PHARMACARE COSTING IN CANADA

Preliminary Report: Assessment of a National Pharmacare Model Cost Estimate Study

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Contents

Executive Summary

- The 2015 "Estimated cost of universal public coverage of prescription drugs in Canada" study (Morgan *et al*)[1] overstates potential savings attainable from the proposed program – actual costs to governments and taxpayers are likely closer to $6.6 billion rather than $1 billion.
- The study relied on average drug prices in the United Kingdom as a proxy for potential savings achievable from monopsony power however it does so using an exchange rate from a time when the British Pound was at historic lows compared to the Canadian dollar.
- The study assumes that unions representing government employees will exchange their private drug plan for an inferior public plan without any collectively bargained offset or quid. This is unlikely.
- Methodological and data concerns lessen confidence in the study's results, including:
    - limitations of the data relied upon, including heterogeneity of underlying data sources and changes occurring since reference period
    - impractical assumptions about the level of generic price reductions achievable; and
    - no accounting for the impact of confidential listing agreements (already estimated to provide annual savings of approximately $490 million).
- The study does not consider other qualitative consequences that loss of private drug plan coverage will have on Canadians including:
    - the significant reduction in the number of drugs covered
    - the longer time to reimbursement for drugs that are eventually covered
    - the impact on the ability of pharmacists to serve patients
    - reduced attractiveness of the Canadian market to manufacturers of innovative medicines; and
    - job losses in the private drug insurance industry
- Extensive restructuring and consolidation of prescription drug coverage under one nationally administered public drug program is not necessary to achieve the objectives of universal coverage, equity and sustainability. Alternatives building on existing foundations can achieve these goals without
    - significantly reducing the quality of drug coverage for the majority of Canadians, or
    - encountering the legislative and administrative barriers which have derailed efforts towards a national pharmacare program in the past.

Introduction

Calls for a national pharmacare program have persisted in Canadian public policy circles since the 1960s, and from time to time have sparked public and political debate. Despite efforts toward a universal, publicly-funded prescription drug reimbursement program and recommendations supporting implementation of such a program – including the 1964 Royal Commission on Health Services (the "Hall Commission"), the 1997 National Forum on Health, and the 2002 Commission on the Future of Health Care in Canada (the "Romanow Commission"), to name a few – to date, progress on implementing a national pharmacare program at the federal or national level has not emerged. Described as the Canadian health care system's "unfinished business"[2] numerous theories and reasons have been advanced to explain barriers to its implementation, including costs and political will, among others.[3,4]

With seeming renewed interest from federal, provincial and territorial (F/P/T) governments to revisit collaboration opportunities on pharmaceutical initiatives such as Pharmacare[5,6], several parties have recently proposed models for such programs with the intent of gathering momentum towards breaking the "gridlock"[7] on the national pharmacare discussion to achieve varying degrees of reform in the way Canadians access and pay for prescription medicines.

The first step in the discussion is to define national pharmacare and its objectives. Often the starting point is to reference 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 health care 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 population. The CHA also explicitly recognizes that provinces and territories have exclusive constitutional authority and responsibility for the delivery of health care. And consistent with the CHA, the provinces have established provincial health care systems that are similar in terms of the core health care services they deliver but have differences at the margins which reflect the evolution of the provincial health care policies and health care delivery mechanisms.

Accordingly, if the CHA were to expand to include pharmaceutical coverage (the "unfinished business") each of the public drug plans would expand eligibility for their plans to include all its citizens, not just those populations currently targeted for coverage (i.e., seniors, social assistance recipients, individuals with high drug costs relative to income, representing approximately 11.0 million Canadians eligible for public coverage today[8]). And the federal government would undoubtedly be asked to contribute – as it does now for the funding of hospital and physician services – though transfers and tax points. The additional cost to the public system would be billions of dollars. And given that the vast majority – 24.2 million[8] – of the population not eligible for basic public coverage in fact already have private coverage (as good or better than public coverage for the most part) there is little political or public appetite to increase taxes to provide an expensive health benefit most Canadian already enjoy. While a majority of Canadians expressed support for the concept of a pharmacare program in a recent Angus Reid poll, most (61%) agreed with the statement "no matter what the research says, a national pharmacare plan will end up costing taxpayers lots of money."[9]

The generally accepted figure is that 10% of Canadians have no or inadequate basic drug coverage (one estimate is as low as 100,000 Canadians or approximately 0.3%[8]). From a policy perspective, the issue therefore is whether it is worth the additional billions in expenditures – and increased taxes by extension – to provide coverage for the few who are currently without coverage (universality) and to satisfy the "public administration" pillar of the CHA. Presumably in such a model, individuals could supplement their plan to gain coverage for drugs not covered by the public system (in the same way that private insurance is used today to gain access for private and semi-private hospital rooms). In concept, the CHA model is feasible within the legislative framework, however, as a practical matter the resulting administrative upheaval is likely not worth the modest net result (coverage of the 10% and satisfying the "public administration" ideal).

Many of the proponents of a national pharmacare program seek to go well beyond the CHA pillars to pursue two more 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 differences in the underlying provincial health care systems. Secondly there is a perception (and supporting analyses) that suggests a single pharmacare program could deliver significant savings compared to what the separate drug plans can realize today.

A recent analysis for such a national pharmacare approach was outlined in the 2015 CMAJ paper by Morgan *et al*.[1] The authors conclude that their proposed "National Pharmacare" program would

result in net savings of $7.3 billion in overall drug expenditures although an increase in public expenditures of approximately $1 billion would be required to achieve it.

In light of renewed interest for F/P/T collaboration on national pharmaceutical policy initiatives[5,6] – including improvement of accessibility, equitability and affordability of prescription medicines in Canada – 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 on potential national pharmacare policies in Canada. This analysis – to provide cost estimates for a sample of potential national pharmacare models – is scheduled to be complete in the first quarter of 2016. These models include:

1. A Modified Quebec Model
2. A Catastrophic Model
3. A Public/Private Basic Coverage Model

The objective of this preliminary report is to summarize PDCI's assessment of the Morgan *et al* study (referred to here as the 2015 National Pharmacare Cost Estimate Study) and identify some alternative mechanisms by which drug coverage in Canada can fulfill the spirit of the CHA pillars (with the possible exception of "public administration") and the additionally desirable objectives of equity and sustainability can be achieved.

Assessment of the National Pharmacare Cost Estimate Study

The study, "*Estimated cost of universal public coverage of prescription drugs in Canada"*, (the "National Pharmacare Cost Estimate Study", or "the study") is a secondary analysis of 2012-2013 data from the *Canadian Rx Atlas, 3rd Edition.* It models the estimated net Canadian prescription drug expenditures estimated if a proposed National Pharmacare plan had been in place at that time.

RESULTS & ADJUSTMENTS

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

- Eliminating private drug plans and transferring all beneficiaries to a National Formulary. This is estimated to save 100% of current direct drug expenditures made under private plans, and a large portion of the "out-of-pocket" costs as well.[i]
- 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-paying public drug plan:

- "Direct public" savings:
    - Removing access to drugs that are currently only available on private plans (i.e., the underlying assumption is that if they are not on the public plan they are not medically necessary – note there are more than 3,300 drug products or Drug Identification Numbers (DINs)[ii] that are funded on private plans but not listed as benefits on public plans). These products represent approximately 476 unique active substances.

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

[ii] 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.

  - Leveraging monopsony pricing power[iii] to lower the prices at which prescription drugs are reimbursed.
- "Indirect public" savings:

Eliminating employer-based drug plan benefits for the approximately 769,000 federal and provincial government employees[10]

Table 1 summarizes the results of the study with respect to the public / private distribution of costs and savings that could be realized under the study's proposed National Pharmacare program.

*Table 1 - National Pharmacare Cost Estimate Study – Distribution of Public/Private Spending on Prescription Drugs**

Spending	Baseline	Change in Spending (base Scenario)	National Pharmacare
	$ millions		
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**

*Note: Rounding in original study.

The savings claimed in this study are contingent on two important, but flawed assumptions:

1. the use of United Kingdom (UK) prices (relative to Canada) as benchmark for achieving brand and generic price reductions, and
2. that government employers can remove private drug plan benefits for their employees without offsetting increases in other employee benefits (given that these benefits are collectively bargained).

Benchmarking to UK prices. The authors assume that lower prices could be achieved if pricing in Canada was comparable to prices in the UK in 2013. In their annual report for 2013, the Patented Medicines Prices Review Board reported that UK prices were 77% of Canadian prices. This differential equates to $3.2 billion – $2.2 from the existing public plans and $1.0 billion (of publicly eligible reimbursement) from the private plans that were converted to public. The PMPRB analysis

[iii] 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.

employed the PMPRB 36-month exchange rate methodology that resulted in an effective exchange rate of 1.00 Great Britain Pound (GBP) = 1.59 Canadian Dollar (CAD). However, that period was a time when the GBP was at historic lows compared to the CAD, as observed in Figure 1.

Figure 1 - Canadian Dollars (CAD) per 1 Great Britain Pound (GBP)

Source: xe.com

As of December 2015 the rate was 1.00 GBP = 2.05 CAD. At that rate almost all of the potential savings associated with pegging to UK pricing disappear. Note that the study's authors do not propose actually pegging Canadian prices to UK prices but rather that UK prices are an appropriate proxy of what would be achievable through monopsony pricing. And herein lies the flaw; the estimated savings tied to UK prices evaporate in 2015 (and probably again in 2016) and therefore any estimate of potential savings from monopsony pricing must be estimated in some other way (and not based on international price comparison subject to vagaries of exchange rate fluctuations). Accordingly the estimates of saving from lower prices have no basis. There is no doubt that lower prices are possible (and are being achieved through the monopsony pricing mechanisms already in place) however they are unrelated to UK price comparison. Later in this report there is a discussion of the existing mechanisms for national price setting power (i.e., the pan-Canadian Pharmaceutical Alliance or pCPA – see *APPENDIX II*).

Indirect Public Savings. The second assumption – that governments will save $2.45B by eliminating their employees' private drug plan benefits – is also flawed. It's true that employers would no longer pay for supplementary drug insurance for their employees once a universal public plan is in place, however it is highly likely that these "savings" will be offset by added costs through the collective bargaining process. Unions are unlikely to give up a benefit (annual premiums are ~$500/year for an individual) without receiving comparable offsetting benefits in return. So while overall drug expenditures may decrease (public plans reimburse fewer drugs than private plans) governments will have offsetting employee costs. In the end there may be some net savings to government however there is no evidence upon which to base such an estimate. The importance of

this issue was highlighted in 2012-2013 when a number of the health sector unions in British Columbia negotiated a "PharmaCare tie-in" such that they gave up their existing private drug plan and replaced it with a plan that mirrored the provincial PharmaCare plan in exchange for other considerations in their collective agreements. The limited benefits available on PharmaCare resulted in extensive grievances, arbitration, reinstatements of some non-PharmaCare drugs as benefits to the employees and millions in payments to employees who had to pay out of pocket for drugs.[11,12] The costs to the health care system associated with added physician visits necessary to switch therapies (from non-PharmaCare to PharmaCare eligible) are not known at this time but would have to be factored into any national pharmacare model that seeks to impose public plan coverage on those currently with private drug plans.

Taking into account adjustments to these two assumptions alone (UK prices as a proxy for monopsony price setting and collective bargaining offset) we can restate the overall cost impact as outlined below in Table 2.

Table 2 - Morgan National Pharmacare – Distribution of Public/Private Spending on Prescription Drugs – ADJUSTED

Spending	Baseline	Change in Spending (base Scenario)	National Pharmacare
		$ millions	
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.

In summary, once adjusted, the overall potential reduction in expenditures is approximately $1.6 billion from implementation of the National Pharmacare program, but the increase in public expenditures is $6.6 billion – much greater than originally estimated. The amount of the adjustments in each case is open for debate and outlined for illustrative purposes and would vary dependent on how and when such a plan was implemented.

DATA SOURCES & ASSUMPTIONS

The authors have conducted extensive analyses using the *Canadian Rx Atlas* ("*Rx Atlas*") in developing some of the estimates in the study. While their methods may be sound there are concerns with respect to the validity and reliability of the underlying data. The *Rx Atlas* is an impressive compilation of several data sources and administrative data sets each with its own strengths and limitations. It is aimed at enhancing the understanding of medicines by providing age- and sex- specific patterns of prescription drug use and costs across provinces. It also estimates the source of financing for prescriptions filled in 2012-2013 in each province. The *Rx Atlas* is a useful resource for attempting to understand prescription drug use in Canada, however, it has limitations. It notes that very few provinces systematically collect and monitor information about use, impact, and cost of prescription drugs and thus the authors rely on market research data to populate their model.[13]

Data in the *Rx Atlas* originates from varied sources with different purposes, primary clients, and geographic coverage restrictions as summarized in Table 3.

Table 3 - Rx Atlas Data Sources[13]

Source	Purpose for Rx Atlas	Primary Client	Coverage
IMS Compuscript	Estimate of retail pharmaceutical sales	Commercial (e.g. pharmaceutical companies)	All provinces but PEI
IMS Rx Dynamic	Longitudinal drug utilization data in select therapeutic markets	Commercial (e.g. pharmaceutical companies)	Select provinces
Provincial Formularies	*Publicly available** price of products covered by drug provincial drug program	Public	Specific province
Statistics Canada	Population estimates	Public	National
Canadian Institute for Health Information (CIHI)	Various indicators of population health and health information system performance	Public	National
World Health Organization (WHO)	Defined Daily Doses and Anatomical Therapeutic Chemical (ATC) drug classification system	Public	International
**Does not reflect the true price paid by public drug plan which could be the subject of a product listing agreement*			

Combining such heterogeneous sources of information, while perhaps useful to provide a general sense of prescription drug coverage, is fraught with limitations when used as a basis to justify cost savings for significant healthcare policy initiatives such as National Pharmacare.

Further, the authors of the *Rx Atlas* acknowledge that certain estimates and judgements needed to be applied during the development of this resource. For instance, they note that the primary

sources of financing information are approximate estimations and that certain anatomical therapeutic chemical (ATC) groups were clustered based on the authors' judgement of primary indication. This raises questions on applicability of information for broader purposes. One important limitation which was not acknowledged in the *Rx Atlas* is the impact of product listing agreements (PLAs) on price effects. It is assumed that the list prices found on the provincial formularies provide an accurate assessment of drug prices when in fact, hundreds of PLAs have been negotiated between manufacturers and various public drug plans, calling into question the validity of the prices it uses.

The *Rx Atlas* is meant to provide useful information for readers to critically assess common hypotheses about why spending is higher in some provinces than others. The authors note they do not draw any conclusions about policy and practice in their document – which is understandable given its data limitations identified so far.

However, since this resource is now being used as the primary data source to calculate potential savings from adopting a National Pharmacare program, a critical review of its limitations is required prior to relying on it as the basis for public policy analysis and decision-making. In particular, more attention must be paid to the impact of using disparate data sources, considering product listing agreements and the seeming arbitrariness in the grouping of therapeutic classes. There is a need to better understand and address such limitations of this data if there is to be meaningful discourse on the potential healthcare policy changes that may flow from its analysis.

Besides the methodological limitations of the data source underlying the study's conclusions, reliance on data from 2012-2013 is also not ideal as it represents an outmoded reimbursement landscape. Much of the savings claimed in the study are dependent on the amount of public spending and the mix of brand / generic drug utilization at that time. In order to understand if a cost estimate based on 2012-2013 data is a reliable basis for policy discussions occurring in 2016, we conducted a preliminary analysis to compare relative spending in the most current fiscal year (2014-2015) with the *Rx Atlas* data (fiscal year 2012-2013).[iv]

The analysis showed that the reimbursement landscape in 2014-2015 is in fact quite different from that in 2012-2013. For example, one of the major sources of costs savings identified in the National Pharmacare Cost Estimate Study involves the drug class for cholesterol-lowering agents (ATC: C10).

[iv] PDCI's *Canadian Drug Claims Database* was used to compare total drug costs reimbursed by provincial drug plans over the two time periods. Because the data origins of the two sources differ, data retrieved from the PDCI *Canadian Drug Claims Database* did not perfectly match those published in the *Rx Atlas*. However, 2012-2013 data from each source was comparable: total provincial drug spending in 2012-2013 differed by only 1.9% between the *Rx Atlas* and PDCI's *Canadian Drug Claims Database*.

The study estimates cholesterol-lowering drugs to be responsible for $957 million in public spending in 2012-2013 and suggests that the National Pharmacare program would result in savings of $244 million in this class alone – a 25.5% reduction in spending. When comparing 2012-2013 data with 2014-2015 data, we found that cholesterol-lowering drugs had already experienced a 37.8% drop in total public spending. This was attributable to a number of factors, including a 30.1% increase in the proportion of generic drug spending in this class. This example not only demonstrates that reliance on data sources even a few years old can greatly misrepresent the dynamic nature of the Canadian pharmaceutical landscape, but also that in absence of a National Pharmacare program numerous initiatives have been highly effective not only in matching but actually surpassing the potential savings projected to be possible under a National Pharmacare program.

ASSUMPTIONS

> *"A universal public drug benefit program would be expected to promote cost-effective product selection through a population-wide, evidence-based formulary with tiered copayments... We used product selection decisions seen under existing provincial drug plans to estimate choices between brand-name and generic drugs under a universal public drug plan."*[xi]

The National Pharmacare Cost Estimate Study achieves large amounts of savings from its assumptions surrounding the National Formulary's ability to promote cost-effective product selections, particularly as it applies to the rate of generic prescribing and substitution. As explained in *APPENDIX II - Existing Initiatives to Achieve Pharmacare Objectives* considerable efforts have already been invested towards ensuring cost-effectiveness is forefront in decisions around product selection. For public drug plans, these efforts have included mandatory generic substitution policies, the growing importance of health technology assessments to reimbursement decision-making [e.g. the Canadian Agency for Drugs and Technologies in Health (CADTH) Common Drug Review and pan-Canadian Oncology Drug Review processes], and the use of restricted access, listing criteria, and step therapy requirements. In addition, some private plans mirror the public formularies, apply prior authorization, listing criteria or step therapy policies, some consider adherence and disease management programs, and others are becoming more attentive to publicly available heath technology assessments to prioritize cost-effectiveness in product selection decisions under their plans.

> *"Such a plan could lower drug prices by consolidating purchasing power into a single-payer system and enabling population-level supply contracts under the program…, we used drug prices found in Canada's official comparator countries to gauge the extent that brand-name and generic drug prices might decrease under a universal public drug plan."*[1]

As previously highlighted, the National Pharmacare Cost Estimate Study assumes monopsony purchasing power will achieve a 23% reduction in brand drug prices, making Canadian brand prices equivalent to the average brand prices observed in the UK. The UK was chosen as a comparator because it was perceived to have moderate prices among Canada's official PMPRB reference countries, it has a universal public health care system and attracts a great deal of pharmaceutical research and development. However as discussed earlier, estimates of costs savings in Canada based on UK prices are inappropriate given shifts in exchange rates (Canadian prices in 2015-2016 are likely already at par with the UK).

The more important point is understanding that monopsony pricing mechanisms are already in place in Canada (*APPENDIX II - Existing Initiatives to Achieve Pharmacare Objectives)*. The authors do not include the value of product listing agreements (rebates paid by drug companies to provinces and territories) in part because they are confidential although some aggregate data are available. The authors also discount the importance of these agreements as there are similar mechanisms in some other countries - which ignores the purpose of these price / volume agreements. These mechanisms are used to ensure the net price of each drug in the respective jurisdiction is cost effective and sustainable. That price / volume agreements exist in other jurisdiction does not mean the agreements in those jurisdictions are the same as those negotiated by pCPA in Canada.

The study also assumes generic prices would drop down to the level of "moderate performing comparators" among the PMPRB reference countries. UK and Sweden which both have single purchasers for generic drugs were chosen. The PMPRB average bilateral foreign to Canadian generic price rations in Q1 of 2013 were 0.55 in the case of the UK and 0.49 in the case of Sweden.[14] In some cases it would result in generic prices that are equivalent to 6% of the original brand in Canada. This analysis suffers from the same exchange rate issue that was highlighted earlier for branded products (i.e. the analysis would look much different in 2015). Moreover, it ignores the progress that the pCPA has achieved in lowering prices of generics (the top selling generic drugs are now set at 18% of the original branded drug). It is important to note that the pCPA has also sought to temper its quest for the lowest commercially viable prices with a sensitivity to the possibility of product shortages if prices are forced too low. And first entry generics are temporarily allowed better prices to encourage generic products to come to market as rapidly as possible. In

other words, a balanced approach taking into account relevant factors. Arbitrarily tying Canadian generic prices to foreign prices ignores these factors. In summary the authors' estimate for generic price reductions suffers from the exchange rate issue and ignores the progress the pCPA has already made.

An important takeaway with respect to monopsony pricing is that it already exists in Canada in the form of the pCPA. As of March 2014, pCPA estimated its collaborative efforts among provinces and territories have resulted in an estimated $490 million in annual savings.[15] A national pharmacare program is not necessary to achieve this objective.

Factors and Consequences Outstanding from the National Pharmacare Cost Estimate Study

Besides cost, there are a number of other differences between Canada's pharmaceutical reimbursement landscape today and the one in which the universal, publicly-funded National Pharmacare program has been implemented. While notable benefits, such as improving equitable access to prescription drug insurance to 100% of Canadians from 90% of Canadians is clearly an admirable goal, there are a number of considerations and consequences of the plan that have not been explicitly considered or factored into the results of the cost estimate. Stakeholders and policy makers must be made aware these consequences and additional analyses must be undertaken to understand the full qualitative and quantitative implications that inclusion of these factors would have on the estimated savings put forth in the National Pharmacare Cost Estimate Study. This section outlines some of these elements for additional consideration when evaluating the tradeoffs necessary to implement the National Pharmacare program as described.

NUMBER OF DRUGS COVERED AND TIME TO COVERAGE

Supplanting 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 post-National Pharmacare Canada.

Examples of a few of the drugs covered by private drug plans but not currently on public plans (using Ontario as an example):

- 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 health care 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.[16]

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 cause the estimated 24.2 million[8] Canadians with private drug coverage both monetary and non-monetary costs.

New Zealand is often cited by health care policy researchers as a market that has successfully contained pharmaceutical expenditures through a coordinated national approach and successfully leveraging purchasing power. Although the per capita pharmaceutical expenditures in New Zealand are relatively low when compared to other OECD countries, this example highlights the impact of reduced expenditures on access and quality of drug coverage outcomes.

Access

- New Zealand ranks last out of 20 comparable OECD countries for access to innovative medicines.[17]
- Out of 13 countries, New Zealand has the lowest ranking for access to cancer medicines.[18]

Time to Listing

- New Zealand lags behind the OECD average for reimbursement of innovative medicines by almost one year.[17]
- 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).[19]

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. 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 meaningful solutions that are applicable to the Canadian healthcare system.

EXISTING CONFIDENTIAL REBATES

> *"We were unable to account for confidential rebates paid by drug manufacturers to public drug plans in comparator countries or to existing provincial drug plans. However, private insurers and patients without insurance in Canada generally do not negotiate discounts with manufacturers"*[1]

The inability of the study to account for confidential rebates on drug prices currently realized by drug plans in Canada diminishes the study's ability to demonstrate that implementation of the National Pharmacare program proposed would have any effect at all on reducing prices of drugs which is one of the two drivers of cost savings supporting the study's conclusion. The study therefore has an imperfect understanding of current drug expenditures in Canada and casts even greater uncertainty in terms of potential savings from a National Pharmacare plan.

Furthermore, private insurers are developing capabilities to engage pharmaceutical manufacturers in confidential product listing agreements. It is anticipated that private payer efforts will escalate in the coming months to negotiate better value for money for plan sponsors (typically employers) through product listing agreements similar to those negotiated by the public drug plans under the pan-Canadian Pharmaceutical Alliance[29] (read more about the pCPA in *APPENDIX II - Existing Initiatives to Achieve Pharmacare Objectives)*.

These developments further challenge the suggestion that substantial reforms to the pharmaceutical reimbursement landscape are necessary to achieve reduced drug costs and sustainability of public and private drug plans.

IMPACT ON CANADIANS' ACCESS TO NEW, INNOVATIVE MEDICINES

If private insurance coverage is discontinued, coverage will be limited to only the most cost-effective (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 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.

IMPACT ON THE PRIVATE DRUG PLAN SECTOR

> *"Reducing the need for work-related private drug insurance plans would also reduce administration costs..."*[1]

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 of extended health care 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 counselling, 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 health care professionals (retails pharmacies are ubiquitous and have extended hours) and are often more cost effective. It will be important to consider the role of pharmacy services in any plan to expand drug plan coverage.

PRACTICAL AND ADMINISTRATIVE CONSIDERATIONS

Other matters which have not been clearly articulated or resolved in the National Pharmacare Cost Estimate Study include:

- National Formulary
    - Who prepares and maintains the national formulary?
    - How are tiered co-payments established for less cost-effective drugs?
    - How will claims be adjudicated?
    - How are "medically necessary" prescription drugs defined?
    - What values or definitions are considered to determine the relative cost-effectiveness of drugs for the purposes of establishing appropriate co-payments?
    - How will a national HTA body ensure timely access to new drugs?
- Administrative and Financial Responsibility
    - How will the National Pharmacare program be funded?

- What portions will require federal and provincial funds?
- How will federal transfers occur to ensure fair compensation in line with provinces' expectations in a federalist system?

Feasibility of Implementing the National Pharmacare Plan

Although not explicitly stated in the study, one option is that a national pharmacare program be led by the federal government (as opposed to a national body like the pCPA). In contemplating national pharmacare as a federal initiative, several important barriers would need to be addressed.

LEGISLATIVE BARRIERS

Canada's Constitution primarily determines the organization of Canada's health care system and outlines the roles and responsibilities for the federal, and provincial and territorial governments. While the federal government is responsible for delivering some services for certain groups of people (e.g. First Nations), the provincial and territorial governments have the bulk of responsibility for delivering health and other social services for people living in Canada.

- ***Federal government:*** *Set and administer national principles for the system under the Canada Health Act; provide financial support to the provinces and territories; and several other functions, including funding and/or delivery of primary and supplementary services to certain groups of people.*
- ***Provincial & Territorial governments:*** *Administer and deliver most of Canada's health care services, with all provincial and territorial health insurance plans expected to meet national principles set out under the Canada Health Act.* [20]

As noted by University of Ottawa Professor Colleen M. Flood in her November 2015 presentation, there are three legislative pathways to universal pharmacare[21]:

1. Federal government unilaterally establishes national pharmacare
2. Federal and provincial governments agree to a transfer of powers to the federal level
3. The federal government enacts Canada Health Act-style legislation requiring provinces to implement universal pharmaceutical insurance

According to Flood, although the federal government has the 'residual' power to enact laws necessary to unilaterally implement such a national program, the likelihood of doing so is "low". With respect to transferring powers to the national level, this has a "medium" likelihood as it may be an expensive proposition to the federal government (unless the provinces transfer current funding). Finally, Flood notes that building on the current Medicare foundation, and being respectful of provincial diversity, there could a "high" likelihood that a universal pharmacare program can be achieved through some form of CHA-style legislation. In summary then, a

universal, federally administered pharmacare plan, is likely not feasible from a legislative perspective.

ADMINISTRATIVE BARRIERS

The recent Canadian experience with major health reform – particularly ones involving significant F/P/T coordination has been mixed. While agreement was successful on the 2003 Accord on Health Care Renewal which provided for structural change to the healthcare system to support access, quality and long term sustainability, there was less success in working together on the National Pharmaceuticals Strategy.

One of the key challenges in administering a national healthcare program involving pharmaceuticals is the integration with other components of the health system. If the federal government were to take on only the drug costs without having any influence on other key factors such as physician prescribing practices, this would greatly impact the cost and overall effectiveness of any federal pharmacare plan.[7]

In addition, the complexities of integrating 10 provincial and 3 territorial drug plans with various structures, funding constraints, and priorities under one plan poses significant challenges. Recent experience with even relatively straightforward exercises at amalgamation, such as the Common Drug Review (CDR) and pan-Canadian Oncology Drug Review (pCODR) moving under one governance model under the Canadian Agency for Drugs and Technologies in Health (CADTH), has been challenging. This has taken more than two years and has required numerous stakeholder consultation sessions with patient groups and manufacturers – a rigorous and time consuming process.

The administrative challenges of moving to a federal or nationally funded and managed pharmacare program and integrating formularies and benefits would be an extraordinary task which will require significant financial resources and political commitment to execute successfully. However, the practical reality from both legislative and administrative perspectives is that there remain significant barriers to overcome before such a federal program could be effectively implemented in Canada.

Conclusion

The recent proposal for a national, universal, publicly-funded, single-payer prescription drug reimbursement plan falls short of providing a practical, affordable option to address universality,

equity and sustainability in prescription drug coverage in Canada. The National Pharmacare Cost Estimate study does not provide an adequate basis from which to understand the true cost implications of a national pharmacare program. Moreover, many of the elements of national pharmacare already exist. CADTH makes clinical and cost-effectiveness recommendations that are common to all jurisdictions except Quebec (which relies on INESSS for similar advice). The pCPA negotiates net prices for all provincial and territorial plans (including Quebec) exercising true monopsony pricing power. And under pCPA there will be incentives for CADTH and INESSS to coordinate and harmonize their advice to the jurisdictions. In addition, some private drug plans are already looking to CADTH guidance to inform their listing decisions and negotiations with drug manufacturers. And with federal drug plan membership in pCPA imminent, a truly national body will be in place with further plans for harmonization and cooperation in the works. For example, PMPRB, the federal price regulator is renewing its mandate and actively seeking opportunities to make meaningful contributions to ensure prices of patented medicines are not excessive for public and private plans and consumers. In essence, national pharmacare is evolving organically within political existing structures but there is work to be done to ensure all Canadians have prescription drug coverage at a sustainable cost.

Further research, analysis and public consultation are required to inform the public policy debate and to consider potential alternatives. In the next phase of this study, PDCI will outline alternative coverage mechanisms along with cost estimates to address the important objectives of coverage for all Canadians, equity and sustainability.

APPENDIX I- Objectives of a National Pharmacare Program

Consensus exists on the importance of ensuring all Canadians have equitable access to necessary health care, including medically necessary prescription drugs. However, agreement on the extent to which this is currently being achieved by the existing patchwork of drug benefit programs, and agreement on the appropriate measures to improve universality equity, efficiency and sustainability continues to seem unattainable.

Among others, authors of the National Pharmacare Cost Estimate Study point to a number of shortcomings of the existing drug reimbursement infrastructure as impetus to implement their proposed plan. In particular they cite a report suggesting 1 in 10 Canadians do not adhere to their prescription drug regimes due to cost barriers and that variations in drug coverage is a key factor behind cost-related nonadherence.[22] The study authors imply these issues would most effectively be addressed through public policy changes - specifically, a shift from the current pluralistic system of public and private prescription drug coverage, to a single, universal publicly funded drug plan.

Others propose that it's this existing patchwork of public and private prescription drug plans currently operating in Canada which, operating together, already very nearly achieve universal drug coverage. In a study examining results from a nationally representative household expenditure survey with a sample size of more than 14,000 respondents (21.1% seniors, 8.9% social assistance recipients, and 69.9% general population), researchers concluded that the financial burden of prescription drug expenditures for the typical household was relatively small, with little interprovincial variation.[23] Furthermore, while a small number of households surveyed stated they incurred drug costs of more than 10% their household budget on out-of-pocket prescription drug expenditures, such households were concentrated in groups that traditionally benefit from provincial government plans (i.e. 2.5% of senior households, 1.1% of social assistance recipient households and 0.3% of general population households).[23]

These authors suggest more moderate alternatives to improve universality, equity, efficiency and sustainability of drug reimbursement in Canada by operating within the existing infrastructure, or by supplementing it with modest additional support and programming from F/P/T stakeholders. In fact, several of these more moderate initiatives are already well underway or are on the horizon to address the very issues that the National Pharmacare Cost Estimate Study implies should be addressed by restructuring the drug reimbursement landscape. These initiatives are described in APPENDIX *II - Existing Initiatives to Achieve Pharmacare Objectives*.

APPENDIX II - Existing Initiatives to Achieve Pharmacare Objectives

Numerous provincial and federal organizations and initiatives described in this appendix have been implemented to improve access, equity and efficiency in the provision of prescription drug coverage across the country. Great achievements towards these goals in the drug reimbursement environment in Canada have been made in absence of any progress on the national pharmacare front, and most importantly, the momentum continues to gather. Progress to date without a national pharmacare program draws into question the necessity of extensively restructuring or requiring federally-led, single-payer initiatives to attain the goals set out in the National Pharmacare Cost Estimate Study as impetus for its National Pharmacare plan.

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"[24], are in effect in most provinces and could be expanded or supplemented to better overcome remaining access and equity barriers for prescription drugs.[7,8] 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.[7]

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 in the National Pharmacare Cost Estimate Study 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

Authors of the National Pharmacare Cost Estimate Study resolve that a universal public drug benefit program would be expected to improve efficiency, reducing prescription drug expenditures both by promoting more cost-effective product selections through a population-wide, evidence-based formulary with tiered copayments, 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

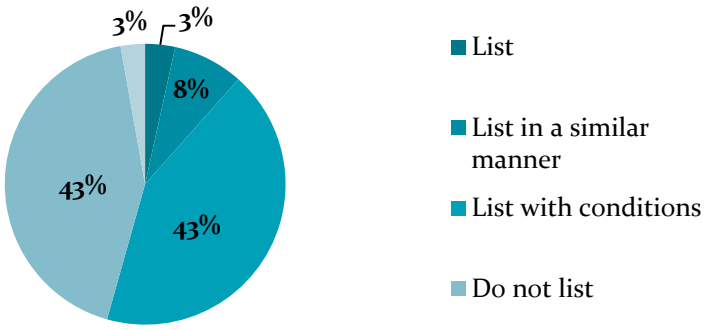
Health Technology Assessment (HTA) is currently a crucial component for public drug plan reimbursement and funding decisions in Canada. Through evaluations of clinical effectiveness, cost-effectiveness, and the ethical, legal, and social implications of health technologies on patient health and the health care 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 health care 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 health care 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)



Quebec 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 medicament to provide recommendations concerning funding of new drug technologies.

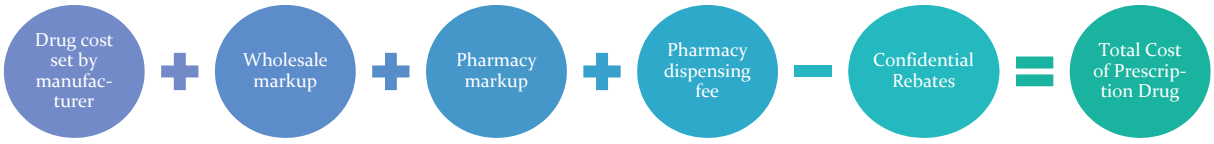
INESSS and the CADTH, CDR and pCODR processes provide public drug programs in Canada not only with recommendations about whether to provide reimbursement for a particular health technology based on their relative clinical- and cost-effectiveness compared with existing health technologies available, they 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, providing public drug plans the ability to impose restrictions to reimbursement in favour of cost-effective product selection.

Achieving Lower Drug Prices

The National Pharmacare Cost Estimate Study also suggests that consolidating drug purchasing under a publicly funded, single payer system would best leverage monopsony power to achieve the lowest brand and generic drug prices possible. Elements of prescription drug costs are

disaggregated in Figure 3. Again, 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.

Figure 3 - Elements Contributing to Total Cost of 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 in Figure 3). 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.

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

Although most manufacturers comply voluntarily with PMPRB guidelines, PMPRB enforcement action is required for 10-25% of all new drug products.[25] Over 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).[25] 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.

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 reduction achieve 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 Health Care 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 pCPA, today, almost all products that will eventually achieve public reimbursement will be considered for negotiation by the pCPA. As of March 2014, pCPA estimated its collaborative efforts among provinces and territories have resulted in an estimated $490 million in annual savings.[26]

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. [26]

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 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. And 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 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, Quebec 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 is expected to sit at the pCPA table in the coming year as indicated in the newly elected government's election platform:

> ***"We will join provincial and territorial governments to negotiate better prices for prescription medications and to buy them in bulk – reducing the cost governments pay to purchase drugs."***[27]

Like the addition of Quebec to pCPA, federal collaboration would further contribute to consolidating 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.

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.

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

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[28]:

> ***"expert negotiations: Manulife's dedicated team of experts work with pharmaceutical manufacturers to seek the best possible drug prices for our clients"***[28]

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. [29]

Results illustrated that though 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 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.

REFERENCES

1 Morgan, Steven G., Law, Michael, Daw Jamie R., Abraham, Liza, Martin, Danielle. Estimated cost of universal public coverage of prescription drugs in Canada, CMAJ March 16, 2015.

2 Morgan, S.G., D. Martin, MA Gagnon, B Mintzes, J.R. Daw, and J. Lexchin. (2015) Pharmacare 2020: The future of drug coverage in Canada. Vancouver, Pharmaceutical Policy Research Collaboration, University of British Columbia.

3 Katherine Boothe (2013). Ideas and the Limits on Program Expansion: The Failure of Nationwide Pharmacare in Canada Since 1944. *Canadian Journal of Political Science*, 46, pp 419-453.

4 Gagnon, Marc-André. (2014) A Roadmap to a Rational Pharmacare Policy in Canada. The Canadian Federation of Nurses Unions.

5 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/

6 Hoskins, Eric. "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

7 Blomqvist, Ake, Busby, Colin. 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

8 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).

9 Angus Reid Institute. Prescription drug access and affordability an issue for nearly a quarter of all Canadian households. Posted July 15, 2015. Accessed 15-Jan-16. http://angusreid.org/prescription-drugs-canada/

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 British Columbia Nurses Union. PharmaCare Tie-In, October 14, 2014. Accessed: 16-Jan-16 https://www.bcnu.org/news-and-events/campaigns-and-initiatives/past-campaigns/pharmacare-tie-in

12 Hospital Employees' Union. Unions file grievance on implementation of PharmaCare tie-in. Newsletter June 17, 2013. Accessed: 16-Jan-16 http://www.heu.org/publications/unions-file-grievance-implementation-pharmacare-tie

13 Morgan SG, Smolina K, Mooney D, Raymond C, Bowen M, Gorczynski C, Rutherford K. (2013) Canadian RX Atlas, 3rd Edition, University of British Columbia: Centre for Health Services and Policy Research. http://www.chspr.ubc.ca/pubs/atlas/canadian-rx-atlas-3rd-edition

14 National Prescription Drug Utilization Information System. (2014) Generic Drugs in Canada, 2013. Patented Medicines Prices Review Board. Accessed 15-Jan-16 http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/2013-GenReport/PMPRB_NPDUIS_GenericDrugs2013_2014-12_EN.pdf

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

16 M. Rovere B. Skinner. (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

17 IMS COMPARE Report, 2015.

18 Office of Health Economics, Richards Report 2014, via Medicines New Zealand, Cancer in New Zealand.

19 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.

20 Health Canada (2012) Canada's Health Care System webpage. Accessed 15-Jan-16 http://www.hc-sc.gc.ca/hcs-sss/pubs/system-regime/2011-hcs-sss/index-eng.php

21 Flood, Colleen. Panel Discussion: How to make universal access to pharmaceuticals in Canada a reality. Canadian Association for Healthcare Reimbursement National Day, Ottawa, November 10, 2015.

22 Law MR, Cheng L, Dhalla IA, et al. (2012) The effect of cost on adherence to prescription medications in Canada. CMAJ 2012; 184:297-302.

23 McLeod, L., B.G. Bereza, M. Shim, and P. Grootendorst. (2011) "Financial burden of household out-of-pocket expenditures for prescription drugs: cross-sectional analysis based on national survey data." Open Medicine, 5(1).

24 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

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

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

27 Liberal Party of Canada, Investing in Health and Home Care website. Accessed 13-Jan-16. https://www.liberal.ca/realchange/investing-in-health-and-home-care/?shownew=1

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

29 PDCI Market Access and H3 Consulting 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/