Abstract
Ontario is a strong candidate for a comprehensive pharmacare program, given that it has a pre-existing public drug benefit program (the Ontario Drug Benefit Program [ODBP]). This paper outlines strategies from New Zealand’s national pharmacare program (the Pharmaceutical Management Agency [PHARMAC]) and compares these strategies to other international examples. It is recommended that the ODBP engage in three strategies currently utilized by the PHARMAC to achieve significant cost savings and create potential to increase their insurance coverage: (i) strict budgeting; (ii) tendering and negotiating; and (iii) reference pricing.
Résumé
L’Ontario est susceptible de se doter d’un régime complet d’assurance médicaments, et ce, en raison d’un programme public déjà en place (le Programme de médicaments de l’Ontario [PMO]). Cet article présente les stratégies du régime d’assurance médicaments de la Nouvelle-Zélande (la Pharmaceutical Management Agency de Nouvelle-Zélande [PHARMAC]), lesquelles sont comparées à d’autres exemples à l’étranger. On recommande que le PMO adopte trois stratégies actuellement employées par PHARMAC afin d’économiser les coûts et d’accroître le potentiel de la couverture d’assurance : (i) établissement d’un budget strict; (ii) soumission et négociation; et (iii) prix de référence.

Introduction
In 2014, Canada demonstrated public, non-catastrophic drug coverage for only 29% of its population (IBM 2014). In 2015, Canada exhibited the second highest cost per capita drug expenditure of the Organisation for Economic Co-operation and Development (OECD) countries ($1,015/capita [all values provided in Canadian dollars]) (OECD 2015; OECD 2017). Comparatively, 21 OECD countries, including Australia, the UK and New Zealand (NZ), have 100% of their population covered by some public non-catastrophic drug insurance (Gagnon and Wolfe 2015). NZ, in particular, is known for its low expenditure ($372/capita in 2015) on pharmaceuticals and extensive drug coverage due to its national pharmaceutical purchasing body (OECD 2017; Medicines New Zealand 2015). In Canada, National pharmacare has been discussed in many iterations over the past 20 years, usually with emphasis on provincial plans that adhere to overarching criteria set by the federal government upon which funding is contingent (Morgan et al. 2016; National Health Forum 1997). In light of the recent announcement of a federal commitment to investigating pharmacare, the procurement and cost-saving strategies laid out in this paper would permit the provinces to maximally benefit from the national pharmacare program with minimal provincial expenditure (Picard 2018).

An estimated 20% of the Ontario (ON) population has no coverage of non-catastrophic prescription drugs by public or private insurance (Gershon 2012). ON has a comprehensive pharmacare program, the Ontario Drug Benefit Program (ODBP), which began in the 1970s (McGurn 2015). The ODBP is part of the Ontario Public Drug Program (OPDP), which includes several funding programs covering areas including: residents with high drug cost to income ratios, new cancer drugs, metabolic disorders and infant respiratory infections (OPDP 2017). The ODBP provides general drug coverage based on a formulary of over 4,400 drugs to individuals under 25 or 65 years and older; residents of long-term care homes and homes for special care; and recipients of social assistance (Office of the Premier 2017).

In 2015, the ODBP provided coverage to 3.0 million people in ON (approximately 33% of the total population), costing $4.7 billion (ODBP 2016). To contain costs and guide new
coverage decisions, the ODBP has established the Committee to Evaluate Drugs, which conducts health technology assessment (HTA) in an advisory capacity to determine if new, brand name drugs are appropriate to be funded within the ODBP. This committee is one of several levels of pharmaceutical evaluation bodies in Canada, including the Common Drug Review, pan-Canadian Oncology Drug Review and the Patented Medicine Prices Review Board (CADTH 2017a; CADTH 2017b; PMPRB 2016). The Common Drug Review and pan-Canadian Oncology Drug Review assess value based on cost-effectiveness at a federal level, producing recommendations regarding the adoption of new drugs by provincial and territorial public drug plans. The Patented Medicine Prices Review Board sets a maximum introductory drug price for new patented drugs at the manufacturer level by acting as an objective organization to determine drug pricing restrictions for drug companies, insurers and policy makers. From 2006 to 2014, through HTA and other efforts, including negotiation and price-regulation strategies, the ODBP was able to save the province over $3.3 billion, resulting in a total expenditure of $37.46 billion (in 2014 dollars) (McGurn 2015; ODBP 2016; OECD 2017).

In comparison to ON, NZ insures 100% of its population. In 1993, NZ implemented a national pharmacare program (the Pharmaceutical Management Agency [PHARMAC]), whereby one body negotiates and controls drug pricing within the country for the entire population (PHARMAC 2017). The Pharmacology and Therapeutics Advisory Committee is the only organization that oversees the national pharmaceutical HTA. From 2006 to 2014, the PHARMAC saved the District Health Boards (DHBs) $2.87 billion, resulting in a total expenditure of $5.33 billion (in 2014 dollars) (OECD 2017; PHARMAC 2016).

Comparing the PHARMAC and ODBP Cost-Containment Methods
The ODBP exhibits structural similarities to the PHARMAC: they are both tasked with price negotiation of pharmaceuticals within their regions; report to the Ministry of Health; have a HTA committee; and have continuously updated formularies of insured drugs. Furthermore, the PHARMAC began by covering out-patient prescription drugs, as does the ODBP, but has now expanded to cover all prescription, hospital and cancer drugs (PHARMAC 2017).

However, there are also significant differences between ON and NZ. The PHARMAC requires that patients pay a fixed copayment of NZ$5 per three-month prescription per drug (Lessing et al. 2015). Those eligible for the ODBP pay a fixed deductible of $100 per person and up to $6.11 per drug that is filled, if their income is of a certain threshold ranging from $19,300 to $32,300, depending on marital status, age and dependents (Government of Ontario 2018). If their income is below, the copayment is up to $2 per prescription filled.

ON faces obstacles in expanding its drug coverage, which, in contrast, have minimal influence in NZ. One such obstacle relates to ON being a regional entity, resulting in reduced power to negotiate pricing with generic pharmaceutical companies, compared with national efforts (Dempster et al. 2013). A substantial potential barrier for implementing
comprehensive pharmacare programs in ON is the contribution of the pharmaceutical industry to the economy. The pharmaceutical industry in ON is a significant contributor to the Canadian economy with extensive political influence. In 2011, ON pharmaceutical companies brought in over $8 billion of revenue (Impact Consulting Group 2011). Although the pharmaceutical industry is not inherently against expansion of public coverage, it is against strategies that control costs through mechanisms that affect their revenue.

In contrast, in NZ, there is a relative absence of brand-name pharmaceuticals in the market due to strong political support towards the PHARMAC and significant barriers towards pharmaceutical companies, such as government hostility and lack of willingness to engage in long-term partnerships with biomedical research (Watson 2006). By placing market restrictions via tendering in ON, there is concern that generic pharmaceutical companies may move to other countries (Dylst and Simoens 2010). Further, the pharmaceutical industry has significant political influence which has prevented prior attempts to implement drug tendering. In July 2017, the Canadian Generic Pharmaceutical Association signed an agreement in principle to save the province $1.5 billion on drug spending over five years by decreasing drug prices. The goal was to prevent the government from implementing tendering (Canadian Generic Pharmaceutical Association 2017; Lee 2017). Following this agreement, the pan-Canadian Pharmaceutical Association and the Canadian Generic Pharmaceutical Association developed a five-year initiative to encourage savings in prescription generic drugs for provinces outside of Quebec with the agreement that tendering will not be pursued, starting with a reduction in the price of almost 70 generic drugs by 25–40% in April 2018 (PDCI Market Access, 2018). The response of the Canadian Generic Pharmaceutical Association to reduce generic prices to assuage the threat of provincial tendering is demonstrative of the potential for cost savings associated with NZ cost-containment methods.

Notwithstanding, the PHARMAC is a suitable model for the ODBP to follow given the many similarities between the two. The PHARMAC uses two overarching methods to increase value and reduce overall drug costs: competitive tendering; and limiting drug entry into the market (based on cost-effectiveness). The primary differences between the ODBP and the PHARMAC, which present opportunities for cost savings in ON, lie in the (i) budgeting processes; (ii) tendering and negotiating; and (iii) reference pricing. This paper provides a high-level overview of the processes and potential impact of these cost-saving strategies; an in-depth analysis of merits and disadvantages is outside the scope of this paper.

**Budgeting processes**

At the beginning of each year, the PHARMAC, the 20 DHBs (government organizations responsible for providing health services within the districts of NZ) and the Minister of Health set an annual budget. There is a legal obligation to stay within the gross budget, thereby creating a stringent restriction on spending (Foster and Preval 2011). The PHARMAC acts as a negotiating body, even though it does not directly purchase stock and does not have control over allocating the national pharmaceutical budget. Budgeted funds
are distributed amongst the DHBs, and the PHARMAC’s role is to seek the best pricing for the DHBs. To keep within the budget, the PHARMAC focuses on two main strategies: tendering of generic drugs and setting reference pricing (PHARMAC 2017).

In Europe, there has been emphasis on the need to constrain public budgets for prescription drug reimbursement by the European Commission (Directorate-General for Economic and Financial Affairs, Pharmaceutical Sector Inquiry) and other organizations (High Level Pharmaceutical Forum) (Carone et al. 2012). Equity concerns regarding setting legally binding budget constraints have been raised internationally, due to the potential lack of flexibility in providing the most cost-effective option (Ubel et al. 1996). To mediate this concern, the PHARMAC has in place a Discretionary Pharmaceutical Fund, which allows shifting of funds from future years, or pushing funds into future years if needed (PHARMAC 2017). In ON, the ODBP has power, through its Executive Officer, to negotiate volume purchase pricing with pharmaceutical companies to enable public reimbursement. However, the current pharmaceutical budget is flexible and has seen significant increases over the past few years, from $3.56 billion in 2006–2007 to $4.74 billion in 2014–2015 (ODBP 2016). This growth appears to be due primarily to a growing population, additional anti-cancer drugs and new drugs for rare diseases (McGurn 2015; ODBP 2016). Although the observed growth is lower than NZ’s (29% in ON versus 32% in NZ from 2006–2014), the spending per capita for eligible recipients in ON is consistently approximately 10 times that of NZ ($150.46 in NZ versus $1,612.24 in ON in 2014). This suggests a need for cost reduction, rather than growth containment which is needed in NZ. Setting a strict annual budget (similar to the NZ model) and making the responsible committee(s) legally bound by dollar limits would be essential to reducing cost for ON.

**Tendering and negotiating**

Pharmaceutical purchasing used in ON differs from NZ primarily in that ON uses a regulatory approach to purchasing by setting maximum reimbursement thresholds, whereas NZ uses a competitive approach. NZ’s competitive bidding and tendering for generic drugs is an intrinsic aspect within the PHARMAC: NZ has a multi-product policy, which prioritizes the best value option for treatment (PHARMAC 2017). The negotiation process allows for open bidding of contracts for generic and brand name drugs to become publicly funded on the country’s public insurance plan for a fixed time period. Only select drugs in each therapeutic class are funded. The bidding process results in the purchase of half of the total volume of drugs per year (e.g., statins and angiotensin-converting enzyme [ACE] inhibitors) with only 20% of the budget. The remainder of the budget (80%; approximately $547 million in 2016) is spent primarily on brand name and specialty drugs (Foster and Preval 2011; PHARMAC 2016). As a result of bidding and tendering, NZ saved approximately $1.19 billion in 2015/2016 (calculated based on growth estimates from 2005) (PHARMAC 2016).

Large price differentials for brand name drugs compared with generic drugs have been tracked among European countries using competitive generic pricing (including Belgium,
Germany, the Netherlands and Denmark) (Dylst and Simoens 2010). These studies have shown that implementation of tendering can negatively impact future pharmaceutical investment. Further, there are critiques that NZ is missing innovative medicines that could provide benefit to the population; however, NZ assesses many of these drugs through their HTA process and chooses to only fund those which demonstrate significant benefit over previously funded drugs (Metcalfe et al. 2003). There is no clear evidence as to whether there are health consequences as a result of lack of diverse coverage within a therapeutic class for prescription drugs. However, Cumming et al. (2010) have observed that the rate of hospital discharges for cardiovascular diseases increased at a time coinciding with a decrease in cardiovascular drug sales, likely due to the PHARMAC cost-containment processes (LeLorier and Rawson 2007).

ON, as part of the pan-Canadian Pharmaceutical Alliance (an alliance of provinces and territories for volume drug purchasing negotiations), has chosen to set regulations for prices paid for certain generic drugs. ON pays between 15% and 35% of the equivalent brand name for generic drugs under contract through the pan-Canadian Pharmaceutical Alliance (Government of Saskatchewan 2017). Law and Kratzer (2013) and Law et al. (2011) recommended that tendering and negotiating (particularly of generic drugs) be introduced as a mechanism to reduce both gross cost and the rate of increase of public drug expenditure in ON. If ON incorporated tendering and negotiating, this could generate savings that could be used to expand public drug coverage.

Reference pricing
NZ uses a reference pricing reimbursement strategy for certain drugs (adopted in 1993) (PHARMAC 2017). Drugs are classified depending on therapeutic effects, and the PHARMAC sets a “reference price” for each drug class. The low-priced drug becomes the maximum price reimbursed within a reference group. Drugs can be sold at prices above reference price; however, the difference is paid by the patient. This allows for potential formation of cross-product agreements: if a pharmaceutical company is seeking coverage for a new product, it will agree to lower the price of another product within a reference group, thereby lowering the reimbursement price for that group and resulting in additional savings (Woodfield 2001). Eighty per cent of European countries had some form of reference pricing system (including determination of a price for a multisource drug) in 2011 (Simoens 2012). As examples, Sweden, the Netherlands and Germany have seen overall cost reductions by 5–30% annually, and drug expenditure on specific drug classes for which reference pricing was used has been shown to decrease (Dylst et al. 2011).

The lack of reference pricing in ON can limit the ODBP’s bargaining power and cost-saving prospects for a given therapeutic class, thereby contributing to the inability of the ON government to publicly cover more than 23% of the population (LeLorier and Rawson 2007). British Columbia implemented a reference pricing system in 1995 for certain drug classes (BC Government 2017). This reference pricing system, which first covered only five classes of drugs, saved the province an estimated $161 million in the first six years on a total
cumulative budget of $3.07 billion (in 2000 Canadian dollars) (Cassels 2002). The introduction of reference pricing in ON has the potential to reduce public expenditure on commonly prescribed drug classes to allow for expanded coverage. There would be cost-containment benefits of reference pricing due to restriction of government spending and encouragement of both generic and brand name pharmaceutical company competition (by reducing profitability of me-too drugs) (Galizzi et al. 2011; Simoens 2012).

Pros and Cons of Implementing NZ Drug Purchasing Policies in ON
There are advantages and disadvantages to both the ODBP and the PHARMAC (Table 1). The PHARMAC uses several restrictions (including their overall budget, the number of drugs funded per therapeutic class and reference pricing) to achieve cost savings and universal prescription drug coverage. These restrictions have not been implemented without criticism. The PHARMAC has been criticized for its strict budgeting and assessment processes leading to delays in access to new drugs and drugs for rare diseases (Wonder and Milne 2011). A previous study indicated that in 2012, Canada covered 54% of included cancer drugs, whereas NZ covered 25%; the US, Finland, France, Germany and Sweden all covered over 90% of studied drugs (Cheema et al. 2012). The PHARMAC has an extensive HTA process, which evaluates new drugs and does not reimburse drugs if they deem to present minimal therapeutic benefit relative to comparable alternatives, resulting in its low coverage. The monopsony (one market/one buyer) market can result in potential drug shortages (Dylst and Simoens 2010); however, inclusion of clauses that require backup supplies to be paid for by suppliers can reduce this risk (Law and Kratzer 2013).

Despite criticisms, sacrificing the variety of drugs covered per therapeutic class in exchange for coverage of the entire ON population could be beneficial. Reference pricing, as an alternative to tendering, poses as a means for controlling costs. However, the resultant overall reduction in drug expenditure from reference pricing would not be as high as that associated with generic competition (Dylst and Simoens 2010; Dylst et al. 2011; Simoens 2012). This is demonstrated through comparison of BC’s reference pricing to NZ’s tendering of ACE inhibitors. According to Morgan et al. (2007), BC’s reference pricing does not result in low prices compared to NZ. Low pricing in NZ is attributed to discounts from brand-name manufacturers and generic competition. Morgan et al. (2007) found that the cost of generic ACE inhibitors in NZ was 93% less than those in BC due to their use of tendering instead of reference pricing, which has been previously supported (Dylst and Simoens 2010; Dylst et al. 2011; Simoens 2012).

Demonstrating cost-saving potential if ON paid NZ prices
Based on potential political controversy of implementing an entirely publicly funded drug program in ON, it would be advisable to start by integrating tendering and reference pricing into select sections of the drug market, specifically for drugs purchased in large volumes. Prior cost comparisons between BC and NZ have shown up to 90% cost difference in statins, ACE inhibitors and proton pump inhibitors (PPIs) (Morgan et al. 2007).
Using a methodology similar to Morgan et al. (2007), we estimated what the cost savings would be in ON, if ON were able to achieve the same price points for drugs listed in NZ. The following three drug classes were included, representing 8.3% of total ON drug spending (or $435 million): statins, ACE inhibitors and PPIs (CIHI 2016). We identified the specific drugs within each class that were reimbursed in both ON and NZ. Prices were reported in 2016 Canadian dollars from the ON Drug Benefit Formulary and from the NZ Pharmaceutical Schedule (ODBP 2017; PHARMAC 2018). The difference in price between ON and NZ was calculated as a percentage of the ON cost, and the drug in each class wherein the NZ cost represented the highest proportion of the ON cost was chosen for analysis. This was done to ensure that the most conservative estimate of savings would be calculated.

The difference in price between ON and NZ was calculated and represented as a percentage of the ON price for each drug class:

\[ \text{Price gap} = \frac{P_{ON} - P_{NZ}}{P_{ON}} \]

\( P_{ON} = \text{price of drug in ON}; \ P_{NZ} = \text{price of drug in NZ}. \)

Using the drug with the conservative price gap (atorvastatin, pantoprazole and cilazapril for statins, PPIs and ACE inhibitors, respectively), the total estimated difference in price between ON and NZ for all three drug classes was calculated.

\[ \text{Total price gap} = \frac{\sum \left( \frac{P_{NZ}}{P_{ON}} \times \frac{\text{Exp}_i}{\text{TS}_{ON}} \right)}{\sum \left( \frac{\text{Exp}_i}{\text{TS}_{ON}} \right)} \]

\( \text{Exp}_i = \text{actual expenditure in each therapeutic drug class in ON}; \ \text{TS}_{ON} = \text{total program drug spending in ON}. \)

Finally, the potential savings were calculated for each drug class:

\[ \text{Potential savings} = \sum \left( \text{Exp}_i \right) - \left( \sum \text{Exp}_i \times \frac{P_{NZ}}{P_{ON}} \right) \]
We found that the savings could be upwards of 85%: $370 million based on the 2016 annual expenditure of $434 million (these calculations do not account for the generic drug prices negotiated by the pan-Canadian Pharmaceutical Alliance) (see Table 2).

**Conclusion**

ON is a strong candidate for a comprehensive pharmacare program given its pre-existing public drug benefit program (ODBP). We have outlined three main strategies focusing on budgeting, tendering/negotiating and reference pricing that could benefit ON’s pharmaceutical policy, drawing upon lessons from NZ and from an international context. Future research ought to contrast the formulary recommendations in ON and NZ. For example, ON may have a comparatively low threshold for reimbursement of new drugs, resulting in a large number of drugs covered by public funding. Whether or not the strategies outlined here are accepted, it is important to note that governments need a framework for coordinated policy action to benefit Ontarians in the purchasing of medicines.

**Note**

1. The total budgets for the PHARMAC and the ODBP from 2006–2014 had to be calculated by the authors, as data provided in the ODBP and the PHARMAC Annual Reports were not in 2014 Canadian dollars. As such, the yearly budgets were converted to 2014 Canadian dollars and summed.

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