides drug plan benefits to Albertans that apply and pay the premiums plus there is a Specialized High Cost Drug Program that provides funding for certain high costs drugs for all Albertans (see http://www.health.alberta.ca/services/benefits-supplementary.html for more information)

definition of "high drug cost relative to income". Geared-to-income plans may include out-of-pocket contributions up to 12% of net household income.

A recent proposal by Blomqvist and Busby to "break the gridlock" on the national pharmacare discussion suggests a catastrophic geared-to-income plan limiting household expenditures to 3% of net income – in line with recommendations from the 2002 Kirby Report, and lower than most existing geared-to-income catastrophic plan maximums. It also proposes a greater role for federal financing and collaboration on pricing, formulary design and a strategy for rare disease and other high-cost drug reimbursement, but argues for this role to be limited, as cost-effective decision making is reduced as the integration of healthcare cost management is reduced.4 That is, because the federal government is not directly involved in the financing of other healthcare components (e.g. hospital and physician services) there are fewer incentives to align these costs for optimal efficiency.

***Ontario Trillium* as a basis for estimating a federal contribution**. In 2015, Ontario reimbursed $411.45 million in drug costs and professional fees through the Trillium Drug Program for patients without access to drug plan coverage in Ontario (typically, under 65 with no or insufficient public or private coverage). This program typically limits out-of-pocket expenditures to 4% of net household income which can be paid in quarterly installments and $2 co-payments per prescription once the deductible is reached. Extrapolating to the rest of the country based on population (Ontario represents approximately 38.5% of the total Canadian population[7]), a harmonized pan-Canadian catastrophic drug program would have an annual cost of just over one billion dollars as estimated in Table 2. The Trillium model could be used as basis for calculating federal transfers to the provinces as part of a modest federal contribution to pharmacare; however provinces and territories would continue to administer and fund catastrophic plans for their residents.

Table 2 - Estimated Cost Catastrophic Coverage in Canada based on Ontario Trillium

	2015 "Trillium" Catastrophic Drug Plan Costs ($millions)			
	Drug Cost	Professional Fees	Co-pay	Net Cost
Trillium Drug Program	$408.17	$41.60	$69.66	$411.45
Pan-Canadian Catastrophic Plan	$1,061.02	$108.14	$181.07	$1,069.55

It is important to note that the costs outlined above are not additional costs - they are already captured in large part in total public drug expenditures today given that each province or territory has some mechanism in place to address high drug costs relative to income.

This analysis of catastrophic costs is intended to isolate the high drugs costs for that part of the population that would not ordinarily have access to catastrophic coverage (under 65, with no or insufficient public / private coverage). The Ontario criterion is 4% of household income – if this was reduced to 3% (as recommended by Kirby and Blomqvist & Busby) the costs would be higher, although further research would be required to determine that cost. Similarly if those over 65 years of age with high drug costs (already covered under a basic plan in Ontario) are included in the analysis, the costs would be significantly higher (this could potentially be modeled using other provinces). Quantifying catastrophic costs is important as catastrophic coverage has previously been discussed as a potential area for federal participation in funding pharmacare.4

Régie de l'assurance maladie du Québec (RAMQ)

Since 1997, a compulsory drug insurance model has existed in Québec requiring all residents to have prescription drug coverage through either private or public drug insurance programs. Residents eligible for a private plan (e.g. through their employer) must enroll and provide coverage for their spouse and children. Only those who are not eligible for a private plan may register as beneficiaries on the public drug plan administered by the Régie de l'assurance maladie du Québec (RAMQ). RAMQ maintains a formulary of benefits for public plan beneficiaries (the "*Liste des* médicaments") and all private insurers in the province must – at a minimum – provide equivalent coverage to the benefits included on the public formulary. Beneficiaries of private drug plans may have more extensive benefits and lower copays / deductibles than those on the public drug plan. While the Québec model has successfully achieved universal coverage, equity among residents is not guaranteed as out of pocket costs for the public plan can be significant and greater than the typical premiums plus copay / deductible for coverage under some private plans.

Québec's public drug plan is funded by compulsory premiums rather than general tax revenues. In 2015-16 public plan beneficiaries can be expected to pay up to $640 as part of their income tax return (regardless of whether they access drugs) and contributions (deductibles and co-payments) up to an annual maximum for purchases of drugs under the plan.

Those exempt from premiums include the unemployed (holders of a claim slip issued by the Ministère de l'Emploi et de la Solidarité Sociale), persons over age 65 receiving 94% to 100% of the guaranteed income supplement (GIS), students up to age 25 and children of people insured under the plan. In essence, the high premiums paid by individuals under the plan subsidize those who pay no premiums.

Public Payer – PEI Generic Drug Plan Variation

Prince Edward Island implemented its Generic Drug Program in October 2015. This plan covers individuals in the province under the age of 65 and who do not qualify for, or otherwise do not have access to prescription drug coverage through either public or private drug plans in the province. The program limits out-of-pocket prescription drug costs to $19.95 per prescription for the more than 1,000 generics[ii] listed as benefits on the provincial drug plan formulary.[8]

Pan-Canadian Initiatives Currently Address Principles for Pharmacare

Accessibility and **Universality** of Prescription Drug Coverage

- Each of the provinces and territories has a drug plan that is integrated into its respective provincial healthcare system and is designed to meet the specific needs of the province's residents within the context of that broader healthcare system.
    - The provincial publicly funded drug plans provide coverage to medically necessary drugs and are typically targeted towards the most vulnerable residents (e.g. those over age 65, those on social assistance, and those with high drug costs relative to income).
- Most citizens without public drug coverage often have private drug plan coverage through their employer.
    - However, most provinces have a small segment of the population with no coverage or inadequate coverage (~10%).
- All provinces provide catastrophic coverage (plans which seek to ensure residents do not incur financial hardship as a result of prescription drug requirements) although there is considerable variation in terms of eligibility criteria and the amount of out-of-pocket expenditures associated with each plan.
- Québec ensures universal drug coverage through a compulsory purchase model and offering a public plan for those who are not eligible for private coverage.
- PEI offers coverage for generic drugs for all residents under the age of 65 who do not have access to public or private prescription drug coverage alternatives.

Equity of Prescription Drug Coverage

- The provinces (other than Québec) fund the Canadian Agency for Drugs and Technologies in Health (CADTH) - a national health technology assessment agency that

[ii] Excluded generics include diabetes drugs (as these are covered through separate funding) and controlled substances.

provides recommendations through its Common Drug Review (CDR) and pan-Canadian Oncology Drug Review (pCODR) procedures with respect to which drugs the jurisdictions should reimburse as public drug plan benefits.

    - There is greater than 90% congruence between recommendations resulting from the CDR procedures and provincial drug benefit listing decisions. This has improved overall concordance of benefits among public drug plans across Canada but has maintained flexibility of decision-making at the jurisdiction level.
    - Québec has a similar health technology assessment agency – the *Institut national d'excellence en santé et en services sociaux* (INESSS) – that provides recommendations for reimbursement that are largely consistent with recommendations from the CADTH procedures.

- Approximately 90% of 2015 expenditures by provincial plans were for drugs with universal listing (i.e. covered in all provinces).[9] Furthermore, some of the 10% difference observed reflects new products that are under review and therefore may soon be listed on any remaining public plans. Drugs without universal public access represent only marginal costs in the current system. This indicates that irrespective of where one lives, if they qualify for provincial public drug plan coverage they have access to a highly similar set of drugs.

Sustainability of Prescription Drug Coverage

- All jurisdictions (including Québec and the federal government) participate in the pan-Canadian Pharmaceutical Alliance (pCPA). The Alliance combines the drug price negotiating power of these drug plans to increase drug treatment options available and improve consistency of coverage across Canada while achieving the best prices for drugs that individual public drug plans may not achieve on their own.
- Private drug plans have begun incorporating results of public health technology assessments into their reimbursement decision-making and are developing internal capacities aimed at negotiating drug prices with pharmaceutical manufacturers to ensure sustained value for money for new prescription drugs. The Canadian Life and Health Insurance Association (CLHIA) representing private insurers has asked to participate in the pCPA process; however, that is unlikely in the near terms given that these are predominantly for-profit entities and there is uncertainty as to how much of the savings would be passed on to the plan sponsors (employers) that pay for these plans.

> Moreover, private insurer participation in the pCPA price negotiation process would change the calculus of the savings that could be offered by manufacturers to the public system. Private insurers are well-equipped to negotiate their own rebates with manufacturers and some already do.

More information on these ongoing initiatives towards pan-Canadian pharmacare is available in Appendix 2.

Given the progress to date on implementing key pharmacare objectives in the absence of a national pharmacare program, it is not apparent that there is any value in replacing the existing drug reimbursement infrastructure (e.g. by requiring federally-led, single-payer initiatives) to attain the goals for pharmacare described in the literature. As outlined in the analysis that follows, the best opportunity for achieving the goals of pharmacare lie within the existing, evolving pan-Canadian structures. This represents an evolution as opposed to a revolution to improve prescription drug coverage in Canada.

Methods, Analysis & Discussion

The "Methods" section explains how costs are quantified for each approach and compared with the 2015 base case of actual drug expenditures in Canada.

The first approach considered is the 2015 *Morgan et al* National Pharmacare Cost Estimate Study. This approach was assessed in PDCI's preliminary report and the qualitative and quantitative results are summarized here for convenience. Quantitative assessment of this model is performed with data from 2012-13.

Next, we consider a number of alternative options to the National Pharmacare approach. These approaches are "Pan-Canadian", meaning that there is coordination and collaboration among jurisdictions to ensure all Canadians have access to prescription drug coverage. Under these approaches, the majority of funding, administration and decision-making concerning prescription drug coverage remains at the jurisdiction level. Not only does this ensure consistency with the division of powers as outlined in the Canadian Constitution, it reflects the needs of separate healthcare systems which have evolved differently over time to accommodate the specific needs of residents across jurisdictions. This approach is preferred to a "national" approach to pharmacare for reasons previously discussed. These approaches build on, or modify the existing pharmaceutical reimbursement infrastructure in Canada to improve or redesign elements to make the approaches

feasible for implementation across the country, while corresponding with the above noted principles and objectives for a pharmacare program (where possible).

The "Discussion" section assesses and compares each approach in both quantitative and qualitative terms within the context of the principles and objectives for pharmacare, and the "Conclusion" summarizes key observations from the analysis.

Methods

PDCI maintains the *Canadian Drug Claims Database* of public drug plan pharmaceutical claims information supplied on a quarterly basis by each of the jurisdictions. Each provincial drug plan in Canada (excluding PEI) and the federal Non-Insured Health Benefits (NIHB) program provide quarterly data (including number of claims, drug costs, professional fees, patient copayments, and more) on the prescription drug claims it reimburses under each of their publicly funded drug plans. PDCI has relied upon this database and the 2015 data supplied by the public drug programs in Canada to model and estimate costs associated with the sample of pharmacare approaches described in this analysis.

2015 PUBLIC EXPENDITURES ON DRUGS

These expenditures represent the actual drug cost of claims reimbursed by the provincial or federal drug plan based on claims provided to PDCI by the respective jurisdictions. The figures represent the actual costs paid by the drug plan (i.e. ex-factory price plus wholesaler and pharmacy markups) with pharmacy professional and dispensing fees identified separately. Patient deductibles and copayments have not been removed from the figures. As such they represent the drug cost processed by the drug plan and not the net cost (after patient deductibles and copayment are removed). By definition, all public drug plan expenditures are "public eligible".

It should be noted that not all public drug costs are for drugs that are listed on formulary benefits – some jurisdictions have programs to reimburse non-benefit drugs under exceptional circumstances (e.g. the Ontario Exceptional Access Program and Québec's "Patient d'Exception"). Where necessary, the claims data from the jurisdictions have been adjusted as follows:

- Where full calendar year 2015 data was not available, the full year was extrapolated from available claims data – every province (except PEI and the territories) had at least 9 months of 2015 claims data.

- PEI and the territories do not supply claims data and their values were estimated based on the proportion of total Canadian drug costs published by the Canadian Institute for Health Information (CIHI).
- Claims for products that do not have a valid Health Canada Drug Identification Number (DIN) were removed from the analysis (e.g. diabetic test strips).
- Some drugs are reimbursed via special health or social services envelopes of provincial funds not directly affiliated with the provincial drug plan budgets (e.g. special programs for cancer, multiple sclerosis, HIV or other disease-specific drugs may be reimbursed with specifically assigned budgets, or other public health or social services department budgets) and therefore these expenditures are not captured in the provincial public drug plan claims data included in PDCI's claims database. (This would also be true of other databases that are built primarily on community pharmacy dispensing.) Further research is required to fully capture all public drug expenditures in those jurisdictions where there are specialized funding and delivery mechanisms.

2015 PRIVATE EXPENDITURES ON DRUGS

Private expenditures were estimated using CIHI forecast data for 2015 and in particular the proportion of public drug expenditures to total expenditures. Given the public expenditures established above, and the percentage of expenditures that are public from CIHI, the remaining proportion is private and this can be estimated for each province. Private expenditures can be separated into private insurance and individual payments.

Private - Uninsured

From CIHI, individual expenditures include out-of-pocket expenditures made by uninsured patients, copayments/deductibles of insured patients and payments for drugs that are not eligible as benefits on drug plans (e.g. certain lifestyle drugs). For purposes of this analysis we have separated private expenditures into insured and uninsured. Uninsured are estimated as the 10% of the population with no basic drug plan insurance (in principle, all provinces have some form of catastrophic coverage). Expenditures are calculated as the annual private drug cost per capita times the number of individuals representing 10% of the provinces population (for all provinces except Québec which has universal coverage and the territories where there is limited information). When expenditures for the uninsured are moved to an insured plan it is assumed that their utilization increases by 15% (consistent with *Morgan et al*).

Private – Insured

The private insured expenditures are calculated as the difference between the uninsured expenditures and the total private expenditures.

Public Eligible and Not Eligible

Each component of the private expenditures is then separated into Public Eligible or Not Eligible. This is established by comparing the Health Canada Drug Identification Numbers (DINs) in the public claims data to a private claims dataset maintained by PDCI and determining the proportion of private claims expenditures that are for drugs with DINs that are reimbursed on the public plan in the respective province. Once switched from private to public, the component of "non-eligible" drugs costs is assumed to be replaced by eligible drugs at 25% of the cost of the "non-eligible" drug. The physician fees for visits to the doctor to change prescription from non-eligible to eligible is not included in the analysis.

Results

BASE CASE – 2015 ACTUAL DRUG EXPENDITURES

Based on the above, all pan-Canadian plans considered in the cost estimate study are compared against the 2015 actual drug expenditures presented in Table 3.

Table 3 - 2015 Actual Drug Expenditures ($ millions)

Payer	Drug Costs	Plus Pharmacist Fees	Less Copay	Net Cost
Public Drug Plan	10,085	3,426	2,230	11,281
Private Drug Plan	9,731	2,556	2,052	10,235
Uninsured Individuals	2,044	426	-	2,470
Total	21,860	6,408	4,282	
Total Expenditures (including Co-pays)				28,268
Total Individual Out-of-Pocket Expenditures (Uninsured + Co-pays)				*6,752*

In 2015, Canadians spent approximate $28 billion on prescription drug expenditures. Except for the 2015 National Pharmacare Cost Estimate Study which relied on secondary analysis of the Rx Atlas for fiscal 2012-13, the models examined in this report compare overall costs and costs to individual payers with the 2015 actual drug expenditures observed in Table 3 above.

PUBLIC-ONLY PHARMACARE APPROACHES

1. 2015 National Pharmacare Cost Estimate Study (*Morgan et al*)

Description

The study, "*Estimated cost of universal public coverage of prescription drugs in Canada"* is a secondary analysis of 2012-2013 data from the *Canadian Rx Atlas, 3rd Edition.* It models the estimated net changes in Canadian prescription drug expenditures if its proposed National Pharmacare plan had been in place at that time (i.e. 2012/13). The plan involves replacing all existing public and private prescription drug coverage plans in Canada with a single, public plan and all Canadians automatically become beneficiaries of this new, nation-wide plan.

The study concludes that Canadian prescription drug expenditures will be reduced by:

- Eliminating private drug plans and transferring all beneficiaries to a National Formulary designed to promote "cost-effective" decision-making. This effectively reduces 100% of private plan drug expenditures, and a large portion of the "out-of-pocket" costs as well.[iii]
- Public spending for prescription drugs reimbursed under the National Formulary will increase to accommodate the former private plan beneficiaries and formerly uninsured Canadians, but by less – the study argues – than the amount of spending that previously occurred under the private plans.

The study suggests these savings – the difference in what the private sector was paying before and the additional amount the public sector will pay after – are attributable to a few key "direct" and "indirect" reductions made possible under a single-payer public drug plan:

- "Direct public":
    - Private to Public: Additional costs to the public system of shifting privately insured patients and the uninsured to the public system (with an adjustment for increased drug utilization by the uninsured).
    - Fewer costs associated with cost-effective product selection (that would necessarily remove drugs not currently eligible under public plans). Note there are more than 3,300 drug products or Drug Identification Numbers (DINs)[iv] that are funded on

[iii] Note that under the National Pharmacare plan proposed, despite all Canadians are covered under the universal public plan, it is estimated that some out-of-pocket costs will be incurred as part of a tiered copayment scheme.

[iv] A comparison of private drug plan claims data and Ontario drug claims identified more than 3300 Drug Identification Numbers (DINs) that were reimbursed on the private plan but not on the Ontario public plan. As there can be several generic versions of the same product, the 3300 represent 1,203 dosage strengths across 476 distinct active substances. The PDCI Drug Claims Database was used for this analysis, Private Claims data 2015 and 2014-2015Q2 Ontario Public Claims Data.

private plans but not listed as benefits on public plans. These products represent approximately 476 unique active substances.

- Savings from lower prices: Leveraging monopsony pricing power[v] to lower the prices at which prescription drugs are reimbursed to levels comparable to the United Kingdom (or Sweden or France depending on the sensitivity analysis employed).

- "Indirect public":
  - Savings to government expenditures (not drug expenditures per se) by eliminating employer-based drug plan benefits for the approximately 769,000 federal and provincial government employees[10] and assuming there would be no offsetting *quid* in the collective bargaining process. (i.e. public sector unions would willingly give up their generous drug benefit for an inferior national plan without anything in return).

Estimated Costs

After making adjustments for assumptions concerning UK price comparisons and the compensation required for eliminating public employee benefits, PDCI estimated that the National Pharmacare approach to universal prescription drug coverage is estimated to result in costs to governments and taxpayers of approximately $6.6 billion with overall savings on prescription drug expenditures of approximately $1.6 billion as presented in Table 4. In particular the analysis relied on international price ratio figures (for the UK and sensitivity analyses for Sweden and France) published by the PMPRB for 2013 that had underlying

International price referencing is limited by important differences between Canada and the UK, France and Sweden:

- **The UK is not a single payer system for pharmaceuticals. There are 4 national systems (England, Scotland, Wales, Northern Ireland) and drug funding is implemented through regional and local systems. England alone has 209 clinical commissioning groups (CCGs) (formerly known as primary care trusts) that are budget holding – they commission and pay for the services patients in the local CCG require including hospital services and prescription drugs. Each CCG has its own formulary (some CCG's develop joint formularies with their neighbouring CCGs) and each CCG had developed procedures for implementing NICE Guidance for those drugs that are reviewed by NICE (NICE does not review all new drugs).**
- **France has a system of significant copayments and patients rely on private insurance ("mutuelles") for coverage of copayments**
- **Sweden makes coverage decisions at the national level but implementation is at the county level (there are 21 county councils) where drug selection and payment occurs. Accordingly there are variations in access from one county to the next.**
- **The UK and Sweden do not use international price referencing and France only uses it in limited cases as part of price negotiations for new drugs offering moderate to substantial improvement in outcomes.**

[v] Sometimes referred to in the media and political circles as "bulk purchasing" which is a misnomer – provinces do not purchase drugs – in bulk or otherwise - provinces reimburse eligible patients for the cost of listed drugs – provinces can set the retail price or negotiate rebates from drug companies – this is the monopsony power they exercise.

exchange rates that were anomalous and inappropriate for modeling potential prices in Canada under a national pharmacare program. As discussed earlier, PPP would have been more appropriate. However even if the more appropriate international reference price ratios are calculated, it is not evident that there would necessarily be savings, and not evident why the countries selected are appropriate (given the differences to the Canadian system even if national pharmacare existed as envisaged). Given that the monopsony buying power that could achieve these lower prices has existed for years though the pCPA and PMPRB, it is not apparent how this would change as a result of establishing national pharmacare. Indeed, the pCPA and the PMPRB are actively addressing pricing issues on an ongoing basis and do not require a national pharmacare program to achieve their objectives.

Table 4 – Adjusted Estimated Costs of National Pharmacare Approach ($ millions)

Spending	Baseline	Change in Spending (base Scenario)	National Pharmacare
Public			
Direct	9,725	+3,383	13,108
Indirect	2,425	-2,425	0
Subtotal	12,151*	+958	13,108
Private			
Private Sector	5,659	-5,659	0
Out of Pocket	4,534	-2,556	1,978
Subtotal	10,193	-8,215	1,978
Total	**22,344**	**-7,257**	**15,087**
Adjustments			
UK Price Adjustment (to Dec 2015)		+3,247	3,247
Collective Bargaining Offset		+2,425	2,425
Adjusted Total Drug Expenditures		**-1,585**	**20,758**
Change in Public Spending (+958 +3,247 +2,425)		**+6,630**	
*Note: Rounding in original study.			

Benefits & Tradeoffs

Benefits of a pharmacare program include its capacity to provide universal and equitable coverage for all Canadians from coast to coast, and estimated overall savings of approximately $1.5 billion on total drug expenditures in Canada. The necessary tradeoffs to achieve these benefits under this program, however, include:

- significant reductions in access to necessary medicines for the vast majority of Canadians;
- high incremental costs to governments and taxpayers to accommodate additional public sector spending to cover uninsured individuals and those who previously enjoyed private insurance;

- foregoing the successful initiatives of the evolving pan-Canadian pharmacare realized to date;
- Canadian market may become less attractive to pharmaceutical manufacturers to introduce important medical advances; and
- provinces would cede control over provision and integration of public prescription drug benefits within the context of their respective healthcare systems.

Access Restrictions: Replacing existing private drug reimbursement with a universal, publicly-funded prescription drug reimbursement program will greatly reduce the number of medicines accessible to Canadians who currently enjoy private drug plan benefits, and likely also for those Canadians who currently have above average public drug plan coverage (the latter depends on whether the National Formulary – as envisioned by the authors of the study – will be equivalent to the existing public plan with the best coverage, the minimum coverage, or somewhere in between). Under the National Pharmacare plan, the promotion of cost effective product selection effectively removes reimbursement for less cost-effective drugs (as defined by the managers of the formulary) causing patients to pay out-of-pocket for a portion if not all of the cost of these drugs. This means that patients who are currently paying nothing, or a small co-pay as part of their prescription drug costs, may be forced to pay much larger co-pays or the full drug costs out-of-pocket if they choose to continue on their drugs in the after implementation of National Pharmacare Canada.

Examples of a few of the drugs covered by private drug plans but not currently included as benefits on public plans (using Ontario as an example) and which presumably would not be available on the national formulary include:

- Nexium (esomeprazole) [reflux esophagitis]
- Tramacet (tramadol + acetaminophen) [pain]
- Vigamox (moxifloxacin) [bacterial conjunctivitis]
- Pristiq (desvenlafaxine) [major depressive disorder]
- Victoza (liraglutide) [type 2 diabetes]
- Neulasta (pegfilgrastim) [febrile neutropenia]
- Relpax (eletriptan) [migraine]

Another concern for patients who are compelled to switch to the (as yet undefined) more cost-effective products reimbursed on the national formulary is that changing treatments could result in increased physician visits, adverse events, reduced medication efficacy or other complications which could impose other healthcare system expenditures.

Beneficiaries of private drug plans not only have access to more new health technologies compared with beneficiaries of public plans, but the time it takes for these technologies to become benefits on the private plans tends to occur much quicker following Health Canada approval as well. A recent study comparing drugs reimbursed on public versus private drug plans found on average that 23% of new drugs approved by Health Canada between 2004 and 2010 were declared eligible for reimbursement under a provincial public drug program while 84% were covered by private sector plans.[11]

Similarly, an analysis comparing public and private drug coverage in 2012 by the Canadian Health Policy Institute showed that of the 39 new drugs approved by Health Canada in 2012, 36 (92%) were covered by at least one private plan while only 11 (31%) were covered by public plans. For the new drugs that were reimbursed by at least one public and at least one private drug plan, the average time to listing for private plans was 143 days while the average time to listing for public plans was 316 days. Reducing both the number of drugs covered and the time to reimbursement for new drugs would result in a significant degradation in access for the majority of Canadians (~ 24.2 million[12]) that currently have private drug plan coverage.

If private insurance coverage is discontinued, coverage will likely be limited to low cost alternatives (and mostly genericized) drugs, and if even lower net prices (or greater discounts) are a condition to reimbursement on the National Formulary, it is likely that the Canadian market will become less attractive for innovative pharmaceutical manufacturers. This could make Canada a lower priority for innovative drug product launches, further delaying or even precluding Canadians' access to important and potentially life-saving medicines. Proposals for significant amendments to the way the pharmaceutical market and drug reimbursement is structured must consider the potential implications to the innovative pharmaceutical industry to ensure Canadians will not be unduly disadvantaged by the creation of unfavourable market conditions for innovative drug manufacturers to bring their drugs to the Canadian market.

New Zealand is often cited by healthcare policy researchers as a market that has successfully contained pharmaceutical expenditures through a coordinated national approach and successfully leveraging purchasing power. However, the impact this policy has had on access in this country – described in the New Zealand Case Study on the following pages – illustrate the tradeoffs that such an approach may have.

High Costs to Governments and Taxpayers: The Morgan et al. study overstates potential savings attainable from the proposed National Pharmacare program – actual costs to governments and taxpayers are likely closer to $6.6 billion rather than $1 billion cited in the study.

Provincial Jurisdiction and Feasibility of National Pharmacare: Under the Constitution, health care is a provincial responsibility. An additional tradeoff of implementing a national approach to pharmacare is provinces ceding provision of drug benefit services to the federal government or a national agency and losing the ability to integrate drug benefits into each jurisdiction's specific health system as they are today. Moreover, there may be political, legislative and administrative barriers to implementing a truly national pharmacare program.

New Zealand Case Study

Created in 1993, the Pharmaceutical Management Agency (PHARMAC) is the New Zealand Government agency that decides which medicines, medical devices and related products are subsidized by District Health Boards. PHARMAC was created to ensure that New Zealanders get the best possible value (outcomes) for money. PHARMAC's role has expanded to include cancer medicines, vaccines, and hemophilia treatments which are all funded by District Health Boards through the Combined Pharmaceutical Budget (CPB) in addition to hospital medicines and medical devices funded through DHB hospitals.[13]

The Combined Pharmaceutical Budget is set each year by the Minister of Health, on the advice of District Health Boards and PHARMAC. PHARMAC decides which pharmaceuticals (medicines and some medical devices) to fund, negotiates prices, sets subsidy levels and conditions, and ensures spending stays within budget. PHARMAC is not able to spend more than the budgeted amount by law although it has access to a Discretionary

New Zealand Quick Facts

- **New Zealand ranks last out of 20 comparable OECD countries for access to innovative medicines. (IMS COMPARE Report, 2015.)**
- **Out of 13 countries, New Zealand has the lowest ranking for access to cancer medicines. (Office of Health Economics, Richards Report 2014, via Medicines New Zealand, Cancer in New Zealand.)**
- **New Zealand lags behind the OECD average for reimbursement of innovative medicines by almost one year. (IMS COMPARE Report, 2015.)**
- **The mean waiting period for all medicines following a positive Pharmacology and Therapeutics Advisory Committee recommendation was 2.8 years. A higher priority recommendation does not seem to correlate to shorter waiting times (mean 3.3 years). (Barber, Jacqueline M. Sheehy, Kevin P. Uptake of new medicines in New Zealand: evidence of a waiting list. New Zealand Medical Journal 17 April 2015, Vol 128 No 1412.)**

Pharmaceutical Fund (DPF) that enables it to manage up to two percent variation in the expenditure figure.[13]

The New Zealand system has been the focus of considerable attention in recent years in part because of the low drug prices and low drug cost per capita it achieves but also because there is a concern that many medicines available in other developed countries (Australia, Europe) are not available in New Zealand. Moreover, there is a dearth of research as to the impacts on health status resulting from having fewer therapeutic options available.[14]

A 2011 study by Wonder *et al*[15] concluded that new medicines are far less likely to be listed in New Zealand than in Australia. Of 136 new prescription medicines first listed in the Australian Schedule of Pharmaceutical Benefits in the study period, only 59 (43%) were also listed in the NZ Pharmaceutical Schedule. Moreover, of the 59 that were listed, the time to listing was on average two and a half years longer in New Zealand than in Australia. These findings are consistent with other studies that have compared New Zealand to European countries and the United States.[16,17]

Interestingly, despite the lower prices (86% of the Canadian prices on average) and very modest copays ($5 NZD maximum $100 NZD per family per year[18]), cost is still perceived to be a barrier to access. A study by Jatrana *et al* found that 6.4% (n=18,320) of New Zealanders deferred buying a prescription because of cost.[19]

A Canadian comparison to New Zealand results in similar differences in terms of drugs covered. Of the 102 new drugs listed on the Ontario Public Drug Plan (excluding Exceptional Access and cancer products) between January 1, 2011 and September 2, 2015, 49% were not listed as benefits in New Zealand.[20] Table 5 summarizes the drugs available in Ontario but not New Zealand.

Table 5 - Ontario Drug Benefits that are Not Benefits in New Zealand

Brand Name	Generic Name	Therapeutic Area
Firmagon	degarelix acetate	prostate cancer
Vyvanse	lisdexamfetamine	obesity
Finacea	azelaic acid	rosacea
Vagifem	estradiol 17-b	estrogen therapy
Enablex	darifenacin	overactive bladder
Trosec	trospium chloride	overactive bladder
Hydromorph Contin	hydromorphone hcl	pain
Janumet	metformin & sitagliptin	diabetes
Onglyza	saxagliptin	diabetes
Prolia	denosumab	osteoporosis
Zenhale	mometasone furoate & formoterol fumarate dihydrate	asthma
Twynsta	telmisartan & amlodipine besylate	hypertension
Edurant	rilpivirine hydrochloride	HIV
Visanne	dienogest contraceptive	contraceptive
Complera	emtricitabine & rilpivirine hcl & tenofovir disoproxil	HIV
Trajenta	linagliptin	diabetes
Asmanex Twisthaler	mometasone furoate	asthma
Acuvail	ketorolac tromethamine	cataract surgery
Lyrica	pregabalin	anti-epileptic
Toctino	alitretinoin	eczema
Toviaz	fesoterodine fumarate	overactive bladder
Stribild	cobicistat & elvitegravir & emtricitabine & tenofovir disoproxil fumarate	HIV
Eliquis	apixaban	heart disease

Januvia	sitagliptin phosphate monohydrate	diabetes
Santyl	collagenase	wound healing
NYDA	dimethicone	head lice
Stelara	ustekinumab	plaque psoriasis
Fycompa	perampanel	epilepsy
Jentadueto	linagliptin & metformin	diabetes
Oralair	grass pollen allergen extract	allergy
Celsentri	maraviroc	HIV
Latuda	lurasidone hydrochloride	biopolar disorder
Lodalis	colesevelam hydrochloride	cholesterol
Levemir Flextouch	insulin detemir	diabetes
Tudorza Genuair	aclidinium bromide	COPD
Janumet XR	metformin & sitagliptin	diabetes
Trelstar	triptorelin pamoate	oncology
Jetrea	ocriplasmin	vitreomacular traction
Komboglyze	saxagliptin & metformin	diabetes
Ragwitek	standardized short ragweed pollen allergenic extract	allergy
Tivicay	dolutegravir	HIV
Triumeq	dolutegravir & abacavir & lamivudine	HIV
Inspra	eplerenone	heart disease
Myrbetriq	mirabegron	overactive bladder
Tapazole	methimazole	hyperthyroidism
Eylea	aflibercept	ocular disease
Abilify Maintena	aripiprazole	antipsychotic
Invokana	canagliflozin	diabetes
Monurol	fosfomycin	urinary tract infection

Although New Zealand, which has a universal public drug plan, has successfully contained pharmaceutical costs, it has accomplished this while facing serious challenges related to access to new treatments. Notably, this above list includes several antiretroviral products used to treat HIV – a number of these are recommended as the standard of care by the US Department of Health and Human Services (DHHS) "*Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*" which are routinely recognized by Canadian clinicians and CADTH. Selectively benchmarking certain measures, such as New Zealand's per capita drug spending, provides a cautionary note on the need to consider the broader healthcare context when seeking solutions for Canadian prescription drug coverage and the broader healthcare system.

Private Drug Insurance Sector Job Losses: Job losses can be anticipated if the existing private drug plans cease to operate in Canada. Not only will this result in foregone tax revenues from these employees, it may also draw upon public social insurance funds in the short term. Moreover, some extended healthcare benefits that are usually bundled with drug coverage may become more expensive to offer. Further research is required to estimate the economic impact as well as the impact on extended health benefits generally.

Impact on Pharmacy Services: Pharmacists are key partners in the provision of health services in Canada and are taking on new responsibilities in the management of patients' health and wellbeing. Dispensing fees and mark-ups represent a key source of revenue for Canadian pharmacies, providing

pharmacists with the necessary resources to offer patient services such as wellness programs, patient counseling, basic and advanced medication reviews, and immunization services. The professional fees and mark-ups are regulated for prescriptions reimbursed by public drug plans in the Canadians provinces and often represent lower amounts than those charged to non-public drug plan customers. The National Pharmacare Cost Estimate Study suggests no change will be made to the existing dispensing fees paid to pharmacies under the proposed National Pharmacare program. This, however, seems unlikely to be maintained in the long run as a universal public drug plan would be in a position to impose lower maximum dispensing fees in light of its significant purchasing power. Moreover, as prices fall, the corresponding revenues from upcharges fall as well, reducing revenues for retail pharmacies. Combined with the recent phasing out of professional allowances, reduced revenues from dispensing fees and upcharges will negatively impact the level of service patients have come to rely on from their pharmacist. Ideally any savings on drug prices would be channeled into funding for pharmacist services that are currently not funded or under-funded. Pharmacists are likely the most accessible healthcare professionals (retail pharmacies are ubiquitous and have extended hours) and are often more cost-effective.

"PAN-CANADIAN" PUBLIC-ONLY APPROACHES

Benefits of all the pan-Canadian public-only approaches include:

- Building upon existing success, investments and infrastructure of pan-Canadian pharmacare building blocks such as CADTH and the pCPA;
- Maintaining jurisdictional control over decision-making, administration and delivery of public drug plans in conjunction with the jurisdictions' unique healthcare system;
- Feasibility of implementation due to an evolutionary rather than revolutionary approach; and
- Equitable access to drugs within province (no private plans offering additional coverage above that which is provided to public plan beneficiaries) and highly comparable access across provinces as well.

Tradeoffs associated with all of the pan-Canadian public-only approaches include:

- Reduced access to many drugs that are currently available only on private plans (only drugs currently listed on at least one public drug plan in Canada are included in this model);
- Large increases in public expenditures on drugs may impose feasibility limitations; and
- Potential for significant job losses in the private insurance industry and potentially added costs for other extended health care benefits.

1. No Co-Pay

Description

This approach assumes each jurisdiction's government funds all prescription drug expenditures for all residents and all drugs listed as benefits on its individual public drug plan formulary. There are no private plans providing any coverage. The No-Co-Pay model includes no out-of-pocket contributions made by individual patients to access any drugs that are benefits.

Estimated Costs

The No Co-Pay approach to public-only universal prescription drug coverage is estimated to result in costs to governments and taxpayers of approximately $16 billion with overall prescription drug expenditure savings of approximately $1 billion as presented in Table 6.

Table 6 - Estimated Costs of Public-Only Pharmacare - No Co-Pay Variation ($ millions)

Payer	Drug Costs	Plus Pharmacist Fees	Less Copay	Net Cost	Differential
Public Drug Plan	20,808	6,472	-	27,279	+15,998
Private Drug Plan	-	-	-	-	-10,235
Uninsured Individuals	-	-	-	-	-2,470
Total	20,808	6,472	-		
Total Expenditures (including Co-pays)				27,279	-989
Total Individual Out-of-Pocket Expenditures (Uninsured + Co-pays)				-	-6,752

Benefits & Tradeoffs

This variation of the pan-Canadian approach completely reduces any cost-related access barriers to all patients as there are no out-of-pocket costs required for any prescription drug that is a benefit on the provincial plan.

Additional tradeoffs associated with this variation of the pan-Canadian public-only approach include its very large increases to public expenditures, and foregone opportunities to incentivize patients and physicians towards cost-effective product choices (as patients have no cost-incentives to limit potentially unnecessary use of prescription drugs or preferences to choose options that have less of an impact on their out-of-pocket costs).

2. Co-Pay Variation 1

Description

This variation assumes provincial governments fund all prescription drug expenditures except for a $10 co-pay per prescription filled which would be paid by the individual patient on an out-of-pocket

basis. All residents would be included in the jurisdiction's plan and all drugs listed as benefits on the jurisdiction's individual public drug plan formulary would be reimbursed. There are no private plans, and no maximum to the amount of out-of-pocket prescription drug costs.

Estimated Costs

The Co-Pay Variation 1 approach to public-only universal prescription drug coverage is estimated to result in costs to governments and taxpayers of approximately $7.9 billion with overall prescription drug expenditure savings of approximately $1 billion as presented in Table 7.

Table 7 - Estimated Costs of Public-Only Pharmacare - Co-Pay Variation 1 ($ millions)

Payer	Drug Costs	Plus Pharmacist Fees	Less Copay	Net Cost	Differential
Public Drug Plan	20,808	6,472	8,090	19,190	+7,908
Private Drug Plan	-	-	-	-	-10,235
Uninsured Individuals	-	-	-	-	-2,470
Total	20,808	6,472	8,090		
Total Expenditures (including Co-pays)				27,279	-989
Total Individual Out-of-Pocket Expenditures (Uninsured + Co-pays)				*8,090*	+1,338

Benefits & Tradeoffs

This variation of the pan-Canadian approach is additionally beneficial among pan-Canadian, public-only approaches as it incentivizes physicians and patients to limit use of potentially unnecessary prescription drugs, as it creates a modest access barrier in the form of a flat co-payment per prescription.

Additional tradeoffs associated with this variation of the pan-Canadian public-only approach include its resulting out-of-pocket costs for patients (which may add up, particularly for patients who require a number of medications), large increases to public expenditures representing feasibility concerns, and foregone opportunities to incentivize patients and physicians towards cost-effective product choices (as patients have equal cost-incentives regardless of which drug is chosen for treatment of a particular condition, there is no incentive to choose products that may offer more value for money).

3. Co-Pay Variation 2

Description

This variation assumes governments fund all prescription drug expenditures for residents in their jurisdiction except for a 20% co-pay on each prescription filled which would be paid by the individual patient on an out-of-pocket basis. All residents would be included in the plan and all drugs listed as

benefits on their individual provincial public drug plan formularies would be reimbursed. There are no private plans, and no maximum to the amount of out-of-pocket prescription drug costs.

Estimated Costs

The Co-Pay Variation 2 approach to public-only universal prescription drug coverage is estimated to result in costs to governments and taxpayers of approximately $10.5 billion with overall prescription drug expenditure savings of approximately $1 billion as presented in Table 8.

Table 8 - Estimated Costs of Public-Only Pharmacare - Co-Pay Variation 2 ($ millions)

Payer	Drug Costs	Plus Pharmacist Fees	Less Copay	Net Cost	Differential
Public Drug Plan	20,808	6,472	5,456	21,824	+10,542
Private Drug Plan	-	-	-	-	-10,235
Uninsured Individuals	-	-	-	-	-2,470
Total	20,808	6,472	5,456		
Total Expenditures (including Co-pays)				27,279	-989
Total Individual Out-of-Pocket Expenditures (Uninsured + Co-pays)				*5,456*	-1,296

Benefits & Tradeoffs

This variation of the pan-Canadian approach incentivizes patients and physicians towards cost-effective product selection as out-of-pocket costs to patients will be directly proportional to the cost of the drug chosen. Overall, it also presents fewer out-of-pocket costs to patients than the $10 flat co-payment analyzed in Co-Pay Variation 1. The average prescription claim cost in Canada is less than $50 which makes 20% of a claim cost less than $10.

Additional tradeoffs associated with this variation of the pan-Canadian public-only approach include significant (and in many cases prohibitive) out-of-pocket costs for patients in need of high-cost drugs. Significant access barriers would still be in place for many patients in Canada, despite the fact that all Canadians would technically have prescription drug coverage.

4. Co-Pay Variation 3

Description

This variation assumes governments fund all prescription drug expenditures in the jurisdiction except for pharmacist professional fees which would be paid by the individual patient on an out-of-pocket basis. All residents would be included in the jurisdiction's plan and all drugs listed as benefits on its individual public drug plan formulary would be reimbursed. There are no private plans, and no maximum to the amount of out-of-pocket prescription drug costs.

Estimated Costs

The Co-Pay Variation 3 approach to public-only universal prescription drug coverage is estimated to result in costs to governments and taxpayers of approximately $9.5 billion with overall prescription drug expenditure savings of approximately $1 billion as presented in Table 9.

Table 9 - Estimated Costs of Public-Only Pharmacare - Co-Pay Variation 3 ($ millions)

Payer	Drug Costs	Plus Pharmacist Fees	Less Copay	Net Cost	Differential
Public Drug Plan	20,808	6,472	6,472	20,808	+9,526
Private Drug Plan	-	-	-	-	-10,235
Uninsured Individuals	-	-	-	-	-2,470
Total	20,808	6,472	6,472		
Total Expenditures (including Co-pays)				27,279	-989
Total Individual Out-of-Pocket Expenditures (Uninsured + Co-pays)				*6,472*	-280

Benefits & Tradeoffs

Much like Co-Pay Variation 1, this variation of the pan-Canadian approach incentivizes patients to limit use of potentially unnecessary prescription drugs, while creating only a modest access barrier of the pharmacist professional fee associated with each prescription.

Additional tradeoffs associated with this variation of the pan-Canadian public-only approach include its resulting out-of-pocket costs for patients (which may add up, particularly for Canadian patients who require a number of medications), large increases to public expenditures representing feasibility concerns, and foregone opportunities to incentivize patients and physicians towards cost-effective product choices (as patients have equal cost-incentives regardless of which drug is chosen for treatment of a particular condition, there is no incentive to choose products that may offer more value for money).

PHARMACARE FOR THE UNINSURED APPROACHES

These models maintain the status quo for individuals who are currently beneficiaries of public and private drug benefit plans, but create an additional coverage option for those who do not currently qualify for prescription drug coverage through the existing means of public and private coverage.

Benefits common to all variations of this approach include:

- Ensuring all Canadians have access to affordable, basic prescription drug coverage and that no Canadian patient remains uninsured. It is highly effective in ensuring accessibility and universality of basic prescription drug coverage.

- Maintenance of a private drug insurance industry:
    - Private drug insurance plans share the risks and costs of providing drug insurance for all Canadians rather than relying exclusively on public funds. This limits the burden on Canadian taxpayers to contribute to pharmacare programs.
    - Avoidance of job losses in the private drug insurance sector.
- Maintenance of high quality and quantity of drug coverage for the majority of Canadians who currently enjoy and are satisfied with their prescription drug coverage.
- Maintenance of a desirable market to which innovative pharmaceutical manufacturers will continue to bring their products.

Tradeoffs common to all variations of this approach include:

- Reduced equity of coverage as private plans may offer additional benefits beyond those that are provided to public drug plan beneficiaries, and
- The "public administration" component of CHA is not fully implemented.

1. Public Payer – "Modified" Québec Variation

Description

Since 1997, a compulsory drug insurance model has existed in Québec requiring all residents to have prescription drug coverage through private or public drug insurance programs. Despite providing universal drug coverage for its residents, the Québec pharmacare model is not without its critics who highlight concerns with:

- Affordability:
    - Premiums, deductibles and co-payment contributions can add up for public plan beneficiaries
    - Premiums for the mandatory private coverage are not linked to income resulting in high costs for lower income residents eligible for private coverage
- Inequity:
    - Private drug coverage is typically more comprehensive or of better quality or quantity than public drug coverage

For the purposes of this cost estimate exercise, the "Modified" Québec Model assumes a compulsory coverage element is expanded to other Canadian jurisdictions with a simpler structure than the current Quebec model. Under this plan, residents not eligible for coverage on a private plan would have to enroll in the public drug plan in the province and receive the established public drug plan

benefits. In Québec, out of pocket contributions (premiums, deductibles & copayments) are made by public plan beneficiaries age 18-64 which appear to subsidize drug costs for children and students up to age 25 for which there are no premiums. This "Modified" Québec Model presented here could be funded through premiums similar to those for private plans of large organizations (e.g. premiums for the University of British Columbia extended healthcare plan which includes prescription drugs for UBC faculty are $624 per year, or roughly $52 per month for an individual[21], which appears both less expensive and offers more generous coverage than what is currently offered in Québec). The PDCI model reflects the drugs costs (as opposed to the premiums to fund it).

Estimated Costs

The "Modified" Québec Variation approach to pharmacare for the uninsured prescription drug coverage is estimated to result in costs to governments and taxpayers of approximately $2.1 billion with overall prescription drug expenditure costs of approximately $100 million as presented in Table 10.

Table 10 - Estimated Costs of Pharmacare for the Uninsured - "Modified" Québec Variation ($ millions)

Payer	Drug Costs	Plus Pharmacist Fees	Less Copay	Net Cost	Differential
Public Drug Plan	12,171	3,916	2,654	13,433	+2,151
Private Drug Plan	9,731	2,556	2,052	10,235	+0
Uninsured Individuals	-	-	-	-	-2,470
Total	21,902	6,472	4,706		
Total Expenditures (including Co-pays)				28,374	+106
Total Individual Out-of-Pocket Expenditures (Uninsured + Co-pays)				*4,706*	-2,045

Benefits & Tradeoffs

Compared to the status quo, this variation of pharmacare for the uninsured approach is additionally beneficial among these approaches as it reduces out-of-pocket costs for patients.

Additional tradeoffs associated with this variation of the pan-Canadian pharmacare for the uninsured approach include an increase in public funds required to accommodate existing uninsured individuals.

2. Public Payer – PEI Generic Drug Plan Variation

Description

Under this plan all provinces would provide any uninsured individuals (who are ineligible for, or otherwise are without access to prescription drug coverage) with funding for drug costs over $19.95 per prescription for any generics listed on the public drug plan formulary in the province.

Estimated Costs

The PEI Generic Drug Plan Variation approach to pharmacare for the uninsured is estimated to result in costs to governments of approximately $93 million, with overall prescription drug expenditure costs of approximately $100 million as presented in Table 11.

Table 11 - Estimated Costs of Pharmacare for the Uninsured - PEI Generic Drug Plan Variation ($ millions)

Payer	Drug Costs	Plus Pharmacist Fees	Less Copay	Net Cost	Differential
Existing Public	10,085	3,426	2,230	11,281	-
+ Generic Program	302	248	457	93	-
Total Public	10,387	3,674	2,687	11,375	+93
Private Insurer	9,731	2,556	2,052	10,235	+0
Uninsured	-	-	-	-	-2,470
Total	20,119	6,230	4,739		
Total Expenditures (including Co-pays)				26,349	-1,920
Total Individual Out-of-Pocket Expenditures (Uninsured + Co-pays)				*4,739*	-2,013

Benefits & Tradeoffs

Compared to the status quo, this variation of the pharmacare for the uninsured approach reduces out-of-pocket costs for uninsured patients with only very modest increases to public drug plans. Furthermore it promotes the preferential selection of generic drugs over brand drugs which will result in improvements to overall sustainability and value for money.

The tradeoff with this approach is that a generics-only plan is akin to an essential drugs list (EDL) common in emerging markets that offers essential coverage but no access to newer more effective therapies until they are off patent. Accordingly, this is an interim approach that provides basic coverage to the uninsured but is an approach that is easily implemented and at a modest cost.

3. Private Payer Variation

Description

Similar to the "Modified" Québec Model described above, this model retains the compulsory purchase parameter but replaces the public plan option with private drug plan options. Private insurers would be required to offer to all residents a basic prescription drug plan covering all drugs listed on the public provincial formulary. The basic coverage plans would be offered at a modest premium. Premiums would be modest because mandatory coverage removes the risk (of only high cost patients signing up) and creates economies of scale. Furthermore the existing high cost pools would eliminate the risk any one insurer ended up with a disproportionate number of very high cost patients. With mandatory coverage for the uninsured, premiums would be well below $50 and competition would likely keep them low.

Estimated Costs

The Private Payer Variation approach to pharmacare for the uninsured prescription drug coverage is estimated to result in no additional costs to governments and taxpayers and an overall prescription drug expenditure increase of approximately $350 million as presented in Table 12.

Table 12 - Estimated Costs of Pharmacare for the Uninsured - Private Payer Variation ($ millions)

Payer	Drug Costs	Plus Pharmacist Fees	Less Copay	Net Cost	Differential
Public Drug Plan	10,085	3,426	2,230	11,281	+0
Private Drug Plan	12,061	3,046	2,523	12,584	+2,349
Uninsured Individuals	-	-	-	-	-2,470
Total	22,146	6,472	4,753		
Total Expenditures (including Co-pays)				28,618	+350
Total Individual Out-of-Pocket Expenditures (Uninsured + Co-pays)				4,753	-1,999

Benefits & Tradeoffs

Compared to the status quo, this variation of the pharmacare for the uninsured approach reduces out-of-pocket costs for uninsured patients with modest increases to private plans and no increase in public drug plan expenditures.

No additional tradeoffs are associated with this variation of the pan-Canadian pharmacare for the uninsured approaches.

Like the other approaches, this model ensures that there is universal coverage and affordable access to a minimum standard of prescription drug coverage. An additional benefit of implementation

through the private sector is that private insurers will compete through premiums and/or plan enhancement such as a broader set of benefits (e.g. dental care) for an additional premium. Individuals without drug coverage likely don't have dental coverage either; dental coverage when bundled with drug coverage would likely be more affordable and accessible than it is today. The private approach also reduces risk that public plans are disproportionately burdened by sicker patients while healthier patients pay into private drug plan insurance.

Discussion

All plans described in this study comparably achieve the goal of providing prescription drug coverage for all Canadians. All plans also confer unique sets of qualitative and quantitative benefits and tradeoffs for Canadian governments, taxpayers and patients. In evaluating these differences, some plans may be considered more desirable, feasible and affordable ways forward to improve prescription drug coverage in Canada and, in turn, health outcomes for Canadian patients. Table 13 summarizes each of the proposed approaches with reference to the stated objectives of a comprehensive pharmacare program in Canada.

Table 13 - Pharmacare Approaches and their Principles

Approaches	Principle/Objective						
	Exclusively Publicly Administered	Comprehensive	Universal	Portable	Accessible	Equitable	Sustainable
Status Quo - Existing Public/Private Mix	✘	✓	✘	✓	✘/✓	✘	✓
National Pharmacare[vi]	✓	✘	✓	✓	✓	✓	✘
Pan-Canadian Public-Only Pharmacare	✓	✘	✓	✓	✓	✓	✘
Pan-Canadian Pharmacare for the Uninsured	✘	✓	✓	✓	✓	✘/✓	✓

In summary:

- The **status quo including the existing public/private mix** of prescription drug coverage provides quality drug coverage satisfying the majority of Canadians but is not universal and allows access gaps for a minority (~10%) of the population. Inequity of coverage for those covered by private versus public plans and between public plans across Canada (though pan-Canadian initiatives have significantly reduced disparities among public plans from jurisdiction to jurisdiction) and its combined public/private drug insurance market have

[vi] As described in the *Morgan et al* study and previously discussed in PDCI's Preliminary Report.

prevented it from attaining consistency with the CHA and other proposed principles for an ideal pharmacare program.

- The **National Pharmacare** approach is effective in eliminating the access gap for the 10% uninsured Canadians, results in equitable coverage across the country, and fulfills the "portable" and "publicly administered" principles of the CHA; however it significantly reduces Canadians' abilities to access new innovative medicines (less comprehensive), would likely be more expensive for governments and taxpayers (the proposed savings are highly unrealistic and largely unrelated to national pharmacare), and is not practical given provincial jurisdiction and the incompatibility a one-size-fits-all approach to pharmacare would have with the underlying provincial healthcare systems.
- The **Pan-Canadian** approaches are effective in providing comprehensive, universal coverage. These plans are likely to prove more feasible than national pharmacare approaches due to their evolutionary rather than revolutionary approach.
    - They maintain provincial and territorial sovereignty over healthcare administration and decision-making which has been critical to the success of ongoing F/P/T collaborative initiatives on health policy. Jurisdictions can continue to make decisions about drug reimbursement consistent with the values, priorities, mandates and specific population needs at the provincial level as is consistent with the Canadian Constitution.
    - They provide feasible, manageable, practical pathways towards overcoming the inertia this policy debate has experienced to date due to the uncertainty of the large costs associated with universal first dollar coverage models and apprehension associated with the effects of a complete restructuring of the existing pharmaceutical reimbursement landscape.
        - A number of political, social and economic barriers have limited progress towards a national universal pharmacare solution to improve access, equitability and sustainability of prescription drug coverage in Canada. However this inertia at the national/federal level has created opportunities for numerous jurisdiction-specific and F/P/T collaborative initiatives to achieve the desirable pharmacare objectives while maintaining jurisdictional sovereignty and fulfilling the many principles of the Canada Health Act. Together a "pan-Canadian" (as opposed to national) pharmacare program is emerging naturally while maintaining the existing

drug reimbursement infrastructure and improving the quality of prescription drug coverage most Canadians currently enjoy.

- Pan-Canadian approaches build upon these existing achievements to improve access to prescription drug coverage for all patients in Canada rather than discard investments made and success achieved to date.

- In addition to the benefits listed for all Pan-Canadian approaches, the **Public-Only** approaches:
  i. Ensure equity of prescription drug coverage across the country;
  ii. Ensure the "public administration" principle of the CHA is upheld;
  iii. But, represent large incremental costs for governments and taxpayers combined with the loss of the Canadian private drug insurance industry.
- In addition to the benefits listed for all Pan-Canadian approaches, the **Pharmacare for the Uninsured** approaches:
  iv. Maintain the quality and quantity of prescription drug coverage for those who currently enjoy private coverage; and
  v. Improve affordability and sustainability by including private drug plan coverage for many Canadians which imposes less upfront costs to the provincial and federal governments for expanding access to those who are currently uninsured or satisfied with their private drug plan coverage. Private plans may have a role to provide a more efficient and cost effective option.

In summary, continuing progress on the existing initiatives underway to improve prescription drug coverage across Canada, in addition to implementing a pan-Canadian program to cover the uninsured would represent an affordable (about $2 billion in added government expenditures) and feasible solution to eliminate existing gaps in prescription drug coverage across the country, while maintaining the quality and quantity of prescription drug coverage that Canadian patients experience today. Harmonizing catastrophic coverage programs across the country (for example, providing programs consistent with Ontario's Trillium Drug Program on a pan-Canadian basis) could provide a basis for establishing and calculating a federal contribution (of approximately $1B) to pharmacare.

Conclusion

Collaborative F/P/T efforts to improve coverage and access to prescription drugs in Canada will require reliable qualitative and quantitative assessments as the basis for sound policy decision-making. Recent proposals for national, universal, publicly-funded, single-payer prescription drug reimbursement plans fall short of providing practical, affordable options to address universality, equity and sustainability of prescription drug coverage in Canada.

While calls for a national pharmacare program have gone unanswered over the last several decades, numerous pan-Canadian initiatives have formed in its place, and have achieved commendable success in fulfilling and improving on many of the desired principles for a pharmacare program in Canada. In essence, pharmacare is evolving organically within existing political, legislative and market structures and this landscape is dynamic: efforts continue to ensure all Canadians have prescription drug coverage at a sustainable cost. The pan-Canadian approaches to pharmacare described in this report are intended to build upon the successes achieved by collaborative F/P/T efforts to date. Those targeted towards uninsured patients will maintain the public and private plans Canadians currently enjoy and will ensure patients continue to have high quality and timely access to important new medicines while not unduly burdening Canadian governments and taxpayers in the way proposals for national, public-only approaches pharmacare are expected to. This study estimates that governments could provide relief to the roughly 10% of Canadians who are not covered, or have inadequate prescription drug coverage, through either private or public drug plans by investing about $2 billion a year in a pan-Canadian pharmacare solution.

Success for any Canadian pharmacare program requires that it be practical to implement, seamlessly integrated into the provincial healthcare systems and respect provincial sovereignty in the provision of healthcare. A “one size fits all” national pharmacare program cannot be effective when superimposed upon 13 distinct provincial and territorial healthcare systems. Pan-Canadian pharmacare is the most appropriate approach in meeting the goals and objectives of universal pharmaceutical coverage in Canada, and those involving private insurance contain costs and risks to Canadians while maintaining quality access to prescription drugs in Canada.

Further research, analysis and public consultation are required to more fully inform the public policy debate concerning access to prescription medicines. Numerous alternatives must be considered as policy-makers and Canadians alike pursue the model of healthcare that most fulfills Canadian values while providing Canadians with the quality drug coverage they deserve and on which the Canadian healthcare systems are interdependent.

While this study does not include analysis for the comprehensive list of potential pharmacare approaches proposed or possible, it qualitatively and quantitatively compares a number of alternatives to consider beyond the universal, first-dollar coverage models for which cost-estimate studies have recently been completed. Not only do these models represent promising alternatives to build upon the existing achievements towards pan-Canadian pharmacare, they also provide ways for Canadian patients to ensure their access to essential medicines continues to facilitate the best health outcomes possible.

Appendix 1 – Cost Estimate Study Comparisons

Element	National Pharmacare Cost Estimate Study by *Morgan et al*, 2015	PDCI Market Access Pharmacare Costing in Canada 2016
Time Frame	2012-13	2015
Data Sources and Inputs	RX Altas – a secondary analysis of IMS survey of retail pharmacies	2015 Provincial & NIHB claims data 2015 Private Payer claims data CIHI National Health expenditures estimates for 2015
Cost effective product selection	3rd highest public plan rates of generic utilization / substitution applied at therapeutic category level – macro level analysis that does not distinguish between indications or patient populations - Drugs for rare sub-indications (e.g., PCSK9 for HeFH) that fit within broad therapeutic categories where there are many options for most patients (e.g., cholesterol lowering drugs) are likely eliminated. Uncertain how this analysis is consistent or inconsistent with limited use / step therapy policies that are already in place to promote use of low cost drug before high cost alternatives (e.g., generic metformin and/or sulfonylurea are already prerequisites for most branded T2 diabetes drugs	Assumes current public drug plan selection is cost effective – products not eligible for reimbursement by the provincial plan would be replaced by a low cost alternative (25% of the non-eligible cost)
Cost savings by tying brand prices to international prices	23% cost reduction based on average price difference compare with the United Kingdom (sensitivity analysis with France and Sweden) sourced from PMPRB 2013 report for patented medicines using 36 month exchange rates ending December 2013	Additional international price referencing not applied to drug expenditure data (Note: the potential merits / costs/ savings from referencing Canadian brand prices to UK (or Swedish / French) prices is not dependent on or resultant of a national pharmacare program – PMPRB already applies international price referencing in regulating brand prices in Canada
Cost savings by tying generic prices to international levels	Cost reduction based on average price difference compare with the United Kingdom and Sweden sourced from PMPRB generic report	The 2015 generic costs in the provincial drug plan data reflect the price reductions that pCPA and the jurisdictions have already achieved (see NDUIS report for progress on price reductions)
Implementation	Impractical - No mechanism described for implementation – does not account for the differences in underlying provincial systems or differences in current levels of coverage	Builds on existing programs – no disruptive changes

Appendix 2 – Building Blocks of a Pan-Canadian Approach to Pharmacare Already Exist

Numerous provincial and federal organizations and initiatives described in this appendix have already been implemented to improve the provision of prescription drug coverage across the country. Despite progress on improving drug coverage and program sustainability through the pCPA, there are continued calls for national pharmacare and momentum continues to gather.

IMPROVING ACCESS & EQUITY

Catastrophic drug coverage programs are aimed at ensuring a basic level of prescription drug coverage for Canadians who experience high drug costs relative to their household income. It is argued that catastrophic plans geared to income – aimed to ensure a general level of coverage to protect Canadians from "undue financial hardship"[22], are in effect in most provinces and could be expanded or supplemented to better overcome remaining access and equity barriers for prescription drugs.[4, 12] It is believed that if the federal government invested in a nationwide "geared-to-income" catastrophic plan resembling those of the provinces, not only would access to prescription drugs be improved (especially for low-income families) but issues that are associated with a single payer government monopoly, such as reduced incentives for cost-effective prescribing quality, could be avoided.[4]

In addition to strengthening and building upon drug coverage in Canada through existing public drug reimbursement systems, numerous other initiatives to achieve the very goals set out by proponents of a national universal, publicly administered pharmacare plan have been undertaken and implemented, which are already resulting in more cost-effective product selections and the achievement of lower brand and generic drug prices for Canadians.

IMPROVING EFFICIENCY, SUSTAINABILITY AND VALUE FOR MONEY

Proponents of a national, universal, publicly administered pharmacare plan resolve that such a program would be expected to improve efficiency by reducing prescription drug expenditures, both by promoting more cost-effective product selections through a population-wide, evidence-based formulary with tiered co-payments, and by consolidating purchasing power to reduce brand and generic drug prices. However, successful mechanisms already exist both in public and private sector drug plans to encourage cost-effective product selection, and reduce prices of brand and generic drugs, both contributing to greater efficiency in prescription drug reimbursement, an overall reduction of total expenditures on prescription drugs, and improving value for money spent on prescription drugs.

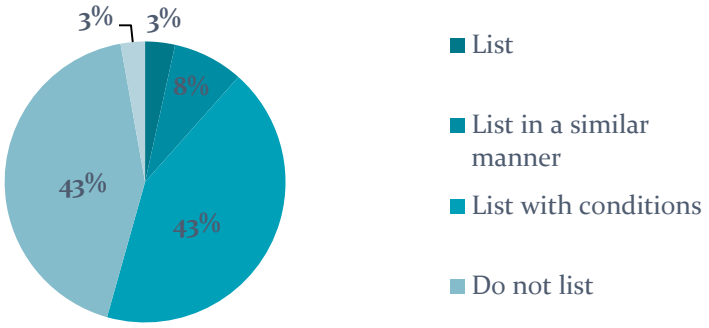
Cost-Effective Product Selection

Health Technology Assessment (HTA) is currently a crucial component for public drug plan reimbursement and funding decisions in Canada. Through evaluations of clinical effectiveness, cost-effectiveness, and the ethical, legal, and social implications of health technologies on patient health and the healthcare system, HTAs are contributing significantly to the products approved for inclusion on the F/P/T drug plan formularies.

Multiple Canadian agencies and organizations contribute to evaluation and decision-making around selection of cost-effective drug products. For example, since 1989 Canada's F/P/T healthcare decision makers have relied on the Canadian Agency for Drugs and Technologies in Health (CADTH) [formerly the Canadian Coordinating Office for Health Technology Assessment (CCOHTA)] to provide public drug plans with credible, impartial advice and evidence-based information about the effectiveness of drugs and other health technologies. Unlike federal regulators who evaluate the safety, efficacy and quality of products and ultimately determine which technologies can be marketed in Canada, CADTH supports decision makers in their determination of which technologies should be used to achieve the best outcome both for patient health and the healthcare system, considering relative costs and benefits of all available health technologies.

In 2003 the Common Drug Review (CDR), a F/P/T government initiative administered by CADTH, was established to conduct objective evaluations of the clinical, economic, and patient evidence for new drugs, drugs with a new indication, new combination products and more recently, subsequent entry biologics (SEBs). A distinct but parallel HTA process of oncology products takes place by CADTH's pan-Canadian Oncology Drug Review (pCODR). The CDR helps reduce duplication, streamline the process for reviewing new drugs for public reimbursement and provides consistent information to inform F/P/T reimbursement decisions. Since its inception, only 3% of medicines reviewed by the CDR have received a "list" recommendation without restrictions whereas 54% have received a listing recommendation with conditions (either, in a similar manner, with specified clinical conditions or at a reduced price based on clinical and/or cost reasons) and 43% were not recommended for listing (Figure 2). Prior to the CDR's creation, publicly funded drug plans each had their own expert committees review new drugs and provide listing recommendations. Some provinces have maintained their own drug review committees to inform decisions at the jurisdictional level.

Figure 2 - CDR Recommendations May 2004 - October 2015 (n=320)



Québec does not participate in the CADTH, CDR or pCODR processes; however the province conducts its own health technology assessment of new drugs via the *Institut national d'excellence en santé et en services sociaux* (INESSS), an agency created in 2011 which replaced the *Conseil du médicament* to provide recommendations concerning funding of new drug technologies.

INESSS and the CADTH, CDR and pCODR processes provide public drug programs in Canada not only with recommendations about whether to provide reimbursement for a particular health technology based on their relative clinical- and cost-effectiveness compared with existing health technologies available, they also provide recommendations for any appropriate criteria or conditions (based on clinical and cost reasons) under which reimbursement of a drug would represent a cost-effective choice, such that the plans can implement appropriate listing criteria that will improve value for money spent. As observed in Figure 2, the vast majority of drugs (86%) are not recommended for reimbursement on public drug plan formularies or are only recommended for reimbursement under circumstances that improve their value for money relative to existing therapies, thereby providing public drug plans the ability to impose restrictions to reimbursement in favour of cost-effective product selection.

Achieving Lower Drug Prices

Several highly effective initiatives are currently underway in Canada to leverage purchasing power to reduce brand and generic drug prices and in turn, improve value for money spent by Canadians on prescription drugs.

Patented Medicine Prices Review Board

Established in 1987, the Patented Medicine Prices Review Board (PMPRB) is a federal quasi-judicial agency with a mandate to ensure the prices of patented medicines sold in Canada are not excessive.

The PMPRB is part of the Health Portfolio which supports the Minister of Health in maintaining and improving the health of Canadians.

The PMPRB protects consumers by regulating the factory gate prices of new medicines sold in Canada (drug costs set by manufacturers). The *Patent Act* outlines the price review factors used to determine if the price of a patented medicine sold in Canada is excessive, and the sanctions applied for excessive pricing. The PMPRB can order price reductions and recover excess revenues for excessively priced drugs. Penalties of up to two times the excess revenues can be imposed if the PMPRB concludes that a manufacturer has engaged in a policy of excessive pricing.

Although most manufacturers comply voluntarily with PMPRB guidelines, PMPRB enforcement action is required for 10-25% of all new drug products.[23] Over the PMPRB's 24 years, more than $125 million in excess revenues have been offset by manufacturers through payments to the government and customers. The three largest annual totals of excess revenues offset have occurred within the last six years of available data (2009-2014).[23,23] Throughout its lifespan, the PMPRB has been highly effective at limiting increases of the prices of patented medicines to less than CPI inflation, and has also ensured that Canadian prices do not exceed prices for the same drug as sold in key comparator countries.

In light of a continually changing pharmaceutical pricing landscape, both domestically and in the PMPRB's international reference countries, there has been a growing perception among stakeholders that the PMPRB's relevance has diminished. As a means to renew its relevance and ensure Canadian consumers continue to be protected from excessive prices, the PMPRB is currently undergoing a 3-year review of its mandate and priorities and substantial changes are expected to renew its authority in the regulation of drug prices.

Over PMPRB's 24 years, more than $125 million in excess revenues have been offset by manufacturers through payments to the government and customers.

Product Listing Agreements

Although the PMPRB is mandated to ensure the prices of patented medicines in Canada are not excessive, to address the increasing affordability issues, public and private drug plans have taken further action to reduce the prices paid for brand and generic drugs included on their formularies. Product listing agreements (PLAs) are contracts negotiated between a drug manufacturer and drug plan representatives detailing mutually agreeable terms of drug reimbursement that are aimed at sharing risks between the manufacturer and the payer. Although some agreements are health-

outcome based, most PLAs involve confidential price reductions achieved through volume discounts, rebates, or expenditure / patient caps. Though the nature of specific agreements and cost-savings that they provide are confidential, common estimates for savings achieved in PLAs range from 15-40% off the publicly available list price for brand drugs.

Provincial Drug Plans – pan-Canadian Pharmaceutical Alliance

Through the Council of the Federation, the Healthcare Innovation Working Group (HCIWG), composed of provincial and territorial Ministers of Health, was created to lower the cost of brand name and generic drug products in Canada. The pan-Canadian Pharmaceutical Alliance (pCPA), established in August 2010 under the governance of the HCIWG, aims to increase access to brand drug treatment options, achieve lower and consistent drug costs and improve consistency of coverage criteria across Canada. It does so by streamlining processes and combining jurisdictions' purchasing power to negotiate lower prices for prescription drugs than could be achieved individually. The pCPA relies on the HTA recommendations provided through the CADTH, CDR and pCODR processes to limit public reimbursement of products to those that have demonstrated clinical value and are cost-effective relative to existing therapies.

As of March 2014, pCPA estimated its collaborative efforts among provinces and territories have resulted in an estimated $490 million in annual savings.

This nationwide collaboration of the provincial and territorial drug plans has had important implications for the pharmaceutical industry and public drug plan beneficiaries alike. While not all products are negotiated through the pCPA today, almost all products that will eventually achieve public reimbursement will be considered for negotiation by the pCPA in the future. As of March 2014, the pCPA estimated that its collaborative efforts among provinces and territories have resulted in an estimated $490 million in annual savings.[24]

The pan-Canadian Generic Value Price Initiative, established in January 2013, aims to optimize savings related to generic drugs for provincial public drug plans. This initiative leverages combined purchasing power of the jurisdictions to obtain the lowest generic drug prices ever achieved in Canada – 18% of the corresponding brand prices. In April 2015 the third phase of the initiative was implemented, bringing the total number of commonly used off-patent drugs included under the initiative to 14. It also introduced a tiered pricing framework and a central price submission process to improve efficiency in administration of generic pricing.[24] The success of the initiative was outlined in the 2016 NPDUIS report "Generics 360" that found that generic prices in Canada fell 45% from 2010 to 2014 and were on average 36% of brand price versus 63% of brand price in 2010.[25] Canadian generic

prices are still relatively high when compared to other countries; however the pCPA has continued to add new products to the 18% group in 2015 and 2016 which further reduce generic prices on average.

Prior to these initiatives, PLAs between drug manufacturers and individual provinces served as the primary mechanism by which prices of drugs reimbursed on provincial drug plan formularies were negotiated. As a result of the pCPA collaboration on PLAs, provinces have effectively combined their market power to negotiate better and more equitable drug prices than they previously could have negotiated individually. Furthermore, the single negotiation also ensures more consistency in the listing criteria for each drug, the timeliness of reimbursement and prices paid by the public drug plans.

Besides the pCPA's achievements to date, provincial and territorial governments and their public drug plans are continuing to find ways to control rising drug program costs while ensuring access to important new therapies is maintained. This is evident through continued collaboration and cooperation of the pCPA, Québec joining in 2015 (which will further consolidate purchasing power of public drug plans in Canada) and growing the Generic Value Pricing Initiative to include 14 generic drugs.

The federal government also recently joined the pCPA table.[26] Like the addition of Québec to the pCPA, federal collaboration further consolidates Canada's public drug plans' purchasing power. For example, the federally funded Non-Insured Health Benefits program provides health benefits to almost 1 million First Nations and Inuit clients.

The pCPA has also stated that it will begin performing reviews for entire therapeutic classes of drugs to review the appropriateness of continuing public drug plans' level of reimbursement for particular products in light of the availability of new clinical evidence and the market entry of new competing therapies. This will continue to improve value for money spent by public drug plans in Canada.

Private Drug Plans

While PLAs have become a common and essential component of securing public reimbursement in Canada, only recently have private payers expressed the need, interest and ability to engage in such negotiations. Private payers – including the community of insurers, Pharmacy Benefit Managers (PBMs) and plan sponsors (employers) – are starting to build internal competencies aimed at negotiating with pharmaceutical manufacturers. For the past several years, private payers have raised concerns about increasing drug costs, particularly for specialty products, and movements are afoot

to achieve savings via PLAs in the same frequency and magnitude as those achieved by pCPA in the public market.

For example, as a component of the DrugWatch™ program, Manulife has promised its drug plans sponsors[27]:

> ***"expert negotiations: Manulife's dedicated team of experts work with pharmaceutical manufacturers to seek the best possible drug prices for our clients"***[27]

The success of these ongoing initiatives demonstrates that replacement of the existing mix of public and private reimbursement with a national, universal, single-payer, publicly-funded model as proposed in the National Pharmacare Cost Estimate Study is not imperative to achieving improved access, equity, efficiency and sustainability in prescription drug coverage in Canada

In summer 2015 PDCI Market Access and H3 Consulting conducted a survey of pharmaceutical manufacturers and private payers to understand stakeholder's interests, existing activities, intentions and expectations concerning PLAs in the private market.

Of the 27 survey respondents, approximately 41% (i.e. 7 manufacturers and 4 payers) indicated that they had experience negotiating private payer PLAs and a further 22% (i.e. 4 manufacturers and 2 payers) did not have experience negotiating private payer PLAs but indicated they would be interested to do so in the future. [28]

Results illustrated that although private market PLAs are not yet as commonplace as in public drug plan reimbursement, several payers and manufacturers had activities underway to prepare for or develop capabilities to negotiate PLAs, suggesting their achievement of lower negotiated prices will follow suit on the achievements of the pCPA to lower prices paid for brand drugs.

The success of these ongoing initiatives demonstrates that replacement of the existing mix of public and private reimbursement with a national, universal, single-payer, publicly-funded model as proposed in the National Pharmacare Cost Estimate Study is not imperative to achieving improved access, equity, efficiency and sustainability in prescription drug coverage in Canada.

OTHER OPPORTUNITIES

Other opportunities that could be explored in the future to improve prescription drug coverage in Canada include:

- CADTH (CDR, pCODR) and INESSS to collaborate on health technology assessment reviews of clinical- and cost-effectiveness for new drugs.
- Drug plans could encourage uptake of subsequent entry biologics (biosimilars) informed by experience in other markets such as Norway and Australia.
- The PMPRB could review the role of international price referencing of patented medicines in Canada and explore opportunities to contribute/inform pCPA negotiations of product listing agreements for brand drugs.
- The pCPA could collaborate with CPhA on opportunities to coordinate and implement best practices for pharmacist services in all jurisdictions.
- The pCPA could collaborate with provincial medical associations to explore strategies for optimal prescribing of prescription drugs.

References

1 Government of Canada Statement of the Federal-Provincial-Territorial Ministers of Health Vancouver, January 21, 2016. Accessed February 5, 2016 http://news.gc.ca/web/article-en.do?nid=1029069

2 Leslie, Keith (2015) "Provincial health ministers call for national pharmacare program". The Globe and Mail. Posted June 8, 2015. The Canadian Press. Accessed 13-Jan-16. http://www.theglobeandmail.com/news/national/health-ministers-discuss-national-pharmacare-program-to-pay-for-prescription-drugs/article24842194/

3 Hoskins, Eric. (2014) "The time for national pharmacare has come". The Toronto Star. Posted December 15, 2014. Accessed 15-Jan-16. http://www.thestar.com/opinion/commentary/2014/12/15/eric_hoskins_the_time_for_national_pharmacare_has_come.html

4 Blomqvist, Ake, Busby, Colin. (2015) Feasible Pharmacare in the Federation: A Proposal to Break the Gridlock. CD Howe Institute E-Brief, October 21, 2015 https://www.cdhowe.org/public-policy-research/feasible-pharmacare-federation-proposal-break-gridlock

5 Lewis S, A system in Name Only – Access, Variation, and Reform in Canada's Provinces, NEJM, 372;6, February 5, 2015.

6 Phillips, Karen. (2009) "Catastrophic Drug Coverage in Canada," Government of Canada, Social Affairs Division, September 2009. Accessed 16-Jan-16 http://www.parl.gc.ca/content/lop/researchpublications/prb0906-e.htm

7 Statistics Canada, CANSIM, table 051-0001. Accessed 26-February-16 http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/demo02a-eng.htm

8 Government of Prince Edward Island. (2015) News Release: New Generic Drug Plan becomes effective October 1st. September 28, 2015, Accessed February 18, 2016. http://www.gov.pe.ca/newsroom/index.php3?number=news&newsnumber=10393&dept=&lang=E

9 PDCI Market Access Canadian Drug Claims Database Analysis, February 2016.

10 Statistics Canada. Table 183-0002 - Public sector employment, wages and salaries, seasonally unadjusted and adjusted, monthly, CANSIM (database) Accessed: 15-Jan-16 http://www5.statcan.gc.ca/cansim/a26?lang=eng&retrLang=eng&id=1830002&&pattern=&stByVal=1&p1=1&p2=37&tabMode=dataTable&csid=

11 Rovere M. Skinner B. (2012) Access Delayed, Access Denied 2012. Waiting for New Medicines in Canada. Fraser Institute. Accessed 15-Jan-16 https://www.fraserinstitute.org/sites/default/files/access-delayed-access-denied-2012.pdf

12 Skinner, BJ, Rovere, M, Mohindra, M, and Tran, K (2015). Pharmacare: what are the costs for patients and taxpayers? Canadian Health Policy, September 24, 2015. Toronto: Canadian Health Policy Institute (CHPI).

13 New Zealand Government Pharmaceutical Management Agency. Fact Sheet #1: Introduction to PHARMAC, Accessed 22-February-16 https://www.pharmac.govt.nz/assets/factsheet-01-introduction-to-pharmac.pdf

14 Badar Z, Vitry A, "Differences in Australian and New Zealand medicines funding policies", Australian Prescriber, July 2014

15 Wonder M, Milne R, "Access to new medicines in New Zealand compared to Australia", Journal of the New Zealand Medical Association, 25 November 2011, Vol 124 No 1346.

16 Aaltonen K et al. (2010) "The impact of pharmaceutical cost containment policies on the range of medicines available and subsidized in Finland and New Zealand", Value in Health, Jan-Feb 2010

17 Ragupathy R, et al. (2012) "A 3-dimensional view of access to licensed and subsidized medicines under single-payer systems in the US, the UK, Australia and New Zealand", Pharmacoeconomics, February 2012

18 New Zealand Ministry of Health. "Questions and answers - $5 pharmacaeutical co-payments" website. Accessed 26-Feb-16. http://www.health.govt.nz/our-work/primary-health-care/primary-health-care-subsidies-and-services/pharmaceutical-co-payments/questions-and-answers-5-pharmaceutical-co-payments

19 Jatrana S, et al. (2009), "Primary health care in New Zealand: who has access?" Health Policy, November 2009.

20 PDCI Market Access. (2015) Internal Analysis – New Zealand Prescription Drug Coverage Comparison to Ontario.

21 UBC Human Resources "Faculty Monthly Premium Rates" website. (2016) Accessed 26-Feb-16. http://www.hr.ubc.ca/benefits/premium-rates/faculty/

22 Phillips, Karen. (2009) "Catastrophic Drug Coverage in Canada," Government of Canada, Social Affairs Division, September 2009. Accessed 16-Jan-16 http://www.parl.gc.ca/content/lop/researchpublications/prb0906-e.htm

23 PDCI Market Access. (2015) Internal Analysis – Assessment of PMPRB Effectiveness.

24 Canadian Premiers pCPA website. Accessed 13-Jan-16. http://www.canadaspremiers.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance

25 NPDUIS. (2016), "Generics 360" Generic Drugs in Canada 2014, February 2016

26 Canadian Premiers pCPA website. Accessed 26-Feb-16. http://canadaspremiers.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance

27 Manulife. (2015) Introducing Manulife DrugWatch™ Brochure. Accessed 15-Jan-16 http://www.benefitsconsultant.ca/wp-content/uploads/2015/09/Manulife-DrugWatch-Brochure.pdf

28 PDCI Market Access and H3 Consulting. (2015) Manulife DrugWatch™ & Private Payer Product Listing Agreement (PLA) Series. Accessed 15-Jan-16. http://www.pdci.ca/2015/09/30/manulife-drugwatch-private-payer-product-listing-agreement-pla-series/