Response to PMPRB Request for Consultation
"Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations"

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Introduction

This document contains responses to the Patented Medicine Prices Review Board (PMRB) request for input on Canadian drug prices. These responses were written by the Quadra Granville Seniors Group; we work with seniors and the community to influence all levels of government to develop and implement supportive policies for seniors.

The Quadra Granville Seniors Group organized a very successful and well-attended Forum on May 26, 2017, "**A Better Prescription: How Government Could Make Medicines Safer and more Affordable for our Aging Population"**. Our keynote speaker, Dr. Steve Morgan is a Professor of health policy at UBC in the School of Population and Public Health. He is an expert in pharmaceutical policy. The other speakers were Joyce Murray, Vancouver Quadra MP and Isobel Mackenzie Office of the Seniors Advocate of BC.

The entire PMPRB Consultation document is on the Health Canada Website: https://www.canada.ca/en/health-canada/programs/consultation-regulations-patented-medicine/document.html

In order to protect Canadians from "excessive drug prices", the following factors must be considered.

- 1 in 3 Canadian seniors receives 1 or more medicine that is a risk for older patients.
- 1 in 5 hospitalizations is caused by prescription overuse, underuse, or misuse.
- The annual cost of potentially inappropriate prescriptions filled by older Canadians is $419 million.
- 46% of Canadians worry about being able to afford medicines they will need in the next 10 years.
- 7 in 10 employers support universal, public PharmaCare.
- 1 in 10 Canadians do not take their medicines as prescribed because of costs. This affects nearly 1 in 4 Canadian households.
- Generic drugs in Canada are nearly double (79% higher than) the median of prices found in other OECD countries and more than four times (445%) higher than the best available prices in the OECD.
- Brand-name drugs in Canada are 30% higher than in comparable countries like the United Kingdom.

Responses to PMPRB Consultation Questions

Proposal #1: It is proposed that the Regulations be amended to include the following **three new factors** for consideration, under s. 85(1), when determining whether a medicine is being or has been sold at an excessive price:

i. The pharmacoeconomic evaluation for the medicine and other medicines in the same therapeutic class in Canada and in countries other than Canada;
ii. The size of the market for the medicine in Canada and in countries other than Canada; and
iii. Gross Domestic Product in Canada. New factor: the pharmacoeconomic evaluation for the medicine

A pharmacoeconomic evaluation identifies, measures, and compares the costs and benefits of a given drug to patients and the healthcare system.

Consultation questions:

1. Do you agree that a pharmacoeconomic evaluation is an important factor for the PMPRB to consider when determining whether a drug is priced excessively? If so, how should the evaluation be considered?

   Response. Its efficacy should be considered; however, it should not result in people with debilitating or life shortening conditions not being able to afford life altering medications. They should not be priced relative to the **highest** priced drug in its therapeutic class but rather to the **median** price? This simple change could save Canadians and their governments billions.

2. Do you agree that the size of the market for the drug in Canada and other countries is an important factor for the PMPRB to consider when determining whether a drug is priced excessively? If so, how should the size of the market be considered?

   Response. For a drug for a common condition and therefore, a large market size, the R&D and production costs will be distributed over many customers. Also, it needs to be affordable to a large sector of the population and to many employers' plans or provincial plans. Conversely, those with rare conditions should not have to pay exorbitant prices.

3. Do you agree that Canada's GDP and GDP growth are important for the PMPRB to consider when determining whether a drug is priced excessively? If so, how should GDP be considered?

   Response. Yes. Our pricing should be based on countries with similar GDP.

4. Are there any other factors that should be considered by the PMPRB when determining whether a drug is priced excessively? How should the factor(s) be considered and what information should be required from patentees?

   Response. Yes, the PMPRB must take into account the fact in Canada 1 in 4 households do not fill their prescriptions because of cost and many of these people

increase our health care costs because of under medication. Our share of people not taking their medications, because of cost, is **10.2%** compared with a median of **3.7%** in other comparable countries.

Discounts should be made available to the PMPRB so that they can ensure all companies are being treated equitably. Production and R&D costs should be factored in as should the extent to which the company is investing in Canada in return for high drug costs here. Currently the reverse is true

Proposal #2: It is proposed that the countries in the Schedule to the Regulations be revised as follows:

France	Australia*
Germany	Belgium*
Italy	France
Sweden	Germany
Switzerland	Italy
United Kingdom	Japan*
United States	Netherlands*
	Norway*
	South Korea*
	Spain*
	Sweden
	United Kingdom

* New countries added to the list

Consultation questions:

1. Are there other countries that should be considered in revising the Schedule?

   Response. Yes, New Zealand, Denmark and Austria. See #2 and 3 for explanations as to why.

2. Are there other criteria that should be considered in revising the Schedule?

   Response. Current drug prices in other countries (New Zealand **$375** vs Canada **$962** per capita spent on drugs annually), lower number of people who don't fill their prescriptions because of cost (New Zealand **5.8%** vs Canada **10.2%,** UK 2%, Germany 3%).

3. Please provide any other comments you may have on the Schedule of comparator countries.

   Response. If one of the goals of drug pricing, is to encourage more R&D investment in Canada, then Denmark and Austria should be included. Denmark spends almost one third less per capita on medicines, but receives about 18 times more drug company research & development per capita then Canada. Factors affecting why head office locations, good clinical trials infrastructure and strong scientific clusters occur in other countries but not in Canada should also be considered.

Proposal #3: It is proposed that the Regulations be amended to set out that patented generic drugs, which received market authorization from Health Canada through an Abbreviated New Drug Submission, be required only to report identity and price information in the event of a complaint or at the request of the Patented Medicines Prices Review Board.

Consultation question:

1. Do you agree that patentees of generic drugs, i.e. drugs that have been authorized for sale by Health Canada through an ANDS should only report information about the identity of the drug and its price in the event of a complaint or at the request of PMPRB?

   Response. The manufacturers of generic drugs **must** be required to submit all information to the PMPRB. The prices of generic drugs in Canada are nearly double (79% higher than) the median of prices found in other OECD countries and more than four times (445%) higher than the best available prices in the OECD. The PMPRB has a **responsibility** to Canadians to reduce these prices.

Proposal #4: It is proposed that the Regulations be amended to set out the information required to enable the PMPRB to consider the new factors as proposed:

1. For the new factor – the pharmacoeconomic evaluation for the medicine and other medicines in the same therapeutic class in Canada and in countries other than Canada – the Regulations would be amended to require patentees to submit:
   - **the cost utility analysis by approved indication of the medicine, where that information is available to the patentee**

   This information would be as consistent as possible with the information required by CADTH's Common Drug Review, pan-Canadian Oncology Review and l'Institut national d'excellence en santé et en services sociaux (INESS).

2. For the new factor – the size of the market for the medicine in Canada and in countries other than Canada – the Regulations would be amended to require the patentee to submit:
   - **the estimated uptake of the medicine, by approved indication, in Canada without restraint on utilization (e.g. market/budget impact analysis in any relevant market), where that information is available to the patentee**

No information would be required from patentees on per capita GDP or growth in GDP.

Consultation questions:

1. Is the information sought in relation to the new factors relevant and sufficient?

   Response. The pharmacoeconomic evaluation is relevant but must be weighed against Canadians ability to afford the drugs they need. This information is not sufficient as factors such as our high percentage of households who do not fill their prescriptions because of cost, discounts, R&D and production costs, and the company's investment in Canada should also be considered.

2. Is this information generally available to patentees?

   Response. The more information the PMPRB has the better. Companies should not be allowed to withhold any information to the PMPRB.

Proposal #5: It is proposed that the Regulations be amended to require patentees to report to the PMPRB all indirect price reductions, given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit in Canada.

Consultation questions:

1. Are there any reasons why patentees should not be required to disclose to the PMPRB information on indirect discounts and rebates provided to third party payers?

   Response. The PMPRB should have access to all relevant information, particularly about the company's biggest customers, if it is going to adequately protect Canadians from the excessive pricing that have been experiencing. To do so would save governments and Canadians billions of dollars.

   This entire process focusses on the pharmaceutical companies and not at all on Canadians and their ability to afford the medicines they need. This is resulting in increased health care costs because of under medication. This **must** be considered by the federal government in proposing new pricing regulations.

   Canadians must stop paying the second highest drug costs in the world. The government has justified these costs on the assumption that these companies would invest significantly in Canada. This has **not** happened and there has been no accountability of these companies to Canadians on this issue.

Appendix A: Dr. Steve Morgan Presentation

Summary of a presentation given by Dr. Steve Morgan to the May 26, 2017 Forum: "A Better Prescription: How Government Could Make Medicines Safer and more Affordable for our Aging Population."

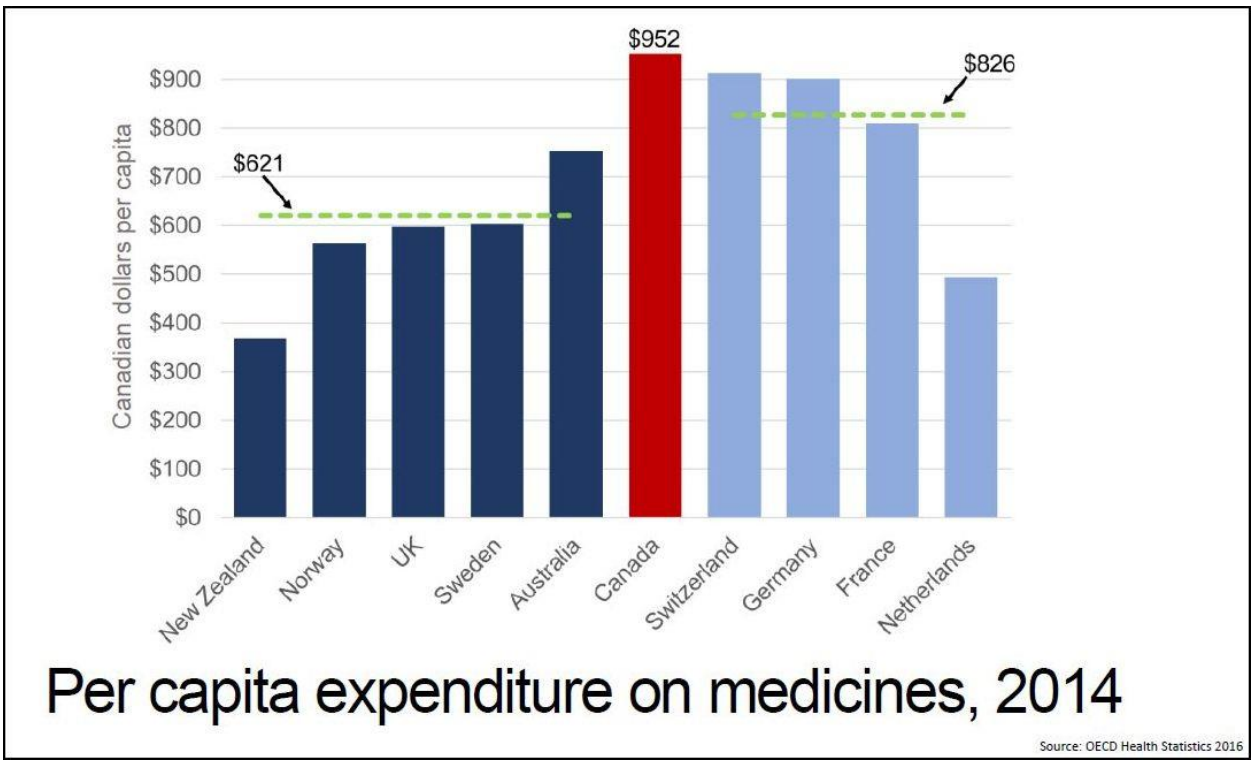
This forum was sponsored by the Quadra Granville Seniors Group; the group works with seniors and the community to influence all levels of government to develop and implement supportive policies for seniors.

Steve Morgan is a Professor of health policy in the School of Population and Public Health. An expert in pharmaceutical policy, Dr. Morgan's research helps governments balance three sometimes-competing goals: providing equitable access to necessary medicines, managing health care spending responsibly, and providing incentive for valued innovation. Dr. Morgan has published over 100 peer-reviewed research papers on pharmaceutical policies. He has advised governments in Canada and abroad and has produced work for the World Health Organization and the Organization for Economic Cooperation and Development.

The following data is from a presentation given by Dr. Steve Morgan to the May 26, 2017 Forum: "**A Better Prescription: How Government Could Make Medicines Safer and more Affordable for our Aging Population**."

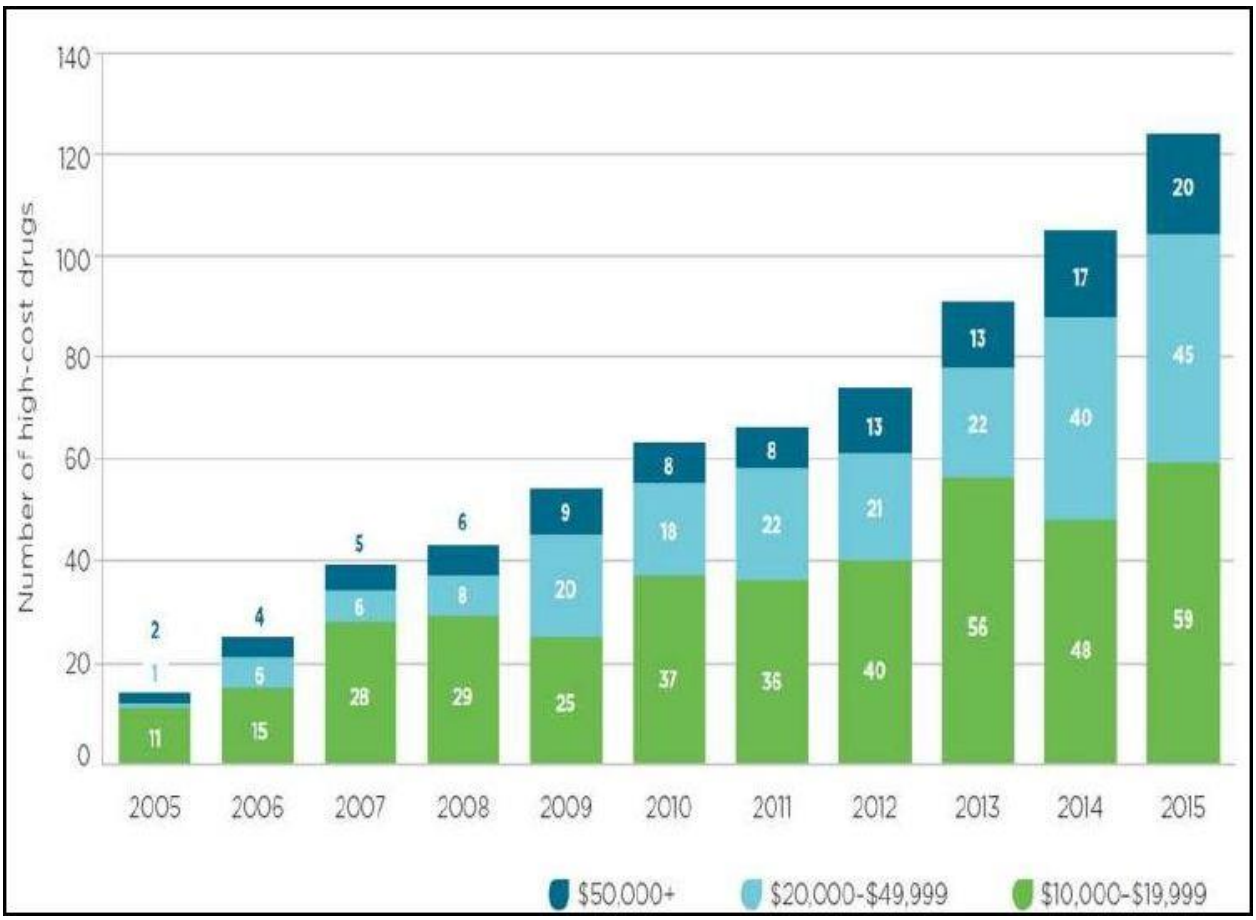
Canada's Medicine Costs Keep Increasing

Canada's per capita expenditure on medicines is much higher than other countries, as shown in the graph below.



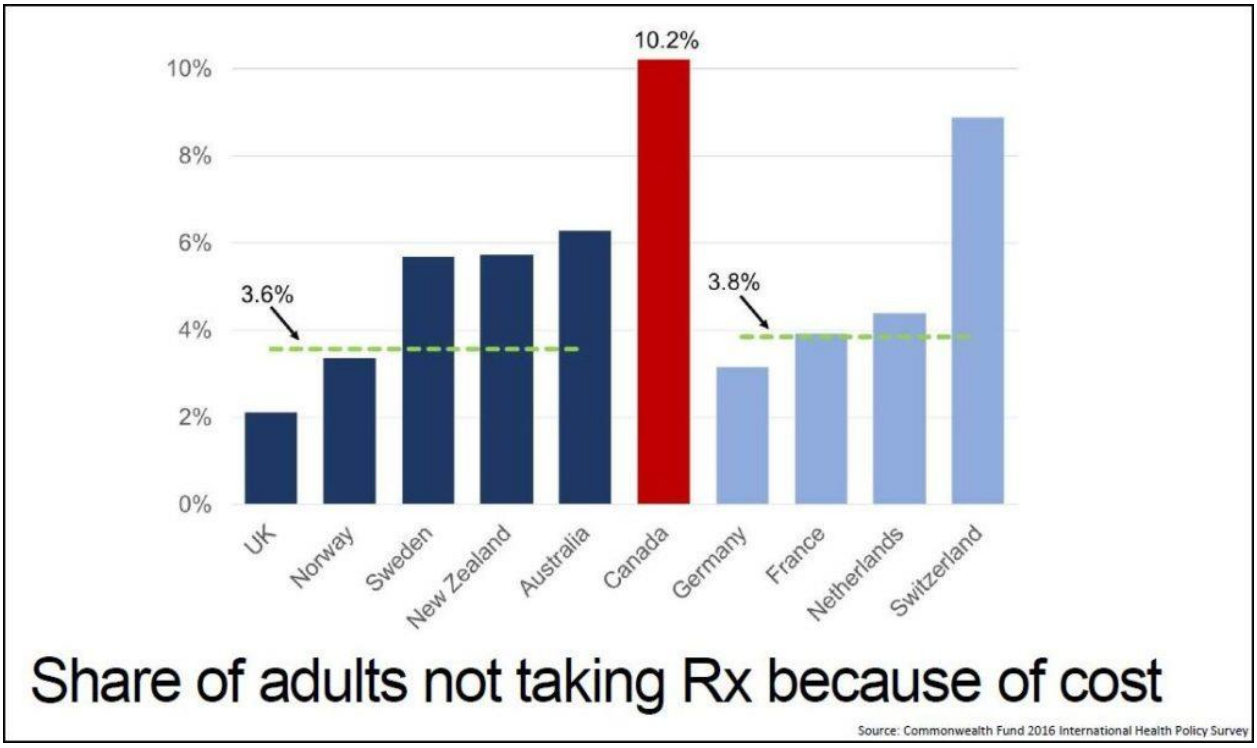
Increasing Number of Expensive Medicines

As shown in the graph below, the number of "**expensive**" medicines are increasing as is the number of Canadians taking these medicines. For example, the number of medicines costing more than $50,000 per year has increased from 2 in 2005 to 20 in 2015.



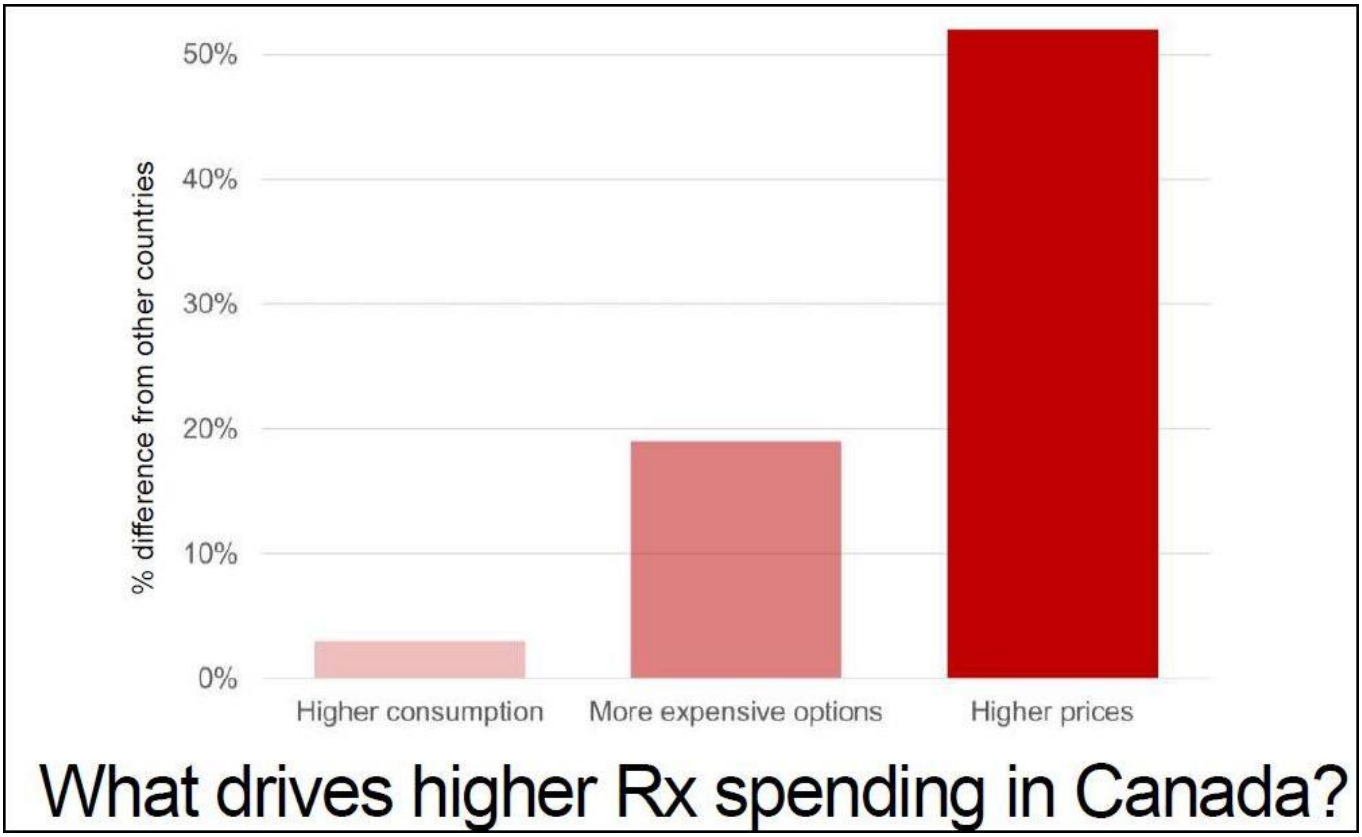
Canadians from 1 in 4 Households do not Take Medications Because of Cost

Compared to other countries, Canada comes out the worst in this category as is shown in the graph below



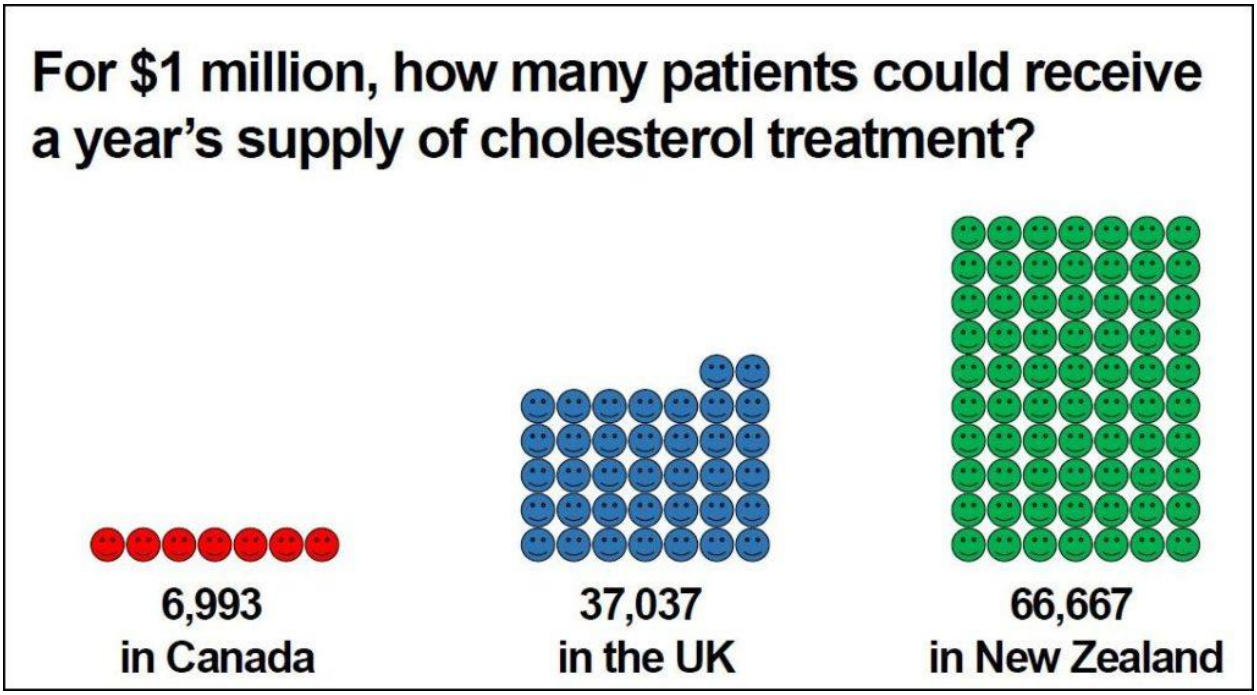
What Drives Higher Rx Spending in Canada?

The major factor leading to the high cost of medicines in Canada is that we simply pay more for them, compared to other countries.



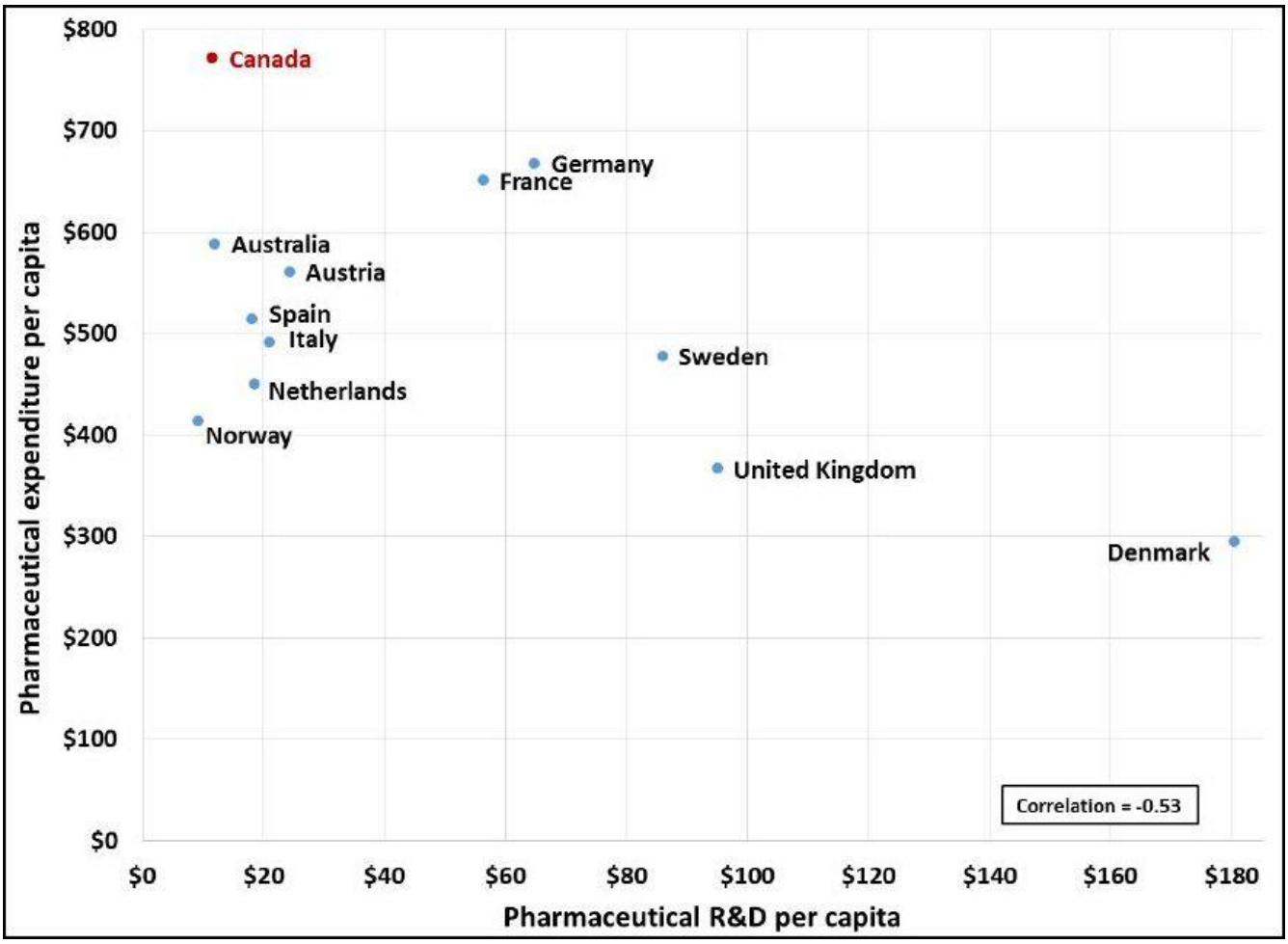
Comparing Costs of One Medicine

Here are how many patients could receive a year's supply of cholesterol treatment for $1 million – in Canada, the UK and New Zealand.



Drug Costs Compared to Drug Company Research & Development

Some people think that if we pay less for medicines, then the drug companies will take their research & development to other countries. This is not true, as shown in the graph below. For example, Denmark spends almost one third less per capita on medicines, but receives about 18 times more drug company research & development per capita.



Appendix B: The Future of Drug Coverage in Canada

Summary of Paper "The Future of Drug Coverage in Canada": see pharmacare2020.ca.

1 in 10 Canadians do not take their medicines as prescribed because of costs. This affects nearly 1 in 4 Canadian households.

Pharmacare by 2020 would mean that more than 2 million Canadians will fill prescriptions that they would not otherwise be able to afford.

Millions of households would no longer have to endure ongoing financial strain owing to their health needs.

Fewer than 1 in 3 doctors in Canada use electronic prescribing tools to help identify problems with drug doses or interactions.

By helping to reduce problems of medicine underuse, overuse, and misuse, Pharmacare would dramatically improve patient health while saving the health care system up to $5 billion per year.

The prices of generic drugs in Canada are nearly double (79% higher than) the median of prices found in other OECD countries and more than four times (445%) higher than the best available prices in the OECD. Similarly, the prices of brand-name drugs in Canada are 30% higher than in comparable countries like the United Kingdom. Take the blockbuster drug Lipitor, for example. A year's supply of the brand-name drug in Canada costs at least $811; in New Zealand, where a public authority negotiates prices on behalf of the entire country, a year's supply of the brand costs just $15. Even the generic version of Lipitor costs at least $140 in Canada, more than nine times more expensive than in New Zealand.

It is estimated that approximately $5 billion spent by employers on private drug benefits is wasted because private drug plans are not well positioned to manage prescribing and dispensing decisions of Canadian health professionals. Pharmacare will save the private sector up to $10 billion.

Specialty drugs – that cost up to$500,000 per year – now account for 25% of private drug spending in Canada.

1 in 5 Canadian households spends over $500 out-of-pocket on prescriptions. Nearly 1 in 10 spends over $1,000.

Preventable underuse of medicines in Canada costs the country up to $9 billion annually.

2 million Canadians – including 500,000 seniors – would have better access to medicines under Pharmacare.

Canadians from nearly 1 in 4 households cannot afford to fill their prescriptions as written.

Appendix C: A Retired Family Doctor's Perspective

One of the measures proposed is to compare prices across the provinces and other countries and choose a price somewhere within the range. However, there does not appear to be any mechanism to assess whether the reference prices are reasonable in the first place.

Transparency

Pharmaceutical companies need to be more transparent in their reporting of costs of getting drugs to market and their analysis of pricing to recoup their investments.

R&D

R&D is a large component. Previous agreements were designed to have more R&D based in Canada. Despite some of the highest drug costs in the developed world, Canada trails in investment in R&D. R&D under Canadian jurisdiction and support, particularly trials, might provide better oversight and ensure that "new" drugs do provide safer and superior outcomes compared to similar classes of drugs already on the market at lower prices.

Promotion & Advertising

The costs of promotion and advertising, often overemphasizing the benefits and playing down the adverse effects, need to be analyzed. In Canada, recent changes have curtailed some of the detailing costs directed at doctors. However, these costs amount to billions (excluding drug samples). Doctors are influenced by academic detailing, CME courses promoting "new" drugs (often in a program on a general topic), guideline statements from their professional associations, journal advertising, direct to consumer advertising and unsolicited pharmaceutical mail. Doctors agreeing to see drug-detailing reps are influenced in their prescribing habits and often will prescribe a brand rather than a cheaper generic. The figures are not readily available but every major drug company budgets $200-$500 per doctor excluding samples.

Hidden Costs: Incentives, Subsidies, Discounts, Commissions

Hidden costs in the form of discounts, subsidies and commissions to corporate customers including provincial health plans must be exposed.

Safer More Effective Prescribing

There needs to be a strategy to assist all physicians in safer and effective prescribing. Clinical trials need to be done better and supported by public funding (provided by the millions of dollars in possible savings) and not just pharmaceutical companies. Improved benefits and safety must be vigorously demonstrated. Copycat drugs of existing cheaper drugs must show a significant improved benefit and safety. Inappropriate prescribing to seniors of behavioral and mood-altering drugs remains a problem. Medical schools and professional associations must be involved. There are opportunities for partnerships with pharmacists with specialized training.

Generic Drugs

Generics need the same oversight as patented drugs. In particular the non-medicinal agents in the formulation must be declared as well as the source of the drug. If the drug is

produced offshore, quality control policies must be reviewed to ensure safety of Canadian consumers. It is not good enough to simply review a generic drug once a problem is exposed.

Possibly the price of generics with high sales volume should rise to offset prices of new biologics with low sales volume to treat cancers and immunologic diseases.

Third Party Coverage

The role of insurers should be included as allies in the process of checking the unreasonable cost of prescription drugs. It is in their interest to be able to sell policies that cover 80-100% of the cost of any new drug. As it is, the cost of the extraordinary drugs such as biologics can be simply prorated or not covered at all.

Expensive Drugs

Some of the diseases that require extraordinary drugs and cost provincial health authorities hundreds of millions of dollars include Hep C, HIV, some cancers and immunological disorders such as rheumatoid arthritis, inflammatory bowel disease and organ rejection. These drugs can be life-saving but will require a federal presence to ensure that all Canadians can access these unique but expensive medicines. Interestingly, cholesterol-lowering drugs are also a driver of rising costs.

National Strategy

Several provinces have introduced variations on a PharmaCare plan for patients. However, the deductibles can be high and coverage of the expensive biological is inconsistent. A strategy to develop a national drug plan is urgently needed. Within this strategy, a national formulary can be developed along with a national procurement plan. This step alone is estimated to save at least $1 Billion.

Summary

The proposed amendments to the Patent Medicine Regulations may protect Canadians from Excessive Drug Prices but the approach does not go far enough and is more designed to improve collaboration and relationships with drug companies so that prices can be renegotiated. These amendments do little to address policies that can be introduced in a timely fashion and would provide immediate cost savings. These policies include banning hidden incentives, subsidies, discounts and commissions given to major purchasers. Drug stores should be unable to accept display bonuses. Curtailing detailing and advertising which often overstate the value of a "new" drug while downplaying side effects could positively change prescribing habits and save hundreds of millions of dollars in direct and indirect costs. Rigorous drug reviews of drugs prescribed to seniors could significantly reduce adverse effects and associated health care costs. More provincial cooperation on bulk buying will also provide enormous savings.

Conclusion

These are reachable goals but must be supported and guided by a national strategy. Canadians deserve nothing less.

Readings

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