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Getting the list right

Development of an essential medicines list for Canada

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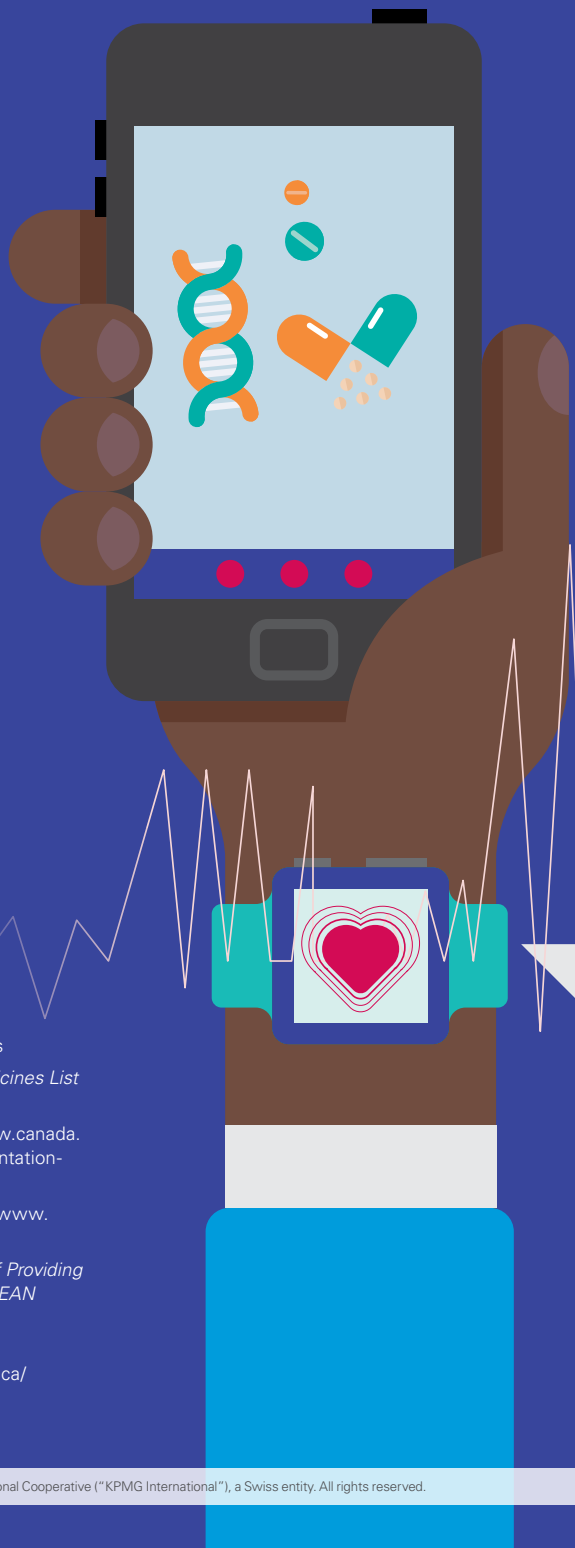
Introduction

The World Health Organization ("WHO") recommends that nations develop a list of essential medicines "that satisfy the priority health care needs of the population"[1]. The implementation of an essential medicines list ("EML"), or national formulary (both terms will be used interchangeably throughout the article), particularly for high income countries, is associated with a range of positive results such as improved quality of care, cost savings and more appropriate use of drugs[2].

Canada is an outlier as the only country with a universal health care system that excludes universal coverage of prescription drugs. The introduction of a national Pharmacare program in Canada, as recommended by the Hoskins report, that incorporates universal access to essential medicines at a very low or significantly reduced cost, is a key pillar in Canada's fulfillment of its universal health care journey. One of the first priorities and most critical steps of a successful national Pharmacare plan is the development and implementation of an EML. The introduction of a wide-ranging EML is also key recommendation of the Hoskins report[3].

Medicine non-adherence is an important public health consideration that not only affects the patient but the health care system as well, and can lead to substantial worsening of patient health outcomes and increased healthcare expenditure[4]. It can also be associated with negative economic costs such as increased use of sick days, inflated insurance premiums, and increased emergency department visits. The most important driver of non-adherence is the cost of medicine[5]. The introduction of a Canadian EML would aim to reduce the cost of and increase accessibility of prescription drugs and consequently increase adherence. Savings from universal public coverage of essential medicines has been estimated at $4.27 billion per year, or a 28 percent reduction for patients and private drug plan sponsors, at an incremental government cost of $1.23 billion per year.[6]



[1] World Health Organization website - https://www.who.int/westernpacific/health-topics/essential-medicines

[2] Michael S. Taglione, Haroon Ahmad and Nav Persaud (2017), *"Development of a Preliminary Essential Medicines List for Canada"* - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5378503/

[3] Government of Canada (June 2019), *"A Prescription for Canada: Achieving Pharmacare for All"* - https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare/final-report.html

[4] Beena Jimmy and Jimmy Jose (2011), *"Patient Medication Adherence Measures in Daily Practice"* - https://www.researchgate.net/publication/51760709_Patient_Medication_Adherence_Measures_in_Daily_Practice

[5] Nav Persuad and other authors (2017), *"Protocols for a Randomized Controlled Trial Evaluating the Effects of Providing Essential Medicines at No Charge: the Carefully Selected and Easily Accessible at No Charge Medicines (CLEAN Meds) Trial"* - https://bmjopen.bmj.com/content/7/5/e015686

[6] Steven G. Morgan, Winny Li, Brandon Yau and Nav Persaud (2017), *"Estimated Effects of Adding Universal Public Coverage of an Essential Medicines List to Existing Public Drug Plans in Canada"* - https://www.cmaj.ca/content/189/8/E295

When creating an EML important consideration needs to be given to what the additional benefits of such a list would be beyond the pocket book savings for Canadians:

Value: Selection of one drug over another is only cost effective relative to the value it generates;

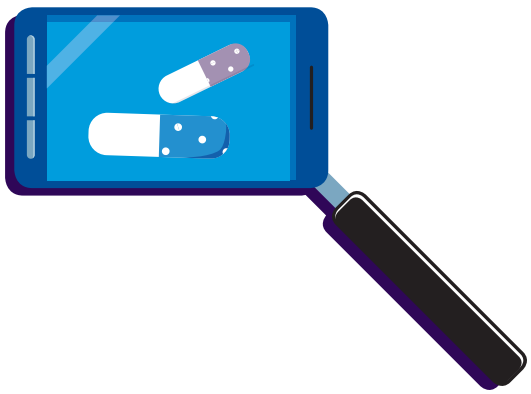
Formulary specific to a Canadian population: It is important that a national Canadian EML is developed specifically with the Canadian population in mind, and that it considers the priorities of Canadians and the medical conditions they face. The EML should be able to serve Canada's diverse population, with varying options required for different ages and ethnicities;

Winners and losers: The scope and expanse of an EML will not only determine access to medication for citizens who currently pay out-of-pocket, but also determine whether Canadians with existing drug coverage will lose coverage for their current prescriptions once national Pharmacare is underway; and

Experience from other countries: What approaches and key learnings from other jurisdictions can Canada consider when introducing a national formulary.

It is anticipated that a newly formed Canadian Drug Agency ("CDA") will be tasked with the development of a "national, comprehensive, evidence based formulary"[7]. Ensuring the list remains current will require time and effort. The efficiencies derived from dedicating one organization to this role, if implemented correctly, should not only drive administrative efficiencies but increase buying power for drug negotiation and procurement which should result in more affordable drug prices for those medicines on the EML and for Canadians overall. It is essential that the selected organization seeks input from all relevant players, as diverse perspectives and diverse leadership are required so that a Canadian EML will reflect the populations it will serve.

This article examines where might be a good place to start in developing a national EML. Provincial and other formularies which already exist could be used as a foundation from which to build upon, complimented by experience from other jurisdictions. In addition, the article emphasizes an EML that encompasses a patient centric approach, specifically reflecting on the requirements of a diverse population, use of generics and switching costs, limited use criteria, list length and over-the-counter medications and devices. Consideration is also given to how an EML for rare diseases should be addressed and how downward pressure on drug prices could affect drug innovation in Canada.



[7] The Council of Canadians (2019), *"Moving Closer to Pharmacare, But Details On Model Still Unclear"* - https://canadians.org/blog/moving-closer-pharmacare-details-model-still-unclear

Getting the list right is imperative, but where to start?

As stated in our first article in the series, "Pharmacare for All – A Big Idea", the expected cost of the national Pharmacare system, of which a national EML will be a large part, will be highly dependent on a number of key factors:

1. **Coverage:** who will have access to and what medicines will be included on an EML?
2. **Price:** how much will the weight of a single national bargaining power affect the drug cost negotiations with drug manufacturers?
3. **Demand**: the utilization of medicines on the EML.
4. **Cost Sharing** – the effectiveness of any cost-sharing mechanisms introduced, such as those proposed by the Federal Advisory Council of co-pays of $2 for essential medicines, $5 for other medicines capped at $100 per household annually, etc.

It is understood that serious consideration, supported by data, should be given to all of the positive and negative implications of the inclusion and exclusion of each item on or off the EML.

- But what types of medications should be included?
- Should certain groups of people or people with certain diseases be given more range or priority for the medications on the list?
- Should the list include medical devices in addition to drugs?
- What about drugs for rare diseases?
- How will new drugs coming into the market be valued and priced?

Factors like these need to be considered while engaging in extensive value and cost/benefit analyses to facilitate evidence-based and objective decision making. Transparency, determination of a drugs' therapeutic value and increasing accessibility for prescription drugs across the country are critical elements of success for a national Canadian EML.

Does Canada have anything in place already?

There are currently eleven public formularies across Canada, all of which vary in terms of the number of medications that are included[8]. Quebec has the most comprehensive list with over 8,000 medications, while Ontario's list has over 4,400 medications[9]. Despite the differences in the number of medications included on these public formularies, a 2015 study conducted by the National Prescription Drug Utilization Information System ("NPDUIS") found a 'reasonably high degree of alignment'[10] between the medications listed on provincial public formularies. In this study, the NPDUIS found that 1,456 drugs (grouped by active ingredients) were listed on at least one of the eleven public formularies, and compared coverage of 729 of these drugs that accounted for the majority (82 percent) of total drug costs. On average, each public formulary listed 79 percent of the selected drugs, suggesting that there is common ground on which to build an EML. Consideration of these lists and understanding what different segments of the population already have available to them, will be important in public responses to the introduction of a national EML.

In addition to the provincial formularies, Canada has already demonstrated its ability to create at least a partial federal EML through the Non-Insured Health Benefits ("NIHB") program. This program provides coverage for approximately 867,000 registered First Nations and recognized Inuit peoples for a variety of health benefits, including prescription medications[11,12]. The NIHB program, when compared to the provincial formularies has a high degree of alignment in terms of coverage, and lists 78 percent of the 729 analyzed medications in the above mentioned NPDUIS 2015 study[13]. Similar to the EML that was suggested in the Hoskin's report, the medications listed under the NIHB program are mainly used in an outpatient setting.

The NIHB program makes decisions about the formulary, based on the advice of a Drugs and Therapeutics Advisory Committee ("DTAC"). DTAC is an organization made up of health professionals who provide expert medical opinion, with the goal of selecting medications which will improve health outcomes of the First Nations and Inuit population that it serves. In addition to the needs of First Nations and Inuit, DTAC considers clinical research, cost-benefit analysis, alternatives, and current provincial drug formularies when putting forth advice on which medications should be covered. Other bodies that influence the decisions of the NIHB include the Common Drug Review ("CDR"), the pan-Canadian Oncology Drug Review ("pCODR"), and the pan-Canadian Pharmaceutical Alliance ("pCPA"). It is important that the input of all these bodies is also considered when compiling a national EML.

As the NIHB drug benefit listing remains the sole national public EML, it is possible that a similar approach could be taken when drafting policy about the creation of a more comprehensive national EML. As the NIHB highlights taking into account the needs and health outcomes of the community it serves, so must a national EML. Moreover, a patient-centred approach must be taken to reflect the diversity and priorities of Canadians and to ensure the success of a national Pharmacare program.

The Hoskins report expressly noted the WHO model list of essential medicines and the CLEAN MEDS

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[8] Patented Medicine Prices Review Board (2017), *"Alignment Among Public Formularies in Canada"* - http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/NPDUIS_formulary_report_part_1_en.pdf

[9] ACTEGIS Consultants Inc. (2018), *"Understanding Quebec's Pharmacare System"* - https://clhia.ca/web/clhia_lp4w_lnd_webstation.nsf/resources/Pharma/$file/Quebec+Pharmacare+Report+-+Claude+Ferguson.pdf

[10] Patented Medicine Prices Review Board (2017), *"Alignment Among Public Formularies in Canada"* - http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/NPDUIS_formulary_report_part_1_en.pdf

[11] Government of Canada (2018-2018), *"Non-Insured Health Benefits Program: First Nations and Inuit Health Branch: Annual Report 2017-2018"* - https://www.canada.ca/en/indigenous-services-canada/services/first-nations-inuit-health/reports-publications/non-insured-health-benefits/non-insured-health-benefits-fnihb-report-2017-2018.html#chp2

[12] Government of Canada (October 2019), *"Non-Insured Health Benefits: Drug Benefit List"* - https://www.canada.ca/en/indigenous-services-canada/services/non-insured-health-benefits-first-nations-inuit/benefits-services-under-non-insured-health-benefits-program/drugs-pharmacy-benefits/drug-benefit-list.html

[13] Patented Medicine Prices Review Board (2017), *"Alignment Among Public Formularies in Canada"* - http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/NPDUIS_formulary_report_part_1_en.pdf

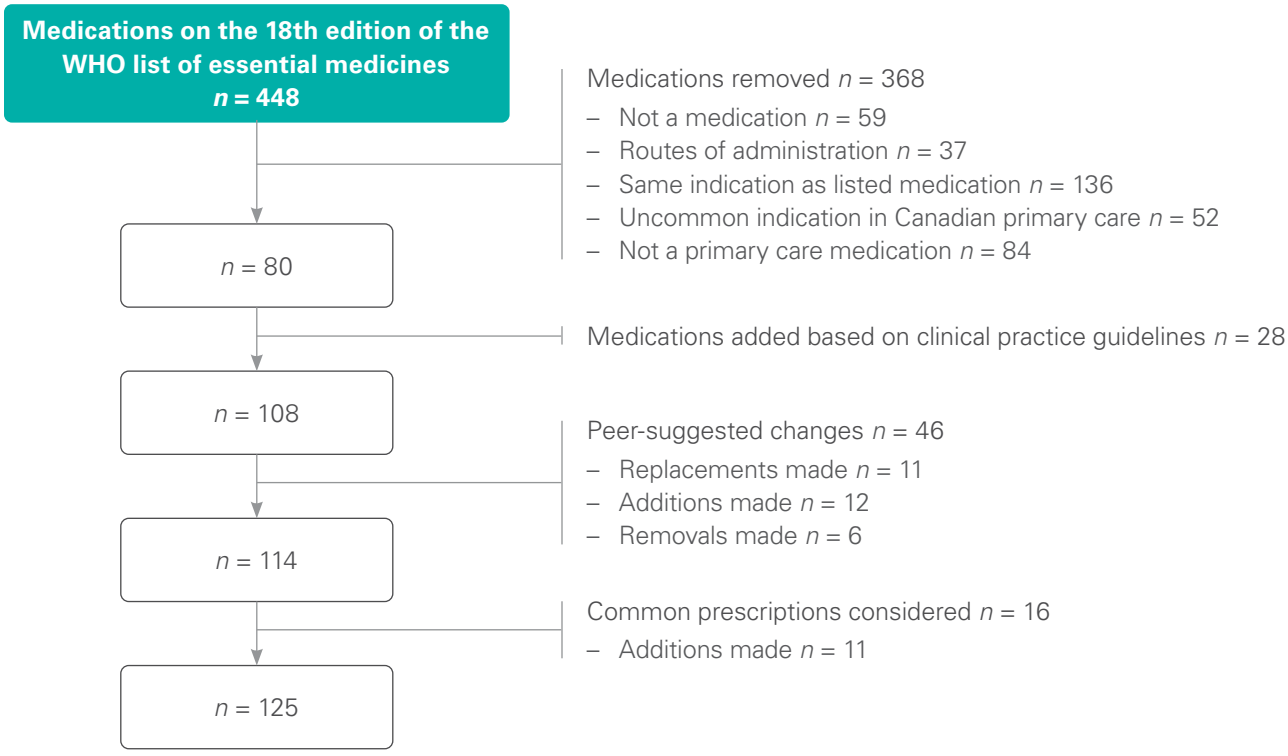
list as optimal starting points for a Canadian national formulary. The WHO EML list, initially containing 205 agents at its inception in 1977, now has more than 400 medications[14]. The aim of the WHO EML is to exemplify the most fundamental medicines that should derive a country's EML, and as such seems like an obvious starting point or at least critical point of comparison.

The CLEAN MEDS list started as a randomized controlled trial in Canada with the aim of measuring the effects of distributing essential medicines for free. The trial's aim was to help inform public policy decisions in Canada and could offer a potentially viable methodology for the selection of medicines that could comprise the Canadian EML list. Interestingly CLEAN MEDS used the WHO model list as a starting point upon which it built and tailored its list to a Canadian population. Steps undertaken to get to the CLEAN MEDS list were as follows[15] (more fully demonstrated in Figure 1 below):

1. Adaptation of the WHO model list of essential medicines for Canadian purposes;
2. Added medicines based on feedback from clinician practice guides, including input from panel of citizens;
3. Decisions made by panel of clinical scientists; and
4. Reviewed national prescribing data and considered medications not covered.

The result was a CLEAN Meds list consisting of 125 essential medicines covering treatments for both acute (i.e. pneumonia, gout) and chronic conditions (i.e. diabetes, HIV). While clinicians were surprised by the brevity of the list, this methodology was wholly evidence based, had a high degree of alignment with both the WHO model list and public drug formularies in Canada, and incorporated feedback from medical professionals and from some members of the general population.

Figure 1: Development of a preliminary essential medicines list for Canada[16]



[14] Navindra Persaud (2017), *"Canadian List of Essential Medications – Potential and Uncertainties"* - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5389750/

[15] Michael S. Taglione, Haroon Ahmad and Nav Persaud (2017), *"Development of a Preliminary Essential Medicines List for Canada"* - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5378503/

[16] Michael S. Taglione, Haroon Ahmad and Nav Persaud (2017), *"Development of a Preliminary Essential Medicines List for Canada"* - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5378503/

How does Canada compare to other countries?

Canadian EML development can also draw inspiration and lessons from national efforts in other jurisdictions. Please see below for a list of other high income countries with national formularies that Canada could seek guidance and experience from. We also discuss specific examples of cost effective, context driven, evidence based formularies in two specific high income countries[17], New Zealand and the UK, that could have particular relevance to the Canadian situation and can provide considerations if Canada were to adopt these regimes.

Table 1: Summary of pharmacare programs available in other high income countries[18]

Pharmacare programs available in other high income countries				
Country	**Population (2019)**	**System type**	**Role of private insurance**	**Copayment/coinsurance**
Australia	25.3 million	Universal, comprehensive public coverage	Public plan is payer of first resort. About half of adults have voluntary, complementary private insurance.	Copayment equal to the lesser of $37.00 (AU$39.50) or the full cost of the drug, per item on the prescription. Once a household has paid $1,425 (AU$1,521.80) in copayments during a calendar year, their copayments for the balance of that year are reduced to $6.00 (AU$6.40).
France	65.2 million	Universal, comprehensive statutory insurance coverage	Statutory plan is payer of first resort. More than 90 percent of residents have voluntary, complementary private insurance.	Ranges from 0 percent to 85 percent of prescription costs depending on the medicine's clinical benefit.
Germany	83.6 million	Universal, comprehensive statutory insurance coverage	Statutory plan is payer of first resort. A small proportion of the population has voluntary, complementary private insurance.	Ranges between $7.60 (€5) and $15.20 (€10) per prescription. Total patient contributions for prescriptions and other insured health care services are limited to 2 percent of gross income (or 1 percent for patients with severe chronic conditions).
Netherlands	17.1 million	Universal, comprehensive statutory insurance coverage	Annual deductible of $584 (€385) toward all health care costs.	After the deductible is reached, cost-sharing for prescription drugs is limited to fees that may be charged in relation to reference-based reimbursement and preference product schemes.
New Zealand	4.8 million	Universal, comprehensive public coverage	Public plan is payer of first resort. About 30 percent of the population has voluntary, complementary private insurance.	$4.30 (NZ$5.00) per item on a prescription. Copayments can be eliminated for families that have paid for more than 20 prescription items in a given year.
Norway	5.4 million	Universal, comprehensive public coverage	Public plan is payer of first resort. About 9 percent of Population has voluntary, complementary private insurance.	
Sweden	10.0 million	Universal Healthcare, public coverage	Public plan is payer of first resort. About 10 percent of Population has voluntary, complementary private insurance.	Copayment capping out at $350 (2,00 Swedish Krona) annually.
United Kingdom	67.7 million	Universal, comprehensive public coverage	Public plan is payer of first resort. About 10 percent of the population has voluntary, complementary private insurance.	No copayments in Scotland, Wales, or Northern Ireland. In England, patients pay $15.00 (£8.80) per item; or prepayment of $50.00 (£29.10) for 3 months or $176.00 (£104) for 12 months.

[17] Michael S. Taglione, Haroon Ahmad and Nav Persaud (2017), *"Development of a Preliminary Essential Medicines List for Canada"* - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5378503/

[18] Government of Canada (June 2019), *"A Prescription for Canada: Achieving Pharmacare for All"* - https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare/final-report.html; and WHO (2015), *"The Wise List 2015"* - https://apps.who.int/medicinedocs/en/m/abstract/Js22130en/; and Benefits Canada (2018, "*Lessons for Canada from Pharmacare Systems Around the World"* - https://www.benefitscanada.com/benefits/health-benefits/bc-9-lessonsfromabroad-121875

As advanced **OECD economies** with universal health care (albeit to varying degrees), and **Commonwealth countries,** comparisons are often drawn between the healthcare systems of **Canada, New Zealand** and the **UK**. In this regard an examination of the **New Zealand** and the **UK healthcare systems,** including their universal drug plans, is insightful.

New Zealand, like Canada, has a universal public health coverage but also pays for approximately 80 percent of the country's drug expenditure. The remaining 20 percent is covered through patient copayments[19]. Medication that makes it to the Pharmaceutical Management Agency's ("PHARMAC") Pharmaceutical Schedule[20], currently consisting of approximately 4,500 drugs[21], is done through a sole tendering process. This process has allowed New Zealand to effectively select limited medications to procure in exchange for being the sole distributor in the market[22]. This has resulted in New Zealand often being referred to as a cost effective national drug plan. On the flip side, the sole tendering process has also resulted in limited access to and limited choice for medications available to the consumer and to an extent, drug shortages and lack of incentive to innovate for newer drugs.

The UK selects its national formulary by using a cost effectiveness analysis model. This model assesses each medication along multiple factors and considerations such as improving health, economics and providing the highest "value for money"[23]. It also incorporates a Quality-Adjusted Life Years ("QALY") mechanism which is the notion of estimating the additional life expectancy gained by the patient while also accounting for their quality of life during that time. The implication of using a QALY to assess whether or not a medication will make it to the UK's national formulary hinges on a moral and ethical dilemma and the notion of placing a value on the quality of human life. At the same time the QALY model could weigh medications differently based on the demand for the medication and neglect patients with rare diseases. Canada will need to decide if it will incorporate such concepts into its decision making. The UK also utilizes a copayment system of $14.50 per person, which is much higher than the Hoskins report co-pay recommendation.

As advanced OECD economies with universal health care (albeit to varying degrees), and Commonwealth countries, comparisons are often drawn between the healthcare systems of Canada, New Zealand and the UK. In this regard an examination of the New Zealand and the UK healthcare systems, including their universal drug plans, is insightful, however with large differences in population, land mass and GDP between the countries[24], it is evident why healthcare solutions and systems need to be tailored to the specific needs of each country.

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[19] PHARMAC Schedule, *"Inside the Pharmaceutical Schedule"* - https://www.pharmac.govt.nz/about/your-guide-to-pharmac/factsheet-14-pharmaceutical-schedule/

[20] The PHARMAC Schedule is the list of all the medicines and therapeutic products that the District Health Boards in New Zealand fund.

[21] PHARMAC Schedule, *"Inside the Pharmaceutical Schedule"* - https://www.pharmac.govt.nz/about/your-guide-to-pharmac/factsheet-14-pharmaceutical-schedule/

[22] Government of Canada (June 2019), *"A Prescription for Canada: Achieving Pharmacare for All"* - https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare/final-report.html

[23] Fraser Institue (2018), "The Unintended Consequences of National Pharmacare Programs" - https://www.fraserinstitute.org/sites/default/files/unintended-consequences-of-national-pharmacare-programs.pdf

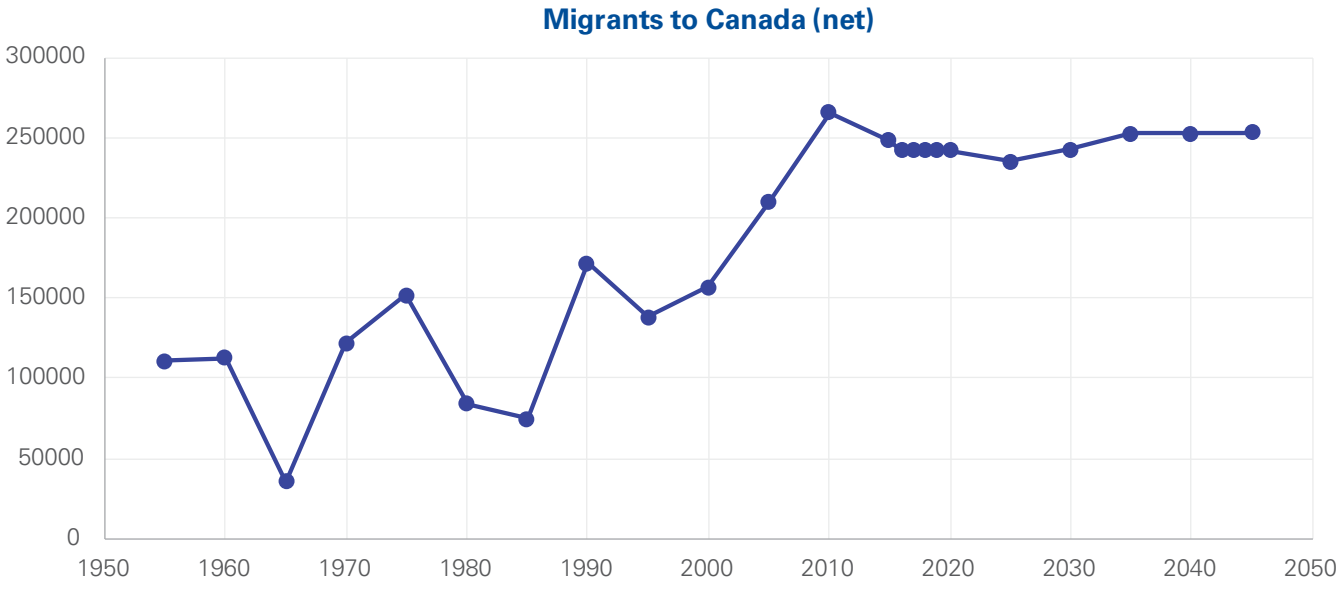
[24] Population 37.4 million (Canada), 4.8 million (New Zealand) and 67.7 million (UK); Land mass 9.985 million km^2(Canada), 268, 021 km^2 (New Zealand) and 242,495 km^2 (UK); GDP 1.7 trillion USD (Canada), 6.6 billion USD (New Zealand) and 2.6 trillion USD (UK).

Patient-centred approach for a Canadian population

A reflection on diversity

Diversity must be inherent to the construction of a national Canadian EML. Consider that the same formulary will be available to all Canadians, irrespective of age or location in the country and this formulary will inherently need to ensure that it is designed for a multitude of health concerns and conditions. In Ontario, the same formulary that seniors access, is now the same formulary that is available to those under the age of 25, and thus medications must reflect a variety of conditions, dosages, and delivery forms (tablets, liquids, etc). In addition to diversity among age groups, ethnic diversity needs to be considered. For instance, carbamazepine, an anticonvulsant drug, has a disproportionately higher risk of life-threatening side effects linked to alleles found more commonly in certain population groups[25]. The EML must therefore take into account both the science behind medications and how they affect different populations, as well as a patient-centred approach to consider the needs and values of our rich diversity of populations.

Figure 2: Trend and Forecasts of Migrants Entering Canada[26]



[25] Laura Dean (2015), *"Carbamazepine Therapy and HLA Genotype"* - https://www.ncbi.nlm.nih.gov/books/NBK321445/

[26] Worldometer website - https://www.worldometers.info/

Use of generics and switching costs

All countries struggle with the rising cost of drugs, but in 2017 Canada paid the third highest prices for brand name drugs and the seventh highest prices for generic drugs among the 34 countries in the OECD[27]. The interesting take away from these statistics is they indicate that Canada can clearly benefit from the potential cost/price reductions resulting from a national EML. The Hoskins report recommends mandatory generic substitution policies to encourage patients and prescribers to choose the most cost-effective therapies and help keep national Pharmacare affordable. However with generics "similar" is not necessarily the same as "identical" to their brand name counterparts. A generic drug contains the same active ingredients as its branded cousin, but it can differ from the reference pharmaceutical in two ways. First, when it comes to the active ingredients, generic drug makers are required to show that their products behave in similar, but not necessarily identical, ways in the body. Second, the non-active ingredients in a generic drug can be different than what is in non-generic drugs[28]. Hence when including generics on a national EML consideration needs to be given to the clinical effectiveness of some generics.

A national formulary, or the EML, will also differ in the drugs they provide coverage for. Depending on the comprehensiveness of a national EML, some Canadians would likely end up switching their currently prescribed medication to that of a comparable medication on the new national formulary. However, even a switch to a comparable medication within the same medication class can induce side effects and suboptimal results. A retrospective study in New Zealand showed that almost one third of patients did not tolerate a switch between the original antihypertensive medication they were on and another medication in the same class on the formulary[29]. Switching costs can impact the overall cost to both the healthcare system and the economy, and need to be taken into consideration when creating an EML. Thoughtful consideration needs to be given to different patient outcomes when assessing a medication's therapeutic value, as cost savings will have to be balanced against clinical effectiveness and "value-for-money". Grandfathering policies for certain medications or heavy marketing campaigns to increase public awareness about equivalency could help combat switching resistance.

Limited use criteria

Many public plans, and some private plans, may include medications that will only be covered under certain specific conditions. In the case of antibiotic use, criteria is present to prevent over prescribing and limit resistance patterns and is based on medical evidence. However, certain criteria may also be interpreted as placing additional barriers on a patient's ability to receive quality care. For example when OHIP+ was introduced in 2018, some pediatric epilepsy patients found that they had to switch their current effective anti-seizure medication to a more affordable alternative, as they did not meet the limited use criteria[30]. Parents were vocal about their concerns that this would result in an exacerbation of their children's illness or side effects that impaired their ability to learn and develop alongside their peers. These instances highlight the sensitivity that needs to be shown when creating lists that impact Canadian lives. Moreover, in a patient-centric approach, ideally voices of patients in addition to medical-experts would be involved in the creation of limited use criteria, balancing the costs of medication with desired health outcomes.

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[27] Government of Canada (June 2019), *"A Prescription for Canada: Achieving Pharmacare for All"* - https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare/final-report.html

[28] Global News (2018), *"You Can Save Big With Generic Drugs – But Sometimes You Shouldn't"* - https://globalnews.ca/news/4251192/generic-vs-brand-name-drugs-canada/

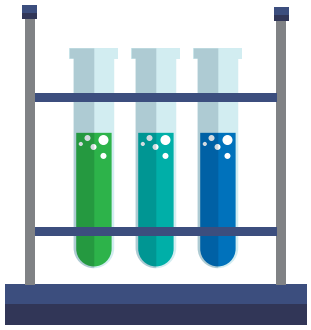
[29] Jacqueline Cumming (2010), *"How New Zealand Has Contained Expenditure on Drugs"* - https://www.bmj.com/bmj/section-pdf/186576?path=/bmj/340/7758/Analysis.full.pdf

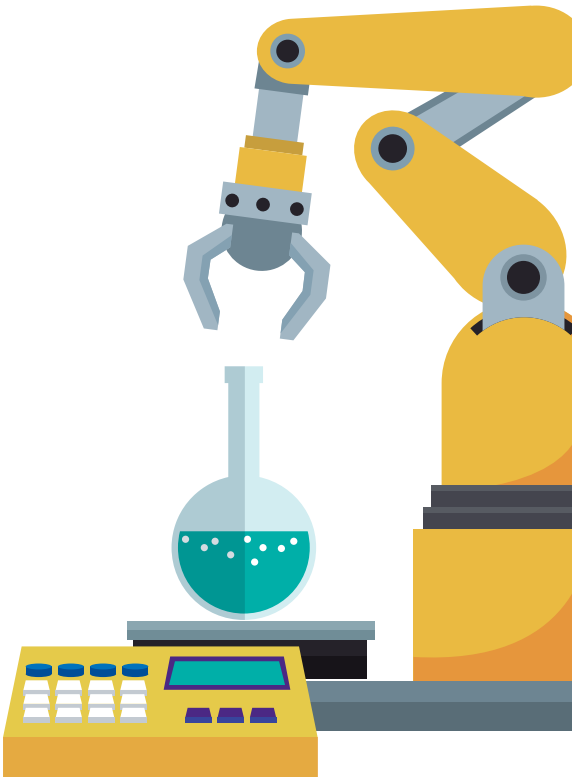
[30] Deron Hamel (2018), *"Toronto Couple Concerned After Learning OHIP+ Will Not Cover Daughter's Anti-Seizure Medication"* https://epilepsyontario.org/toronto-couple-concerned-after-learning-ohip-will-not-cover-daughters-anti-seizure-medication/

List length

The introduction of a national EML may have a serious financial impact on Canada and its economy, with a broad list and its potential cost being more than the government has projected. Conversely a list that is too narrow could lead to higher healthcare expenditures by inadequately treating or preventing certain diseases. However to be "essential" or effective a Canadian EML should not be determined exclusively by size/breadth. The Hoskins report's stated goal of the initial formulary is to cover approximately half of all currently prescribed medications in Canada and should service most major medical conditions, such as diabetes and hypertension. The top five therapeutic categories in which the provinces spent almost 70 percent of their total prescribed drug spend in 2019 included antineoplastic and immunomodulating agents, nervous system, alimentary tracts and metabolism and cardiovascular system and anti-infectives for systemic use[31]. However, such a large formulary may not be sustainable at the beginning, for cost and procurement reasons, and it may in fact be prudent to "start small"[32]. Expansion of the list can then take place gradually through a phased approach once it is seen how it all operates in practice and the costs and implications can be fully analyzed.

There is also evidence that restricted formularies improve prescribing practice and reduce inappropriate prescribing[33] which can also harm people. This is mainly because clinicians find it easier to master and prescribe a small subset of all available medications as it reduces the number of drugs that they are required to have a good understanding of[34]. This makes it easier for clinicians to prescribe the most effective, safe and appropriate medications for their patients[35] and could also help prevent over prescribing. The large number of medications currently available on existing formularies in Canada poses a challenge for clinicians[36]. Sweden's Wise List contains only 200 medications and has led to decreased regional variation in prescribing behaviour and achieved 87 percent adherence to its recommendations among primary health care centres[37]. A smaller list, at least at the start, could also lead to lower medication costs by concentrating on price competition on a smaller number of drugs and could serve as a starting point for the development of a national drug coverage system[38].





[31] Canadian Health Institute for Health Information (2019), *"Prescribed Drug Spending in Canada"* - https://www.cihi.ca/sites/default/files/document/pdex-report-2019-en-web.pdf

[32] Steven G. Morgan, Winny Li, Brandon Yau and Nav Persaud (2017), *"Estimated Effects of Adding Universal Public Coverage of an Essential Medicines List to Existing Public Drug Plans in Canada"* - https://www.cmaj.ca/content/189/8/E295

[33] Nav Persuad and other authors (2017), *"Protocols for a Randomized Controlled Trial Evaluating the Effects of Providing Essential Medicines at No Charge: the Carefully Selected and Easily Accessible at No Charge Medicines (CLEAN Meds) Trial"* - https://bmjopen.bmj.com/content/7/5/e015686

[34] Navindra Persaud (2017), *"Canadian List of Essential Medications – Potential and Uncertainties"* - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5389750/

[35] Michael S. Taglione, Haroon Ahmad and Nav Persaud (2017), *"Development of a Preliminary Essential Medicines List for Canada"* - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5378503/

[36] Michael S. Taglione, Haroon Ahmad and Nav Persaud (2017), *"Development of a Preliminary Essential Medicines List for Canada"* - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5378503/

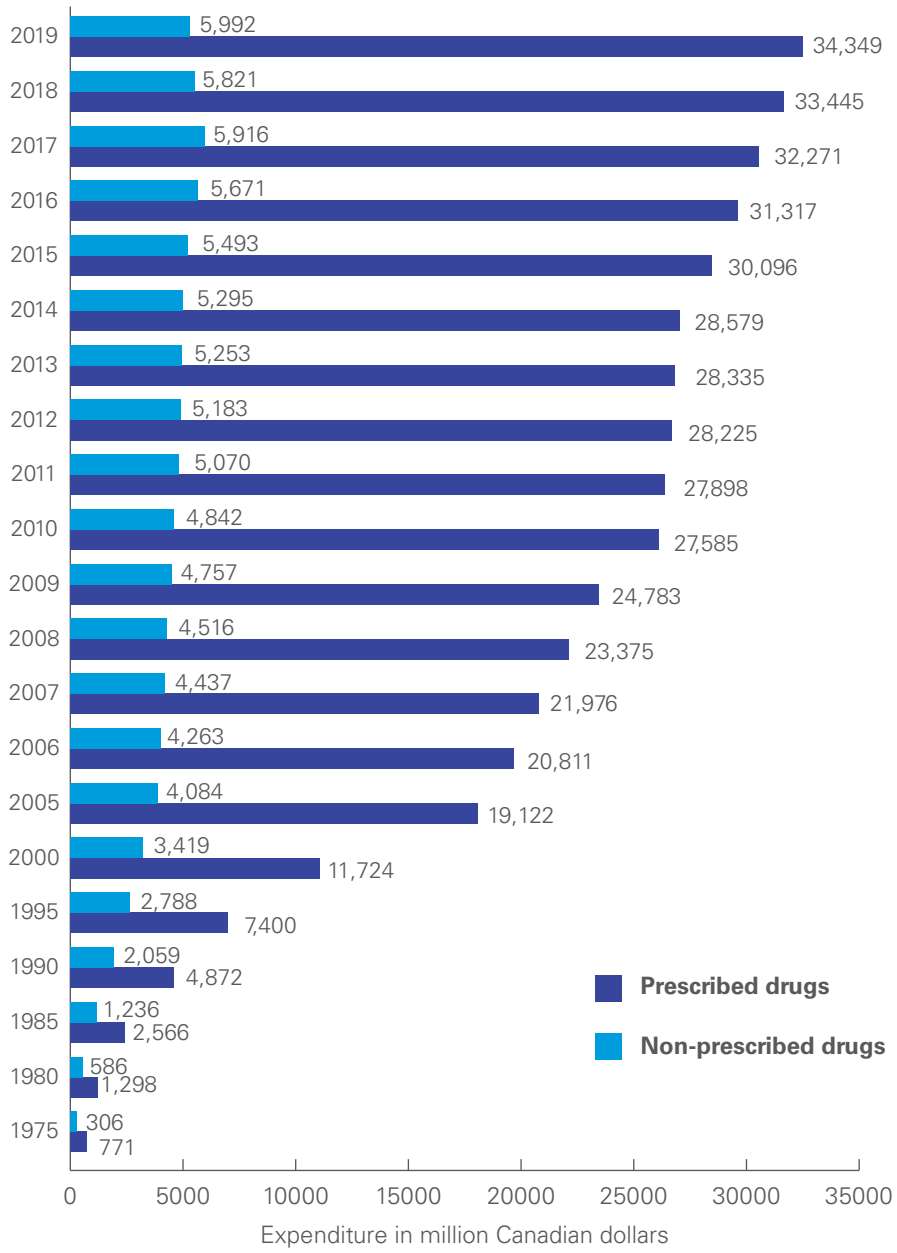
[37] Navindra Persaud (2017), *"Canadian List of Essential Medications – Potential and Uncertainties"* - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5389750/

[38] Michael S. Taglione, Haroon Ahmad and Nav Persaud (2017), *"Development of a Preliminary Essential Medicines List for Canada"* - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5378503/

Over-the-counter medications & devices

While the majority of the focus of a national EML has been on prescription medications, some public formularies (such as the NIHB) go beyond this and provide over-the-counter medication as well as medical devices and supplies. Acetaminophen is often the first-line medication recommended for osteoarthritis in the elderly[39], and is thus covered on certain public plans despite being an over-the-counter medication. Furthermore, diabetic test strips are critically important for any person with diabetes treated with insulin. While neither of these examples are prescription medications, they illustrate how integral non-prescription medications and devices are to the health of Canadians. The discussion becomes more complex as certain provinces provide coverage for medical devices through alternate-non Pharmacare programs. If the government chooses not to include these two categories on a national Pharmacare plan, then provinces may need to be prepared to provide programs that can fill in the gaps.

Figure 3: Expenditure on prescribed and non-prescribed drugs in Canada from 1975 to 2019[40]



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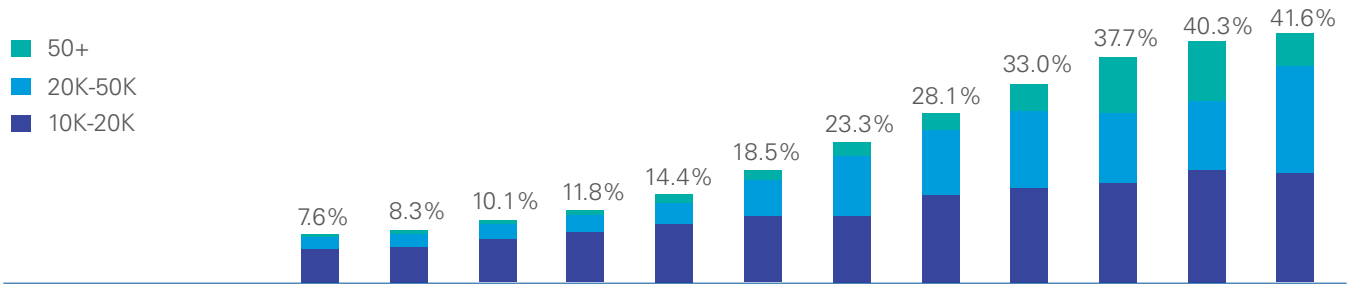
Rare diseases

Rare diseases affect less than 1 percent of the population, but have quickly become the most expensive budget item with a cost trajectory that seems to be unsustainable. Between 2006 and 2017, the number of medicines in Canada with an annual per beneficiary cost of at least $10,000 increased by over 200 percent and now accounts for 42 percent of patented medicines sales per annum[41].

At the end of 2018 there were 79 Expensive Drug for Rare Diseases ("EDRDs") approved in Canada[42]. Increasing accessibility to rare disease drugs is a key priority with the Canadian government pledging an investment of up to $1 billion over two years, starting in 2022–23. This pledge also included up to an additional $500 million per year on an ongoing basis, to help Canadians with rare diseases access the drugs they need[43]. Due to their nature and the nature of the rare disease drug market, the Hoskins report recommends that procurement strategies and a separate formulary be specifically designed for rare diseases. The Canadian government will need to work with provinces, territories and other partners to develop a national strategy for high-cost drugs for rare diseases in which it also engages patient groups and clinicians throughout this process. There needs to be

Figure 4: Share of sales for high-cost patented medicines, 2006 to 2017[44]



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Medicine cost	$967M	$1,090M	$1,372M	$1,701M	$1,982M	$2,518M	$3,105M	$3,843M	$4,503M	$5,746M	$6,985M	$6,314M
Total no. of molecules	44	53	61	67	74	93	97	108	116	126	135	144
Share of total Cdn. population	0.20%	0.21%	0.27%	0.32%	0.36%	0.43%	0.51%	0.60%	0.67%	0.77%	0.86%	0.93%

[41] Patented Medicine Prices Review Board (2019), *"What is the "Expense" for Expensive Drugs for Rare Diseases?"* - http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1461&lang=en

[42] Patented Medicine Prices Review Board (2019), *"What is the "Expense" for Expensive Drugs for Rare Diseases?"* - http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1461&lang=en

[43] Benefits Canada (2019), "Budget 2019: Feds to develop a strategy for high-cost drugs for rare diseases" - https://www.benefitscanada.com/news/budget-2019-feds-to-develop-a-strategy-for-high-cost-drugs-for-rare-diseases-127434

[44] Patented Medicine Prices Review Board (2019), *"What is the "Expense" for Expensive Drugs for Rare Diseases?"* - http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1461&lang=en

Increasing accessibility to rare disease drugs is a key priority with the **Canadian government** pledging an investment of up to **$1 billion** over **two years**, starting in 2022–23. This pledge also included up to an additional **$500 million** per year on an ongoing basis, to help **Canadians** with rare diseases access the **drugs** they need.

given careful consideration to the performance-based funding formulae used for the procurement of drugs for rare diseases. A performance-based funding agreement for its rare disease procurement strategy will need to consider the benchmarks that it will utilize to measure performance, the timelines associated with these benchmarks, and a value-based pricing model to continue to support R&D in this sector.

While the Canadian government looks to develop its strategy on how to tackle rare diseases and the growing costs, it is important that it doesn't create unintended incentives. In the US the Orphan Drug Act was passed in 1983 to encourage pharmaceutical manufacturers to invest in treatments for rare or "orphan" diseases and conditions[45], as with their small population numbers these areas were considered unprofitable. The intent was to create incentives to encourage drug makers to develop treatments for rare diseases by enabling them to realize a modest profit. Drug makers have responded by building lucrative business models that can achieve gross profit margins of more than 80 percent, compared to an average gross profit margin of 16 percent for the rest of the pharmaceutical industry[46]. Orphan drugs are also proportionally more of the approvals granted each year (over 50 percent in the US in 2018). In addition, orphan drugs go to market at an average price that is 25 times more expensive than traditional drugs[47].

While it is important to encourage innovation and increase access to these drugs, organizations should be developing inventive and coherent nationwide policies to balance timely and fair access to drugs for rare disorders with appropriately competitive pricing and value based negotiations that are based on patient outcomes so that drugs are accessible and affordable to Canadians who need them.

[45] Katie Thomas and Reed Abelson (2019), *"The $6 Million Drug Claim"* - https://www.nytimes.com/2019/08/25/health/drug-prices-rare-diseases.html

[46] AHIP (2019), *"Drug Prices for Rare Diseases Skyrocket While Big Pharma Makes Record Profits"* - https://www.ahip.org/drug-prices-for-rare-diseases-skyrocket-while-big-pharma-makes-record-profits/

[47] Laura Joszt (2019), *"Orphan Drugs Are Driving Skyrocketing Drug Costs, AHIP Finds"* - https://www.ajmc.com/newsroom/orphan-drugs-are-driving-skyrocketing-drug-costs-ahip-finds

Innovation

From the discovery of insulin and radiation therapy, to the development of infant formula and vaccines, Canadians have always been at the forefront of medical innovation[48]. For continued progression and sustainability of health care in Canada the importance of R&D and innovation in the pharmaceutical sector cannot be underestimated and must be considered when developing a national Pharmacare plan and EML.

Canada is already one of the most expensive jurisdictions with respect to drug prices, with Canadians paying the third highest price for drugs per person in the OECD, behind USA and Switzerland[49]. One of the reasons why Canada is so expensive is its drug regulatory regime, Canada's drug approval process takes between 10 to 15 years and approximately $2.6 billion of R&D spending to create an innovative medicine[50]. While there appears to be room for reduction from a cost perspective, it is important to consider if further downward pressure on drug pricing will stifle drug development innovation in the Canadian healthcare market. It is feared that further reduction in drug prices will only serve to reduce competitiveness and may even result in Canadians not being near the top of the line when it comes to access to new drugs. In fact according to Life Sciences Ontario the federal government's new price control policies for patented medicines in Canada are already resulting in delayed product launches in Canada and in losses of jobs in the pharmaceutical industry[51].

The pharmaceutical innovation industry in Canada creates an overall economic impact of more than $3 billion a year on Canada's economy[52]. Currently, Innovative Medicines Canada's ("IMC's") 40 member companies fund 93 percent of the 500 medicines in development in Canada[53]. IMC is encouraging the introduction of a strengthened intellectual property regime to boost Canada's competitiveness and foster innovation. IMC member companies generated $19-billion in economic activity, invested $1.2-billion (9.97 percent of revenues) into R&D and supported 30,000 high-value jobs[54] in Canada. Thus, it is vital to signal to the law makers and program leads the importance and value of innovation by having a pre-determined formula that includes R&D as a consideration.

One of the biggest issues going forward is the ability of Canadian companies to successfully compete with other countries on many keys factors including cost, talent and market attractiveness; market attractiveness as defined by regulatory requirements, market access, IP legislation and pricing controls. In order for Canada to remain competitive and assure access for Canadians to innovative drugs in the future a robust and balanced patented medicines regulations that are both predictable, equitable and creates balanced incentives need to be introduced. Any analysis regarding the introduction of Pharmacare or a national EML will also have to assess the economic implications of a change to Canada's drug innovation market. Adopting a longer-run policy perspective will be key. Perhaps public policy decision makers should be encouraging an efficient level of expenditures on pharmaceutical drugs, not simply containing expenditures on those drugs.

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[48] Innovative Medicines Canada website - http://innovativemedicines.ca/medicines/

[49] Government of Canada (June 2019), *"A Prescription for Canada: Achieving Pharmacare for All"* - https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare/final-report.html

[50] Innovative Medicines Canada website - http://innovativemedicines.ca/medicines/

[51] Life Sciences Ontario (February 2020), "New Federal Drug Pricing Rules Are Already Delaying Medicine Launches and Costing Jobs in Canada, Survey Reveals" - https://lifesciencesontario.ca/news/new-federal-drug-pricing-rules-are-already-delaying-medicine-launches-and-costing-jobs-in-canada-survey-reveals/

[52] Innovative Medicines Canada website - http://innovativemedicines.ca/medicines/

[53] Innovative Medicines Canada website - http://innovativemedicines.ca/medicines/

[54] Innovative Medicines Canada website - http://innovativemedicines.ca/medicines/

Conclusion

Ultimately, creating a national EML will be a sum of trade-offs between cost and value, economics and health, and practical and ethical considerations.

While a number of public formularies already exist in Canada there is inconsistency between what is being offered across the country. A national EML offers consistency to those across the entire nation. While the aim of a national EML will be to make improvements for the majority, with the right EML significantly improving Canadian lives and providing cost savings, the change to an EML may also disadvantage some. It is important to recognize the trade-off that each model poses and how these ideas can be implemented in the Canadian landscape.

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