Response to the PMPRB Guidelines Modernization Discussion Paper

Executive Summary

Eli Lilly Canada Inc. (Lilly Canada) appreciates the opportunity to provide feedback and input to the Patented Medicine Prices Review Board (PMPRB) on the areas for discussion outlined in its *PMPRB Guidelines Modernization Discussion Paper*. Lilly Canada is concerned that some of the changes proposed by the PMPRB, including a shift to focus on "affordability" and away from therapeutic benefit in determining excessive pricing, extend beyond the appropriate mandate for the PMPRB and intrude on what is a provincial and territorial jurisdiction. Lilly Canada believes that all Canadians should have timely access to the medicines they need without affordability as a barrier; we will stand with federal, provincial and territorial governments as the appropriate stakeholders to tackle this issue.

PMPRB's Scope and Mandate

The PMPRB, in its current form, holds the appropriate mandate and pricing strategy, as established in the *Patent Act*. The architects of the *Patent Act* assigned the PMPRB a consumer protection role – a counterbalance – to guard against the potential for "excessive" drug pricing that could result from the exclusive rights afforded to innovators. To now, determinations of excessive price have been applied against a standard that measures the value of a medicine in terms of its therapeutic benefit, a marker that is directly tied to the primary mandate of the *Patent Act*: innovation. Therapeutic benefit is the same standard applied across the globe: we know of no jurisdiction that assesses the value of a medicine in another manner.

In contrast to statements that Canadian prices are out of line internationally, the PMPRB's own data finds, consistently, Canada's prices sit well below median international prices. In particular, the PMPRB has maintained exceptional regulatory performance for prices of innovative medicines that have no generic competitors on the market (single-source medicines). For this segment, in 2015, Canada ranked sixth out of eight amongst its basket of comparator countries, with median international prices of single-source medicines ***43% above*** those in Canada.[1]

Affordability and the Role of PMPRB

The PMPRB's current mandate also respects the constitutional responsibilities of the provincial and territorial (P/Ts) jurisdictions under the unique requirements of our federal system and the mix of publicly and privately funded drug plans. The current system leaves the final decisions of affordability and the reimbursed price of a medicine with the appropriate stakeholder – the payer, who, as the budget holder, is in the best position to determine societal need and ability to pay. The PMPRB's proposed changes do not acknowledge the rapid evolution that has occurred in Canada's pharmaceutical pricing and reimbursement system, largely at the behest of the P/Ts exercising their constitutional mandate within Canada's federated system. Most recently, P/Ts joined together in a pan-Canadian Pharmaceutical Alliance (pCPA) to negotiate pricing agreements. Via the pCPA, over $712 million in combined savings[2] annually have been realized for publicly funded drug plans, while increasing access equitably across Canada's provinces.[3] Private payers also

[1] Innovative Medicines Canada, 2016. International Price Comparison of Patented Medicines in Canada: Innovative Medicines Canada Member Companies Source: Form 2 Block 5 data submitted to PMPRB, July-December 2015, Innovative Medicines Canada members.

[2] Combined savings on 95 innovative medicines and 18 generic drugs.

[3] The pan-Canadian Pharmaceutical Alliance. The Council of the Federation. Available at: http://www.pmprovincesterritoires.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance

initiate their own confidential negotiated agreements; we know of no other jurisdiction where for-profit private payers have lobbied government agencies to do so on their behalf.

Differential Pricing in Canada

Of critical concern to Lilly Canada, the Discussion Paper also refers to the need to revise the Guidelines to better enable the PMPRB to execute its consumer protection mandate *for all Canadians* and, so, eliminate differential pricing. Currently, the PMPRB's ceiling prices make it possible for innovative medicines companies to offer volume discounts and other benefits and to negotiate confidential pricing below that maximum, resulting in preferential pricing for public payers. Lilly Canada strongly believes that this preferential pricing is fully aligned with Canada's social contract. This social contract benefits public payers, as custodians of those individuals they have deemed to be society's most vulnerable, and who also cover more than 70% of overall health care costs in Canada.

Affordability Concerns

Lilly Canada recognizes that payers face difficult funding decisions, in particular for medicines that are anticipated to have a high budgetary impact as well as those that treat a very small patient population at a price that is perceived by payers to be very high. However, it is not appropriate for the PMPRB to target a subset of innovative medicines and hold them to greater regulatory scrutiny for these reasons alone. To do so would be at odds with the very purpose of the PMPRB's enabling legislation, the *Patent Act*, to *protect* innovation. Lilly Canada also understands that some individual Canadians struggle with affordability because they lack adequate coverage. The problem of individual affordability is complicated and multifactorial. For example, international comparison shows that roughly the same percentages of people cite affordability problems in accessing medicines regardless of differences in system design and coverage.[4] Neither of these issues raised can be solved by the PMPRB because the responsibility for drug and health system design, income security, and the social determinants of health rest elsewhere. Lilly acknowledges these areas of concern that payers have expressed. We further acknowledge that we must stand with governments, who hold accountability for their budgets and to their constituents, to define the scope, magnitude and causes of these problems as well as the best ways to address them.

Lilly Canada respectfully requests a formal role within the PMPRB's consultation as it progresses. A meaningful consultation with innovative medicines companies is fundamental to the process and a statutory obligation within the *Patent Act*. In line with the guiding principles of the PMPRB's Consultation Policy[5] and the commonly understood principles of effective regulation, we would ask the PMPRB to identify a clear problem statement supported by robust analysis. For example, the Discussion Paper implicitly suggests that the United States should be removed from the PMPRB's set of comparator countries. However, there is no rationale or evidence provided to support this notion or, in particular, how a change here would address a specific problem. A fair and balanced consultation process is requested that can gather the best evidence to inform decisions. In doing so, it should also consider the environment in which the PMPRB operates, its appropriate role and the implications changes may cause across the health care system.

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

[5] The guiding principles of PMPRB's Consultation Policy are to build relationships and trust, enhance openness, and ensure an effective process though a "solid, mutual understanding of the issues, objectives, purpose and expectations" PMPRB Consultation Policy available at: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1028

Response to the PMPRB Guidelines Modernization Discussion Paper

Eli Lilly Canada Inc. (Lilly Canada) appreciates the opportunity to share our perspective as part of the Patented Medicine Prices Review Board's (PMPRB) public consultation on the *PMPRB Guidelines Modernization Discussion Paper* (Discussion Paper) and the *Strategic Plan 2015-2018*. According to the PMPRB, the aim of the consultation is to obtain input from stakeholders to ensure the *Compendium of Policies, Guidelines, and Procedures* (Guidelines), which are "grounded in decades-old understanding of the Canadian and global pharmaceutical sector", remain relevant and effective in enabling the PMPRB to protect consumers from excessive prices in Canada's evolving pharmaceutical market. To do so, the PMPRB suggests its Guidelines should move away from setting an innovative medicine's ceiling price based on its therapeutic value and toward one that focuses on affordability.

Lilly Canada strongly supports the written responses by both Innovative Medicines Canada and BIOTECanada. Our submission serves to complement these responses and the core elements we feel are vital for consideration within the consultation. As we will outline in the response, it is clear to us that, in assessing the current pharmaceutical landscape, the PMPRB in its current form holds the proper mandate. It is *not* the appropriate agency to solve concerns and considerations with respect to affordability. However, Lilly Canada acknowledges this expressed payer concern and is committed to work with the appropriate stakeholders – the federal, provincial and territorial governments – to understand and address this issue.

PMPRB Scope and Mandate

Patents exist to reward innovation. In Canada, the *Patent Act* affirms the inherent value of innovation to society by awarding a period of exclusivity – a statutory monopoly – to the patent holder. It is this patent regime that sets the broader context from which the PMPRB's mandate and authority are derived. The PMPRB was created to "protect consumers" from the possibility that innovators could charge excessive prices because of their exclusive patent rights. Lilly Canada agrees that the PMPRB was created to protect the public interest; however, this must be viewed in the context of the PMPRB's constituting statute, the *Patent Act*, a regime that encourages and rewards innovation. In this context, the PMPRB's consumer protection mandate must be regarded as two-fold: guarding against excessive prices, and encouraging the research and development necessary to provide the innovative medicines that will benefit the health of all Canadians.

The concepts of innovation and therapeutic contribution are inextricably woven into the fabric of the PMPRB's mandate. This is because, in the pharmaceutical industry, the true marker of innovation is not just in a medicine's novelty, but the benefit it provides to *patients*. Section 85 of the *Patent Act* defines those factors that must be taken into account to determine if a price of a patented medicine is excessive[6] and, to date, the PMPRB's Guidelines have achieved an appropriate counterbalance between its two competing objectives. This is largely because the current Guidelines apply the factors in section 85 to considerations of a medicine's level of therapeutic contribution, a marker of innovation consistent with the purpose and objectives of the *Patent Act*.

[6] These factors include: the price in the market, the price of other medicines in the market, the price internationally, and the consumer price index.

Additionally, the Guidelines set the ceiling price of an innovative medicine, a concept that is enshrined in the *Patent Act* and its Patented Medicines Regulations (Regulations). This allows the flexibility in pricing – both transparent and confidential – that is needed within a dynamic pharmaceutical market that involves a mix of public and private drug plans and a number of different channels (wholesalers, hospitals, provinces, retail pharmacy, etc.). Though not posited by the PMPRB, preferential pricing to public payers, who act as custodians of society's most vulnerable, also aligns with Canada's approach to consumer protection and its social contract to deliver extra resources to those who need them. This is evidenced by federal and provincial government programs which apply the same system of preferential benefit, for example, the Federal Child Tax Credit, the Seniors' Old Age Pension Income Supplement, the Ontario Drug Benefit program, the Ontario Post-secondary Tuition Subsidy Program and Alberta's Low-Equity Loan Program for Seniors. Thus, the current rules allow industry to effectively collaborate with payers to achieve better value for their vulnerable citizens – if price equality is mandated by the PMPRB, there would be fewer resources directed to those in greatest need.

Price and Therapeutic Benefit

A paramount feature in determining the ceiling price of an innovative medicine is the level of therapeutic benefit it provides: the higher the benefit, the higher the potential price. Using therapeutic value as the starting point for price determinations is consistent with the patent regime in which the PMPRB finds its home. Statutory factors in section 85 of the *Patent Act* reference "therapeutic class" when assessing an excessive price, clearly pointing to the importance of therapeutic value as a basis for pricing. This is consistent with other jurisdictions – while pricing strategies may vary internationally, innovation is a key determinant in setting price.[7] By ensuring a scaled recognition and reward for incremental benefits, clear and consistent expectations are signaled to the innovative medicines sector on what their research and development should deliver.[8] This is commonly understood as the appropriate incentive and reward for bringing innovative medicines to market, which is consistent with the overall purpose of the *Patent Act*. Therapeutic benefit is the same standard applied across the globe: we know of no jurisdiction that assesses the value of a medicines in another manner. For example, in both France and Germany the degree of therapeutic benefit an innovative medicine provides is first assessed, through the National Authority for Health (Haute Autorité de Santé) and the Federal Joint Committee (Gemeinsamer Bundesausschuss – G-BA), respectively, and only then is a pricing and reimbursement strategy assigned as a result of this assessment.

PMPRB's Track Record

The Guidelines, as currently drafted, achieve the mandate of the PMPRB in ensuring that the prices of patented medicines are not excessive in Canada, in a manner that is consistent with the overall legislative scheme of pricing regulation and the intention of Parliament in drafting the *Patent Act* and its Regulations.

Since 1987, the PMPRB itself has consistently reported to Parliament that it has met its mandate. It has done so by ensuring the average prices of patented medicines in Canada are below the median of a group of seven international comparator countries, the

[7] Ruggeri, K. and Nolte, E. Pharmaceutical Pricing: The use of external reference pricing. The RAND Institute, 2013. Available at: http://www.rand.org/content/dam/rand/pubs/research_reports/RR200/RR240/RAND_RR240.pdf

[8] European Commission. Guiding principles for good practices implementing a pricing and reimbursement policy (Pharmaceutical forum - Working Group on Pricing and Reimbursement). Available at: http://ec.europa.eu/DocsRoom/documents/7584?locale=en

PMPRB7.[9] Indeed, the PMPRB deserves credit for its role in regulating prices: Canadian prices were 23% higher than median international prices prior to its establishment; in every year since, Canadian prices have been well below the international median. In fact, in 2015 the PMPRB reported that median international prices were 18% above those in Canada and that Canada was tied with Switzerland[10] in a country-to-country ranking of the PMPRB7, placing both countries third after Germany and the United States. Hence, despite PMPRB's remarks to the contrary, its relevance and the regulatory relief it provides to Canadians remains meaningful.

The value of the PMPRB's regulatory relief is further exemplified for those innovative medicines that do not have any generic competition in the market and are, thus, market exclusive. It is these "single-source medicines" where the architects of the *Patent Act* were likely most concerned that consumer protection was warranted. This fact is often lost because the PMPRB regulates and reports on the prices of ***all*** prescription medicines for which there is evidence of a Canadian patent, despite the fact that many patented medicines have lost exclusivity in Canada, and so face generic competition. Known as multisource medicines, the innovator product still in fact holds a patent and reports to PMPRB, even though they have limited share in a highly competitive market.[11] These medicines account for almost one-third of DINs reported to the PMPRB.[12] A recent analysis by Innovative Medicines Canada found that when the data are analyzed to directly compare the prices of single-source medicines alone, Canada actually ranks ***sixth out of the eight*** in the PMPRB7, with median international prices ***43% above*** those found in Canada.[13] This finding suggests that the PMPRB has maintained exceptional regulatory control on the prices of innovative medicines where a monopoly exists and that statements arguing that Canadian pricing is out of line with relevant international comparators do not stand up to scrutiny.

Finally, the PMPRB's Guidelines and industry's practices have successfully reflected the guiding principles of regulation: predictability, simplicity and fairness. The greatest evidence of this success is the industry's excellent rate of compliance with the Guidelines. It is only in a small percentage of cases that the prices of products are found to have exceeded the Guidelines and trigger an investigation. Even then, the majority of companies work with the Board and *voluntarily* reduce the price of the product or offset excess revenues through payment. For example, in 2015, of 1,359 products reported to PMPRB, only one has been issued a Notice of Hearing by the Board.[14] Though rare, these hearings and judicial reviews have helped strengthen our collective understanding of the Board's mandate and regulatory role, and have resulted in appropriate adjustments to the Guidelines and industry practices.

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[9] The PMPRB7 includes: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.
[10] A country that the PMPRB applauds in its discussion paper for its pricing reforms.
[11] A typical patented medicines will see up to 95% of its market erode in favor of the generic medicine within one month of losing exclusivity.
12 Innovative Medicines Canada, 2016. International Price Comparison of Patented Medicines in Canada: Innovative Medicines Canada Member Companies. Source: Form 2 Block 5 data submitted to PMPRB, July-December 2015, Innovative Medicines Canada members
13 The PMPRB's analysis is also sales weighted. It does not just compare price to price, but more heavily weights the price of a particular medicine if it is sold more in Canada. Thus, variances in utilization between countries can become an important factor and skew the analysis depending on how often the medicine is used in Canada. The analysis by Innovative Medicines Canada simply compares the prices in Canada with those in the PMPRB7 providing a true reflection of how actual *prices* compare internationally.
[14] PMPRB Annual Report 2015. Available at: http://www.pmprb-cepmb.gc.ca/en/reporting/annual-reports

Affordability and the Role of the PMPRB

The Canadian health care system, with its mix of public and private payers and limited role for the Federal Government, is unique among countries. This is important to consider as it may be inappropriate for the PMPRB to use other jurisdictions as a "model" for Canadian pricing regulation given the complexity of our system. Importantly, in its Discussion Paper, the PMPRB fails to acknowledge this unique dynamic and the rapid evolution that has occurred in Canada's pricing and reimbursement environment to address concerns of payer affordability. This has occurred largely at the behest of provincial and territorial governments (P/Ts) exercising their constitutional mandate within Canada's federated system for the delivery of health care.

The Constitution of Canada firmly places the authority of a government's budgetary allocation on health with the P/Ts.[15] They are accountable to their constituents and are in the best position to assess value and make trade-offs within and across budgets based on their priorities, needs, and unique understanding of their jurisdiction. Budget holders are the only legitimate arbiters of affordability. Given Canada's federated system and mixed public and private drug plan funding for prescription medicines, this concept is fundamentally important. Each jurisdiction, or payer, will have a different assessment of what is an affordable price for its drug plan based on their 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 a particular medicine.

There is no uniform determination of what is affordable. Affordability is a subjective concept that can only be determined by the particular payer in the larger context of its operating budget. The PMPRB's suggestion to set an arbitrary economic threshold for what would be considered an affordable price for all Canadian payers would not only intrude on a jurisdiction that rightly sits with provinces, but also do a disservice to the complex value judgments and trade-offs that the P/Ts and other payers make in determining how best to allocate finite resources to serve their constituents.

Canada's regulatory and reimbursement environment has evolved to assist P/Ts in making difficult funding decisions. This has occurred incrementally, in a manner that has allowed it to keep pace with international drug evaluation and reimbursement standards. Based on the initiative of cooperative affiliations of the P/Ts to leverage common interests, while allowing each member to remain accountable to its own electorate for its budget in accordance with the priorities of its government, two new types of agencies were created. The Canadian Agency for Drugs and Technology in Health (CADTH) and Institut national d'excellence en santé et en services sociaux (INESSS) assess and make *recommendations* to the P/Ts on clinical and cost-effectiveness, or value for money, of a medicine or class of medicines. Most recently, the P/Ts joined together in a pan-Canadian Pharmaceutical Alliance (pCPA) to negotiate pricing agreements, with affordability as one criterion for the budget holders.

While the PMPRB is an important and relevant contributor to this overall system in Canada, it is not the appropriate agency to address a medicine's affordability. Consideration should be given to how the PMPRB can best complement the work of CADTH/INESSS, the pCPA and private payers through its reporting function. For example, through NPDUIS, the PMPRB has evolved effectively to support the pCPA as a centralized and credible source of rigorous analyses to assist in the negotiation process. Other areas that have not been

[15] See section 92 of the Canadian *Constitution Act*, 1867.

subject to much monitoring or analyses by the PMPRB include the downstream costs related to innovative medicines (e.g. distribution costs, retail/specialty pharmacy mark-ups, etc.). While the PMPRB does not have the jurisdiction to regulate or otherwise act on these downstream costs,[16] through its Advisory Committee and by canvassing other stakeholders, NPDUIS could identify how, and with what information, it can most effectively assist decision makers in the reimbursement process.

Differential Pricing in Canada

Of critical concern, the Discussion Paper also refers to the need to revise the Guidelines to better enable the PMPRB to execute its consumer protection mandate for all Canadians, implying a proposal to encourage uniform pricing. Under the current system, where the PMPRB sets the ceiling price for each new medicine, it is possible for companies to set lower prices or 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. This is specifically contemplated in the *Patent Act* and its Regulations.[17]

Lilly Canada strongly believes that this system of 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. This social contract supports preferential targeting of resources to protect against an inability to pay. 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%[18] – of healthcare costs for all Canadians. Via the pCPA, joint negotiations are conducted specifically to achieve greater value for public drug plans and their patients. The pCPA has succeeded in doing so, realizing over $712 million in combined savings annually (on 95 patented medicines and 18 generic drugs).[19] If all innovative medicines companies were to spread across all Canadians the resources they provide to governments' vulnerable citizens through lower pricing, there would inevitably be fewer resources directed to those in greatest need.

Preferential targeting of resources is essential to levelling the playing field for individuals who may suffer poorer health outcomes because of low income. Recent 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.[20] Acknowledging the issue's complexity, CIHI concludes that closing the gap requires *preferentially targeting resources across the spectrum of health, income, and social services.*

We know of no other jurisdiction where private for-profit insurance providers have lobbied government agencies to negotiate confidentially on their behalf. In fact, the insurance carriers who provide health benefits exert considerable market power when they enter into negotiated agreements with innovative medicines companies. The three largest providers (Manulife, Great-West Life and Sun Life) each cover approximately the same number of people as the Ontario Drug Benefit program, and, together, they hold between 60-70% of

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[16] Pfizer Canada Inc. v. Canada (Attorney General) 2009 FC 719.
[17] And see also Leo Pharma Inc. v. Canada (Attorney General) 2007 FC 306.
[18] Canadian Institute for Health Information (CIHI), National Health Expenditure Trends, 1975-2015. Available at: https://www.cihi.ca/sites/default/files/document/nhex_trends_narrative_report_2015_en.pdf
[19] The pan-Canadian Pharmaceutical Alliance. The Council of the Federation. Available at: http://www.pmprovincesterritoires.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance
[20] Canadian Institute for Health Information. Trends in Income-Related Health Inequalities in Canada. Ottawa: November 2015.

the group health benefits market.[21] With over 24 million Canadians covered by a private health benefits plan[22], insurance carriers are well positioned to make their own value assessments and negotiate with innovative medicines companies on behalf of their clients. They have the ability to customize, modify or change drug plan designs and features during their annual contract renewals with clients. This gives them great flexibility and creativity in the agreements they negotiate. For example, Manulife's DrugWatch[23] program quickly launched across its private drug plans. The DrugWatch Program places selected innovative medicines through a protracted HTA and negotiation process prior to Manulife's making a decision to reimburse a medicine. These approaches are possible within a commercial setting where providers and suppliers work business-to-business to reach mutually agreeable terms and remain competitive in the market.

Other Discussion Paper Themes

While Lilly Canada believes that the PMPRB is not the appropriate agency to address issues of affordability, we recognize that solutions are needed to resolve payer concerns. Here, Lilly Canada is a committed stakeholder. Lilly Canada has identified three areas arising from the Discussion Paper where we feel there is insufficient information to help us contribute meaningfully either to the consultation process or with the appropriate stakeholders to devise a worthy solution. These include the concept of market power as it pertains to PMPRB's regulation of high priced and high budget impact medicines, the composition of the PMPRB7 for international price referencing, and affordability considerations for those without adequate insurance.

Market Power: High Priced and High Budget Impact Medicines

Lilly Canada appreciates that governments and private payers face difficult funding decisions particularly for medicines that are anticipated to have a high budget impact and for medicines that treat a very small patient population at a price that is perceived to be very high. The PMPRB suggests that its Guidelines should focus on indicators of potential for abuse of statutory monopoly, such as high therapeutic benefit, projected usage and absence of comparators, in order to determine which innovative medicines should face greater scrutiny in setting a ceiling price.

It is not clear that the PMPRB itself could or should target a subset of innovative medicines and hold them to greater regulatory scrutiny simply because they offer a higher level of therapeutic benefit. While the mandate of the PMPRB is price regulation, this arbitrary segmentation runs counter to the very essence of the *Patent Act* and its legislative intent – to reward innovation. Additionally, as discussed previously, considerations of cost, budget impact, and affordability of medicines should be left to payers, the budget holders. Mechanisms already exist at this level, through the pCPA and confidential negotiations with private drug plans, to resolve price and affordability concerns. In the vast majority of cases, an innovative medicine designated as breakthrough or with substantial therapeutic improvement will see subsequent entries in its therapeutic class in short order, which keeps the market highly competitive for payers. Payers are well equipped in the negotiated terms of their agreements to manage these situations and to re-evaluate the terms of their

[21] Benefits Canada Special Feature: 2016 Group Benefits Providers Report. Available at: http://www.benefitscanada.com/wp-content/uploads/2016/04/2016-Group-Benefits-Providers-Chart.pdf
[22] Canadian Life and Health Insurance Facts: 2016 Edition. Available at: http://clhia.uberflip.com/i/726639-canadian-life-and-health-insurance-facts-2016/
[23] Manulife launches DrugWatch. Available at: http://www.benefitsconsultant.ca/insurance-insights/manulifes-launches-drugwatch.html

agreements when market dynamics change significantly, a new indication comes to market, or upon contract renewal. It is unclear how the PMPRB could improve upon this process which already ensures that the payers are in the best position to achieve the overall value for their plans.

Lilly Canada does acknowledge, however, that outliers can exist within the current system. For example, in a few exceptional circumstances, an innovative medicine that treats a disease for a *very* small patient population comes to market where there are no other treatments available to patients – now or in the foreseeable future – and offers a significant benefit to patients. These medicines should be afforded the highest price premium by the PMPRB by virtue of their substantial or even breakthrough therapeutic benefit; however, the introductory price can be perceived to be very high. In some cases, public and private payers struggle to negotiate what they would deem to be an affordable pricing arrangement because alternatives do not exist and the public pressure to reimburse the medicine is high. While we recognize this potential area of concern, it is not within the jurisdiction of the PMPRB to address such issues. We stand with payers to define and understand this issue to ensure the right information is available and to find a solution that is tailored to the particulars of this specific problem.

International Price Comparisons: The Composition of the PMPRB7

International price referencing is the most common pricing policy applied in advanced economies. All but two of the twenty-eight European Union member states use some form of comparisons with other countries as considerations when setting prices. While the size and composition of the baskets of comparator countries vary, consistently the major criteria include geographic area and economic situation. When comparing prices internationally only officially published list prices are used – confidential and/or statutory rebates are not taken into account – even though these financial arrangements are wide-spread throughout the European Union.[24] This enables the best value to be reserved for public payers globally, depending on the characteristics of the market, its reimbursement system, population needs and health priorities.

As an international leader and a member of the G7, Canada sits comfortably in the PMPRB7 amongst countries of similar economic standing and health systems. The prices of innovative medicines in Canada are reasonably placed at the median of these countries. The Discussion Paper suggests that the prices in the United States (U.S.), one of seven comparator countries, "skew" the median international price and it appears to implicitly recommend its removal from the PMPRB7. Lilly Canada believes this to be misleading. There is no evidence in the Discussion Paper to suggest that the current set of comparator countries, including the United States, is inappropriate or that a change to the PMPRB7 would directly solve any of the concerns raised by the PMPRB. We would ask for the opportunity to review the analysis that points to this conclusion, the number and type of medicines that are affected and the details of the relevant situations. Most importantly, an assessment of how changing the composition of the PMPRB7 might appropriately address a particular concern is warranted. For example, approximately 10% of all patented medicines only have U.S. comparator prices. It is only in this small number of cases that the prices in the U.S. would set the Canadian ceiling price.

[24] Vogler, S. et al. Study on enhanced cross-country coordination in the area of pharmaceutical product pricing: final report. European Commission, 2015. Available at: http://ec.europa.eu/health/systems_performance_assessment/docs/pharmaproductpricing_frep_en.pdf

Affordability Gap: Uninsured and Underinsured Canadians

Lilly Canada understands that some individual Canadians struggle with affordability due to lack of coverage or inadequate coverage. As the PMPRB notes, it is these individuals who may end up paying the full price of medicines out-of-pocket. Over the years, Lilly Canada and other companies have been addressing such concerns by providing compassionate use and financial assistance programs. From 2010 to 2014, product donations to patients through compassionate use and special access programs alone totaled $770 million.[25] We recognize this does not fully address the affordability gap. Interestingly, across the globe, roughly the same percentage of people report affordability problems in getting needed medicines whether they live under a fully-funded public system or in a mixed private-public system like Canada.[26] Affordability is a vastly complicated problem that cannot be solved by the PMPRB because the responsibility for drug and health system design, income security, and the social determinants of health rest elsewhere.

Governments that hold accountability across the spectrum of health and social services are in the best position to make decisions regarding how best to meet their obligations to their citizens. Thus, each province designs and allocates resources to its health system differently. For example, pubic drug plans vary notably across Canada in their population and/or income eligibility requirements, coverage rates, deductibles and/or co-payments. We are committed to work with governments, private payers, and other relevant stakeholders to define the scope of the coverage problem and work toward a sustainable solution to close this access and affordability gap.

Conclusion

Lilly Canada believes that the PMPRB, in its current form, executes the appropriate mandate and pricing strategy, as established in the *Patent Act,* to ensure the prices of innovative patented medicines are "not excessive"– a unique responsibility assigned to it. This mandate respects the constitutional responsibilities of the P/Ts under the unique requirements of our federal system and the mix of public and private drug plans. The current system leaves the final decisions of affordability and the reimbursed price for all drugs (not only innovative medicines) with the appropriate stakeholder – the payer, as the budget holder in the best position to determine their individual need and ability to pay.

The PMPRB has also provided meaningful regulatory relief since its creation, and continues to do so. When the data are analyzed to focus on patented medicines with no generic competitors on the market, the PMPRB has ensured that median international prices are 43% above those in Canada in 2015. This is a notable achievement. Any consideration for change within the PMPRB's mandate and Guidelines should respect the statutory obligation for meaningful consultation with industry as outlined in the PMPRB consultation policy, including clearly stated objectives and a transparent engagement process. Lilly Canada looks forward to the opportunity to continue our engagement throughout the consultation process.

[25] KPMG, R&D Spending and Investments by IMC Members - Product donations to patients through compassionate use and special access programs

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