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ELI LILLY CANADA SUBMISSION TO THE CONSULTATION ON THE IMPLEMENTATION OF NATIONAL PHARMACARE

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Key Points

- Lilly believes that all Canadians should have access to the medicines they need without the ability to pay as a barrier. Most Canadians are fortunate to have that access now.
- However, in some provinces/territories, gaps in affordable access may exist for certain groups, such as the working poor or those facing catastrophic drug costs. Lilly is committed to working with government to ensure these gaps are closed.
- The current discussion on options for national pharmacare provides Canadians and their governments with an opportunity to develop the most appropriate solutions to address the challenges related to individual affordability.
- With an eye towards health care sustainability, Lilly believes that governments' attention should be directed at finding practical solutions targeting those Canadians most in need of support, and that national pharmacare options should focus on addressing these remaining coverage gaps by leveraging the strengths of Canada's current mix of public and private drug coverage.
- Lilly currently participates with public payers through initiatives such as the pan-Canadian Pharmaceutical Alliance (pCPA) to ensure that cost is not a barrier for the most vulnerable populations that governments target their support --- seniors, those with low-income, and for high-cost medicines. The over $1 billion in annual savings that the pCPA has been able to achieve has ensured that government support for drug coverage is directed to those who need it most, and has resulted in greater alignment and consistency amongst public drug plans.
- Lilly encourages the Council to work collaboratively with Health Canada and the PMPRB to integrate discussions related to the proposed regulatory pricing reforms with national pharmacare to ensure that decisions related to PMPRB do not restrict options available for national pharmacare implementation.

Leveraging the Current Mix of Public and Private Drug Coverage to Target Those Most in Need

The *Constitution Act* firmly places the authority of a government's budgetary allocation with the provinces and territories.[1] They are accountable to their constituents and are in the best position to assess value and make trade-offs within and across health care and drug budgets based on their priorities, needs, and a unique understanding of their citizens. Given Canada's federated system and mixed system of public and private drug plan funding for prescription medicines, this concept is fundamentally important.

Each jurisdiction, and payer, whether public or private, will have a different assessment of what is affordable for its drug plan based on their specific economic and fiscal realities, health system priorities, demographics and disease prevalence of the population they cover, the downstream costs they pay for, and the health outcomes they hope to achieve with drug coverage. Drug plans are designed and levels of drug coverage are tailored and targeted to the specific needs of the population(s) that are covered. For example, private drug plans cover younger, healthier working populations, and the drug coverage under these plans is aimed at this population.

Under the current system of price regulation in Canada, where the Patented Medicine Prices Review Board (PMPRB) sets the ceiling price for each new medicine, it is possible for payers to negotiate confidential pricing below that ceiling. This results in differential pricing across different payer groups, most notably between public and private payers. Lilly Canada strongly believes that this system of

[1] Section 92, *Constitution Act*, 1867

differential pricing, which preferentially benefits public payers as custodians of those individuals they have deemed to be society's most vulnerable, is fully aligned with Canada's *social contract*, which supports preferential targeting of resources to protect against an inability to pay. The Government of Canada's own Ministerial mandate letters have reiterated this commitment: "We committed to provide more direct help to those who need it by giving less to those who do not."[2]

It is not unreasonable for public payers to receive preferential pricing, based on the nature of the patients they cover and the fact that they absorb the majority – more than 70%[3] – of healthcare costs for all Canadians. This preferential targeting of resources is essential to levelling the playing field for individuals who may suffer poorer health outcomes because of low income. Data from the Canadian Institute of Health Information (CIHI) shows definitively that poorer health outcomes in Canada are linked strongly to income; those of lowest income have the worst health outcomes.[4] Acknowledging that it is a complex problem, CIHI concluded that closing the gap requires preferentially targeting resources across the spectrum of health, income, and social services.

Through the pan-Canadian Pharmaceutical Alliance (pCPA), the innovative medicines industry contributes more than $1 billion in negotiated annual savings targeted to public drug plans and their vulnerable populations. We believe the decision by the federal Minister of Health to have federal plans join the pCPA is a key step forward in addressing Canada's affordability issues. In addition to the achievement of savings, the joint negotiations undertaken by pCPA have helped to support greater alignment and consistency across F/P/T public drug plans in terms of how new drugs are listed and reimbursed.[5]

Under the current system, Canada's public payers, are able to achieve prices amongst the lowest in the world, with the size of the rebates related to the current degree of differential pricing between the public and private market. Through the pCPA, a transfer of value occurs from those who need less help – the private market – to those who require more – the vulnerable populations who are eligible for government-sponsored drug coverage. Private payers pay the "list price" (i.e. no higher than the federally regulated ceiling price), enabling public payers, through pCPA, to pay a significantly reduced price. The size of the rebates achieved by the pCPA is dependent on the size of the pool of resources from which the rebates are drawn. The size of that pool is determined by the level of the price paid by the private market.

If the Government of Canada were to adopt a universal, single-payer pharmacare model that, in effect, eliminated drug coverage through the private insurance market (and current system of differential pricing and Canada's two market system), it would result in inevitably fewer resources being available to innovative medicines manufacturers to support governments' public drug plans and the vulnerable populations that they cover.

Recommendation: As such, Lilly recommends options for national pharmacare that continue to leverage Canada's current system of public and private drug coverage, allowing public resources to continue to be targeted towards those Canadians in most need, and most affected by affordability challenges.

[2] https://pm.gc.ca/eng/minister-health-mandate-letter

[3] Canadian Institute for Health Information (CIHI), *National Health Expenditure Trends, 1975-2015*. https://www.cihi.ca/sites/default/files/document/nhex_trends_narrative_report_2015_en.pdf

[4] Canadian Institute for Health Information. *Trends in Income-Related Health Inequalities in Canada*. November 2015.

[5] Patented Medicine Prices Review Board. *Alignment Among Public Formularies in Canada – Part 1: General Overview*. October 2017.

Proposed Changes to Federal Pricing Regulations Could Impact Options for National Pharmacare

In December 2017, Health Canada published proposed changes to the *Patented Medicines Regulations*. The proposed changes are aimed at lowering the ceiling price of patented medicines across all markets. There are (2) significant impacts that the lowering of ceiling price via the proposed regulatory changes could affect the Council's recommendations regarding an approach to national pharmacare:

- ***The value that public payers are able to negotiate through pCPA.*** The size of the rebates achieved by the pCPA is dependent on the size of the pool of resources from which the rebates are drawn. The size of that pool is determined by the level of the ceiling price paid by the private market. A drop in ceiling prices according to the proposed new pricing regulations would mean manufacturers have a smaller pool from which to draw rebates. This is because the benefits that would accrue to the private payers through a drop in the ceiling price are not "new" dollars, but rather would represent a transfer in benefit that public payers currently receive through confidential rebates negotiated by the pCPA. The drop in ceiling price across all markets would mean a smaller pool overall from which to draw these rebates for public payers.

- ***Access to new medicines in Canada.*** A country's pharmaceutical pricing policy and approach to determining the price of patented medicines is a key factor taken into consideration by manufacturers when they are making decisions on when – or if – to launch a new medicine in a jurisdiction.

  Canada's current pricing regime - consisting of the PMPRB, national and regional health technology assessment (HTA) bodies and listing negotiations by public and private payers - has established a balance that protects Canadians from high prices while allowing manufacturers to launch more new medicines, and in most cases, earlier in Canada than in many other international markets. A recent study by the PMPRB shows that Canada currently has one of the highest shares of new medicines launched in the world (at 61% vs. 45% OECD median). In terms of launch timing for all new active substances, only the United States, Germany, the United Kingdom, and Sweden launched ahead of Canada.[6] For many manufacturers, Canada typically launches in the "first wave" with leading markets, such as the United States. In countries where pricing reforms have significantly lowered the price of patented medicines, there have been delays in the launch of new medicines, and in many cases, new medicines were not launched at all. There is evidence that shows that drug launches are less likely to follow launch in a low-price country with launch in a high-price country. Moreover, countries with lower expected prices or smaller expected market size due to cost containment measures, technology assessment, and other pricing and reimbursement hurdles have fewer launches.[7,8,9,10,11]

Federal pharmaceutical price regulation and national pharmacare are linked. The development of options for national pharmacare --- seeking to balance the need for affordability with continued access to new,

[6] Patented Medicine Prices Review Board. *Meds Entry Watch, 2015*. April 2017.

[7] I Cockburn, J Lanjouw and M Schankerman, Patents and the global diffusion of new drugs *Am Econ Rev*, 106, 136-164 (2016).

[8] Danzon, Patricia & W Mulcahy, Andrew & Towse, Adrian. Pharmaceutical Pricing in Emerging Markets: Effects of Income, Competition, and Procurement. *Health economics*. 24.10.1002/hec.3013. (2015).

[9] P.M. Danzon, and M. F. Furukawa. International Price and Availability of Pharmaceuticals. *Health Affairs*, January 2008.

[10] Margaret K. Kyle. Pharmaceutical Price Controls and Entry Strategies. *Review of Economics and Statistics*; Volume 89, Issue 1.p.88-99. February 07, 2007.

[11] Danzon PM, Wang YR, Wang L. The impact of price regulation on the launch delay of new drugs--evidence from twenty-five major markets in the 1990s. *Health Econ*. 2005 Mar; 14(3):269-92. 2005.

innovative medicines that support Canadians' health outcomes --- could be significantly impacted by the proposed changes to Canada's pharmaceutical pricing regime.

Recommendation: Given the significant impacts that the proposed *Patented Medicines Regulations* could have on the pharmaceutical market in Canada, Lilly encourages the Council to work collaboratively with Health Canada and the PMPRB to integrate discussions related to regulatory pricing reform with national pharmacare to ensure that decisions related to PMPRB do not restrict options available for national pharmacare implementation.

Publicly Funded Medicare and Pharmacare – Insight from Other Countries

It is often noted that Canada is the only member country of the Organisation for Economic Cooperation and Development (OECD) with a universal public health care system that does not include coverage for prescribed medicines. As the Council considers the implementation of options for national pharmacare alongside our publicly funded system of health care, it is important to understand health care and pharmaceutical coverage in other countries.

Drugs constitute a large share of health expenditure across countries in the OECD. In 2015, Canada spent CA$1,012 on drugs per capita, less than the United States (CA$1,457) but more than most other OECD countries.[12] The public share of drug spending among the OECD countries, ranges from 34% in Poland to 84% in Germany. Canada, with a public share of 36%, was among the countries with the lowest shares. However, while Canada spends less public money than the OECD average on pharmaceuticals, Canada spends more than the OECD average on hospitals and doctor visits. In a 2017 study of 29 countries, Canada ranked eighth highest for heath care expenditure as a percentage of GDP and 11th highest of health care expenditure per capita,[13] more than the majority of high-income OECD countries with universal health care.

This difference in spending is directly related to Canada's single-payer, universal health care system, where Canadians don't pay out-of-pocket for essential medical services like doctor and hospital visits. Co-payments are a foreign concept, and purchasing private insurance for medically necessary health care procedures is banned. Nearly two-thirds of Canadians have supplemental private insurance or employer-sponsored plans to cover the costs of prescription drugs, dentistry, vision care, rehabilitative service and home health care --- all things not included under the *Canada Health Act*. Provincial and territorial governments have also implemented public coverage for elements not enshrined under national medicare, to reflect their specific health care priorities, the evolving nature of health care, and to direct support to the vulnerable populations they serve.

Canada's approach to and funding of medicare is unique in comparison to other OECD countries. In addition to funding through taxation, many countries, including France, Germany, New Zealand, Sweden, Australia, and the Netherlands, charge co-pays and/or deductibles for medical care (e.g., physician visits, specialist consultations, and hospital stays). Canada remains one of only three nations in the industrialized world that does not require its citizens to pay some form of user fee for publicly-funded medical services.[14]

[12] National Health Expenditure Database, 2017, Canadian Institute for Health Information.

[13] Barua, B et al. Comparing Performance of Universal Health Care Countries, 2017. Fraser Institute. September 2017.

[14] Mossialos, E. 2015 International Profiles of Health Care Systems. Commonwealth Fund. January 2016.

While Canada's lower public (i.e. government) spending on pharmaceuticals has been used by some stakeholders to argue for the expansion of public coverage for pharmaceuticals, it is important to understand that pharmacare (public drug insurance) plans in place in other OECD countries, and even those that are considered 'universal,' do not cover pharmaceutical expenses in their entirety. There is a non-negligible portion of costs that must be paid by the insured, often through required patient deductibles and co-payments, and it generally accounts for a larger share of the total public spending on prescription drug spending in those countries than it does in Canada. For example, out-of-pocket expenses represent over 40% of total spending in Australia, Norway, Finland, and Sweden, all countries with public drug insurance plans covering their entire populations.[15]

Countries with universal pharmacare programs still continue to struggle with individual affordability issues. International comparison has shown that roughly the same percentages of people cite affordability problems in accessing medicines regardless of differences in system design and coverage.[16] Based on data from the OECD, the proportion of patients who report not filling a prescription for cost reasons is higher in countries such as Australia (13.4%), Germany (11.5%), and New Zealand (10%) – all of which have a universal public pharmacare system – than in Canada (8.5%).

Also, in those countries with universal public pharmacare, patient outcomes are not necessarily better. For example, in the United Kingdom, touted by pharmacare advocates for its strong, single-payer system, some cancer survival rates are one-to-two decades behind many other European countries – and well behind Canada (e.g., lung cancer 5-year survival in the UK is 10% vs. 17% in Canada; colon cancer, 60% UK vs. 64% Canada).[17]

Understanding the Uninsured and Underinsured Gap in Canada

In order to determine which options for national pharmacare program may be most appropriate, it is important to understand the public policy problem that exists related to access to drug coverage in Canada, and how this may impact individual affordability. A Conference Board Report published in December 2017 found that more than 34 million Canadians are estimated to be eligible for some form of prescription drug coverage, leaving 5.2 percent of the total Canadian population uninsured.[18] Most interestingly, it was found that nearly 4.1 million Canadians are eligible for public or private coverage but are not enrolled in either program. These findings suggest that most of the Canadian population is eligible for either public or private coverage for prescription drugs in each province/territory, making the uninsured gap very small (and mostly concentrated in Ontario).

The issue of underinsurance was also examined by the Conference Board, which noted that most of the individual cost burden was experienced by those who are enrolled in a public program but not in a private plan and who experience a high cost-sharing burden, as well as those who are enrolled in a private plan but have higher drug costs. Even when an individual is enrolled in a drug plan (public or private), they may be subject to out-of-pocket costs due to plan design features such as premiums, deductibles or co-payments, or annual or lifetime caps required by the drug plan. Most public programs have premiums or

[15] Labrie, Y. "Do we need a public drug insurance monopoly in Canada?" Montreal Economic Institute: Health Care Series. August 2015.

[16] Labrie, Y. "Do we need a public drug insurance monopoly in Canada?" *Montreal Economic Institute: Health Care Series.* August 2015.

[17] Jönsson B, Hofmarcher T, Lindgren P, Moen F & Wilking N. Comparator report on patient access to cancer medicines in Europe revisited – A UK perspective. IHE Report 2017:1, IHE: Lund, Sweden.

[18] Sutherland, Greg, and Thy Dinh. Understanding the Gap: A Pan-Canadian Analysis of Prescription Drug Insurance Coverage. Conference Board of Canada. December 2017.

annual fees as well as deductibles and co-payments that may lead to significant out-of-pocket costs. There is also the possibility that the prescribed drug is not on the formulary, meaning the prescription must be paid out-of-pocket. For the estimated 8.5 million Canadians who are enrolled in a public program but who have no access to a private plan, deductibles and co-payments can be a financial burden. For Canadians enrolled in a private program, formularies are more comprehensive, but there is also a risk that specific drugs (mostly high-cost drugs) may not eligible for coverage, have limited coverage criteria, or have limits on how much of the cost will be reimbursement. In addition, cost-sharing is also common in private plans. There has been an increasing trend toward plan members having to pay more through higher co-insurance rates, and multiple types of cost-sharing mechanisms simultaneously, as well as annual or lifetime spending caps.

Similar to the findings by the Conference Board, research on drug coverage in Canada in 2016 published in *Canadian Health Policy* found that out of a total population of almost 36.3 million people, it was found that over 13.1 million Canadians were covered under a public drug plan and nearly 23.2 million Canadians were covered under a private drug plan.[19] The researchers concluded that "Canada has achieved universal population coverage under its pluralistic system of private and public prescription drug plans."

The same research did, however, also note that some Canadians face financial challenges related to drug coverage. They concluded that most of these challenges were as a result of underinsurance within existing public drug plans, and not due to a lack of insurance coverage. Middle to higher income families that do not have a private drug plan are often exposed to progressive income-adjusted deductibles, co-payments and/or premiums before qualifying for full public drug benefits, and depending on level of income, this cost-sharing can be problematic.

And, while it has been found that a significant portion of Canadians benefit from some form of drug coverage, there are still some individual Canadians who may continue to struggle with affordability because they may lack any form of drug coverage or have inadequate coverage.

Recommendation: Lilly believes that the options for national pharmacare should focus on addressing this coverage gap --- those Canadians who are hardest hit by drug costs, either as a result of no drug insurance or underinsurance. And, because the problem of individual affordability is complicated and multifactorial, there are a number of solutions that may be required. One size will not fit all.

[19] Skinner, Brett J (2018). "Prescription drug plan coverage 2016: how many Canadians were insured, under-insured or uninsured?" *Canadian Health Policy*, June 18, 2018. Toronto: Canadian Health Policy Institute. URL: www.canadianhealthpolicy.com