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Patent Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, ON
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Re: PMBRP Guidelines Modernization

We would like to thank the Patent Medicine Pricing Review Board (PMPRB, or the Board) for the opportunity to participate in the review and modernization of its Guidelines. Sustainable access to medicines is an important issue that impacts, or will impact all Canadians at some point in their lives. As will be expanded upon below, current pricing trends for patent medicines threaten sustainability and the access of all Canadians to the medicines they need, making this consultation welcome and timely. It is obvious from the excellence and thoroughness of the PMPRB Guidelines Modernization Discussion Paper (the Discussion Paper) that the Board recognizes that there are challenges with the current process for determining the maximum price of pharmaceuticals in Canada and that changes are necessary. We compliment the Board for displaying a keen awareness and depth of knowledge of these challenges.

Operating in every province and territory with over 12,000 employees and celebrating its 125th anniversary this year, Great-West Life is a leading Canadian insurer. Together with its subsidiaries London Life Insurance Company and The Canada Life Assurance Company, Great-West Life serves the financial security needs of more than 12 million people across Canada and has as its corporate goal the physical, mental and financial well-being of Canadians. Our companies have had a front-row view of patent medicine pricing trends over many decades. In 2015 we paid over 50 million claims representing more than $4 billion in health and dental benefits for group insurance plan members.

As the Discussion Paper notes, Canada's current patent medicine pricing regime was created in 1987 and has not been significantly modified in the years since. Notwithstanding the merits of the patent medicine pricing process when it was created, the environment has changed greatly since the mid-1980s. Advances in computing power, bio-technology and engineering and the understanding of human genetics have resulted in an ever-expanding number of drug treatments. Certain of these medicines, including those that can be described as biologic or speciality drugs, could not have been conceived of in 1987 and create enormous cost-pressures for both public-sector and private-sector purchasers of drugs.

As affirmed by the Supreme Court of Canada, (*Celgene Corp.* v. *Canada (Attorney General)*, [2011] 1 SCR 3), the Board was created with a consumer protection mandate to protect Canadians from "excessive" prices for patent medicines. However, Canadians currently pay the third-highest drug prices in the Organization for Economic Cooperation and Development (OECD), behind only the United States, a

noted outlier in drug pricing policy, and Germany. The Board was also created as a type of *quid pro quo* for the extension of greater patent protection to brand name drug manufacturers based upon an understanding that a lengthier patent protection period would result in greater levels of pharmaceutical research and development spending in Canada. As pointed out in the Discussion Paper, empirical analysis demonstrates that this has not been the case. It is therefore clear that Canada's current patent medicine pricing system is failing to meet its public policy objectives. We believe that the Board recognizes this as well. While this current exercise is limited to a modernization of the Guidelines, we are of the view that a broader review of the Board, its enabling legislation and associated regulations are necessary. Such a review should be ambitious and consider how countries such as the United Kingdom, the Netherlands, New Zealand, Australia and other international peers address these challenging issues. Many OECD countries have lower prices despite smaller markets. There may not be one best system to emulate, but by seeking global best practices and involving all stakeholders in the discussion, a solution can be found that allows all Canadians to enjoy world-leading patient outcomes on a sustainable and equitable basis.

Before proceeding further there is one point that should be clarified. Ultimately, through one mechanism or another, it is drug plan sponsors (employers) and plan members (employees) that pay the cost for drugs. In some circumstances, insurers may benefit from higher drug prices where premiums or fees are charged as a percentage of benefits paid. Despite this, the insurance industry is united in advocating for policy changes to lower the prices of drugs paid by all Canadians. Our interest is in sustainability, as we are of the view that if current pricing trends continue plan sponsors will no longer be capable of sustaining broad drug coverage under group benefit programmes, potentially leaving millions of Canadians with no coverage for certain drug expenses. The industry has worked very hard and cooperated in efforts to contain the cost increases passed through to plan sponsors and to maintain access to the latest drug treatments through such mechanisms as the Canadian Drug Insurance Pooling Corporation (CDIPC). However, these mitigation mechanisms may be reaching their limit as they are overtaken by continued cost increases. Plan sponsors are increasingly requesting limited formularies and annual coverage limits which will inevitably lead to more Canadians having to fund sometimes astronomical drug costs directly out of their own pockets, turning to already strained public drug purchase programmes or choosing not to get the treatment that they need.

Our views on sustainability are not simply anecdotal. Drug purchases under group plans offered by our company totaled more than $1.5 billion in 2015, with one percent of claimants accounting for approximately 30% of total drug spend. Notably, 0.4% of DINs were responsible for 30% of drug costs under our plans in the same year. If present pricing trends continue, and given the pass-through of costs to employers and employees, there may be larger public policy considerations around employment and economic competitiveness.

Finally, before considering the questions outlined in the Discussion Paper directly, it must be said that we recognize the importance of innovation in the pharmaceutical sector and that some drugs, notwithstanding the costs involved, have a dramatic impact on quality of life and in some cases, mortality. As a provider of group benefits including drug coverage and short and long-term disability, we are well-aware of these realities. However, we are of the view that it is a false trade-off to suggest that prices must be sustained at current levels in order for research and development to continue, or in order for Canadians to have access to the most recent and innovative medicines. If this logic held, Canada, with some of the highest prices in the OECD, would have access to a greater basket of innovative drugs than other lower-priced OECD jurisdictions. There is no evidence that this is the case. For example, the U.K. Pharmaceutical Price Regulation Scheme (PPRS) has been successful in controlling prices while seeking to assure access to innovative drugs.

It should be noted that our companies are members of the Canadian Life and Health Insurance Association (CLHIA). We participated in the development of and endorsed the CLHIA's response to this consultation. However, these issues are of such importance to our organization, and, we believe to all Canadians, that we feel it necessary to submit a response in our own capacity to support and expand upon the points raised by the CLHIA on behalf of the industry.

Our thoughts on the specific questions raised in the Discussion Paper are as follows:

1. **What does the word "excessive" mean to you when you think about drug pricing in Canada today? For example:**

As the case law notes, the *Patent Act* (the Act) and associated regulations provide very little guidance as to the meaning of "excessive" (*Leo Pharma Inc. v. Canada (Attorney General)*, 2007 FC 306 (CanLII)), leaving the Board to exercise a high degree of discretion in making determinations regarding excessive pricing. The PMPRB Guidelines have been developed in part to assist the Board in the exercise of this discretion and focus on international price comparisons and the prices of drugs in a similar therapeutic class. Employing this concept of "excessive" has resulted in Canadian drug prices being the third highest in the OECD, making for a strong argument that the meaning of "excessive" as used by the Board should be reexamined. As mentioned above, Canadian drug prices have evolved so that 1% of claimants covered under our group benefit plans account for approximately 30% of drug expenditure. We would submit that at a very minimum, this suggests that the prices for drugs taken by this 1% may be excessive.

Some would argue that in a market economy any price that the market will pay would be a fair, non-excessive price. This logic may be sound in the domain of consumer goods and services but it breaks down in the realm of medications that are in some instances necessary to maintain quality of life, if not life itself. Perhaps not all, but some medications can be considered necessities of life, leaving those that rely upon them vulnerable to the pricing power of monopolist providers. The fact that Parliament considered it necessary to create the PMPRB to protect Canadians from excessive drug prices is a public policy acknowledgment of this reality, as is the fact that almost all developed countries regulate drug prices to some degree.

Stepping back from the particulars of the pharmaceutical sector and thinking more broadly about the meaning of "excessive" and "excessive pricing" leads inevitably to considerations of cost, and this is part of the problem when considering what would be an excessive price for a drug. There is a lack of cost transparency with regard to pharmaceuticals. Some medications are undoubtedly very expensive to develop, test and bring to market; others, subsequent entry drugs for example, much less so. The PMPRB is tasked with determining maximum prices for products without any knowledge of the true cost of bringing those products to market.[1] Further, given the widespread practice of discounting of list prices, there is also no transparency with regard to actual prices in comparator countries.

There are other sectors where private sector companies provide goods that are considered necessities, namely utilities. Utility prices in Canada are highly regulated with an aim of safeguarding access while providing investors in a very capital intensive industry with a reasonable rate of return. It may be beyond the scope of the current reconsideration of the PMPRB Guidelines, but ultimately such a system may be the only way of ensuring Canadians access to needed drugs and the sustainability of public and private drug plans while appropriately compensating pharmaceutical investors and incenting innovation.

[1] We note s. 88(1)(c) of the *Patent Act* which allows the Board by order to obtain information on research and development expenditure in Canada. This is unlikely to give a true picture of cost unless all development takes place in Canada.

The U.K. PPRS model with its emphasis not on price but rather on profitability and return on capital or return on sales may serve as an informative international precedent.

Finally on this point, regardless of any academic discussion of what "excessive" may mean in the context of drug prices, the fact is that when both public and private drug plans are unable to maintain plan members' access to drugs, as illustrated by the increasing use of restricted formularies and price caps, there is a problem with drug prices being too high.

a. Should a drug that costs more annually than a certain agreed upon economic metric be considered potentially excessively priced?

This is difficult to answer without knowing what that metric might be. However, we would welcome a dialogue on this point and an examination of foreign practices such as the metrics created by the Institute for Clinical and Economic Review in the United States.

On the other hand, group benefit plan sponsors are essentially making such a determination by insisting on caps and limits in their plan designs. The economic metric in these situations is internal to the plan sponsor and reflects their ability or lack thereof to sustain ever-escalating costs.

b. Should a drug that costs exponentially more than other drugs that treat the same disease be considered potentially excessive?

In the absence of dramatically improved efficacy, yes. No more efficacious should equal no higher cost. This would be the dynamic in any unregulated competitive market. In such a market a new entrant that was of no greater utility would be priced lower than incumbents in order to build market share. The fact that this is often not the case in the Canadian marketplace, and that new drugs with little marginal therapeutic benefit tend to be priced higher than existing equally effective treatments, is another illustration of problems with the current drug pricing system.

c. In considering the above two questions, does it matter to you if a very costly drug only treats a small group of patients such that it accounts for a very small proportion of overall spending on drugs in Canada?

The question refers to so-called "orphan drugs," drugs that treat only a small number of people suffering from a rare disease or condition and that are typically quite expensive. It is our experience that orphan drugs, while targeting small numbers of patients, account for a disproportionate share of total drug costs. There is also the fact that when all of the "small groups of patients" that suffer from a rare disease or condition are considered together, the potential market for orphan drugs is approximately 10% of the population.

d. Conversely, if a drug's price is below an agreed upon metric and in line with other drugs that treat the same disease, should it be considered potentially excessive if it accounts for a disproportionate amount of overall spending on drugs in Canada?

Please see the response about to question 1.c. We would also point out that a drug being priced in line with other drugs that treat the same disease is not necessarily an indication that the price is not excessive. It could be that all the drugs in questions are excessively priced.

e. What economic considerations should inform a determination of whether a drug is potentially excessively priced?

Sustainability of both private and public drug plans should be considered when determining if a drug is excessively priced. All other questions such as price comparisons, efficacy or reasonable rates of return fade into irrelevance if prices are such that the drug in question will not be covered by a drug plan and will therefore be inaccessible to almost all Canadians.

2. Given that it is standard industry practice worldwide to insist that public prices not reflect discounts and rebates, should the PMPRB generally place less weight on international public list prices when determining the non-excessive price ceiling for a drug?

To the extent that the PMPRB looks to other countries for pricing guidance, it should look to prices actually paid, not the marketing practices of the pharmaceutical industry. If actual prices paid in comparator countries are not available, the PMPRB model is based upon flawed information and unworkable. We question the validity of a system that looks to international prices in the absence of any knowledge of actual international prices. We would therefore suggest that not only should less weight be placed on international public list prices, but that no weight at all should be placed upon such fictions.

We note that the requirement for patentees to submit pricing information to the Board if they sell the drug in question in PMPRB7 countries arises from s. 4(1)(f)(iii) of the *Patent Medicines Regulations* (the Regulations) and the associated Schedule to the Regulations. Neither the Regulations nor the Act provide any guidance as to how the Board is to use this information: this is entirely at the discretion of the Board. In exercising this discretion the Board has created the Guidelines in order to provide a level of transparency and predictability. However, as the courts repeatedly point out, the Guidelines are not binding and too strict adherence to the Guidelines risks fettering the Board's discretion and duty to make a reasonable decision in light of all the circumstances. Further, the Board is empowered to make its own guidelines and change such guidelines subject to a requirement to consult per s. 96(5) of the Act. This leads to a number of conclusions with regard to the international price comparison model: 1) the only duty connected to the PMPRB7 arising at law is a duty on patentees to disclose pricing information in applicable circumstances, 2) the Board has the power to do with this pricing information whatever it determines to be appropriate. The lowest price of the seven countries could be looked to as a benchmark for "excessive," an average of the seven could be considered, the highest price could be backed out of the equation, all international prices could be discounted to take into account widespread discounting and the lack of price transparency, or the average of the seven could be compared with some other benchmark such as the OECD average, etc., all without changing Guidelines to which the Board is not bound, and 3) the Board is empowered to change its Guidelines as it sees fit in any case.

In the absence of greater statutory or regulatory guidance, when considering the international pricing information that patentees are require to provide, the Board should err on the side of protecting all Canadians from excessively-priced patent medicines in line with the PMPRB's consumer protection purpose.

3. In your view, given today's pharmaceutical operating environment, is there a particular s. 85 factor that the Guidelines should prioritize or weigh more heavily in examining whether a drug is potentially excessively priced?

Consistent with our response to Question 1, we are of the view that s. 85 (2)(a) (additional factors) and (3) (research costs) should be more heavily emphasized. Any consideration of research costs should exclude public funding (both domestically and globally) received in the development of the drug.

4. **Should the PMPRB set its excessive price ceilings at the low, medium or high end of the PMPRB7 countries (i.e. the US, the UK, Sweden, Switzerland, Germany, France and Italy)?**

As suggested in our response to Question 2, the treatment of PMPRB7 pricing information is purely discretionary. However, within the confines of the question asked and again as indicated in our response to Question 2, the Board's consumer protection purpose suggests that the low end would be most appropriate. This view is fortified by two compelling factors: 1) the inclusion of the United States (the only OECD country without some type of regulation of drug prices) in the PMPRB7, distorts the average. It is clear that the U.S. is an outlier on drug prices and its inclusion among the comparator countries inflates the average and results in Canadians paying higher prices. We submit that as the home of many of the world's pharmaceutical manufacturers, U.S. public policy considerations around drug pricing are different from that of other OECD countries and that Canadian considerations are more in line with these other countries. We note also Guideline B.6.1. which states that, "Board Staff may exclude from the price tests any drug product identified for comparison purposes, both patented and non-patented, if it has reason to believe it is being sold at an excessive price." Given that U.S. drug prices are on average more than double the OECD average we would argue that they are *prima facie* excessive and should not be used in any international price comparison, and 2) the number of comparator countries is small. The addition of more countries would mitigate the impact of outliers and may be an alternative to excluding the United States. Adding countries such as Australia, New Zealand, the United Kingdom and the Netherlands to the list would make the comparison more representative of the OECD experience and result in Canadian prices closer to the OECD average. If Canadian prices reflected the OECD average, Canadians would pay approximately $4.6 billion a year less for drugs.

5. **Does the amount of research and development that the pharmaceutical industry conducts in Canada relative to these other countries impact your answer to the above question and if so, why?**

The PMPRB does not have an industrial development mandate, but rather a consumer protection mandate. Questions of industrial development fall to other branches of government. Therefore, we submit that consideration by the PMPRB of R&D spend, other than perhaps as a component of determining cost, is inappropriate. In any case, the empirical evidence as acknowledged by the Discussion Paper indicates that increasing drug prices have had no influence to increase R&D spending in Canada. In fact, the correlation is negative.

6. **What alternatives to the current approach to categorizing new patented medicines (based on degree of therapeutic benefit) could be used to apply the statutory factors from the outset and address questions of high relative prices, market dynamics and affordability?**

As suggested in our responses above, and as echoed by the submission of the CLHIA, a regime based upon a reasonable rate of return for manufacturers may be the only manner by which all the competing interests can be balanced. Having said that, we would emphasize once again that what is needed is a very deep and thorough reconsidering of Canada's entire drug pricing system. All options should be on the table including regulatory and statutory changes.

Canada is not the first or only country to grapple with these issues and the experience of OECD peers should be looked to for best practices and lessons learned. All stakeholders including public and private buyers, brand name and generic manufacturers, patient advocacy groups and academia have a role in devising a drug pricing system that allows all Canadians regardless of their circumstances to enjoy the best patient outcomes on a sustainable basis.

7. Should the PMPRB consider different levels of regulatory oversight for patented drugs based on indicators of risk of potential for excessive pricing?

As a financial institution we are familiar with the global trend toward risk-based regulation. It is a trend that we commend as it focuses regulatory resources where there is the greatest need. Such a risk-based approach would be consistent with the Board's mandate to protect Canadians from excessively-priced patent medicines.

8. Should the price ceiling of a patented drug be revised with the passage of time and, if so, how often, in what circumstances and how much?

There are circumstances under which it would be appropriate for the Board to reconsider the price ceiling of a patented drug. The most obvious of these would be when subsequent therapeutic uses (indications) post initial fixing of the maximum price expands the market/demand for the drug, resulting in higher volumes and revenues for the manufacturer. Soliris serves as a good example. When initially approved in 2009 it was estimated that there were approximately 90 Canadians in the patient population. Subsequent indications with differing dosing protocols have effectively more than doubled the market for the drug with no reduction in price. To the contrary, the price in fact went up.

We recognize that a balance must be stuck when considering any impact of subsequent indications on the maximum non-excessive price. Manufacturers should be incented to seek approval for subsequent indications where there is demonstrated therapeutic value.

We question the practice of allowing annual price increases tied to the Consumer Price Index. This links the drug prices Canadians pay to a number of factors including monetary policy, the international balance of payments, commodity prices etc., that properly have nothing to do with a statutory pricing regime the purpose of which is to protect Canadians from excessive drug prices. Further, the experience with most products that are "innovative" is that they become less expensive over time as development costs are amortized, production volumes increase with wider adoption and competitors/imitators enter the market. This has not been the case with drugs in Canada. It may therefore be appropriate for the Board to reconsider prices on a regular and recurring basis, perhaps every five years, as a price that was not deemed excessive upon initial approval may become so due to subsequent developments.

Additional resources would likely be necessary if the PMPRB were to undertake more regular reviews. The Board would benefit from greater resources in any case as it operates in a space inhabited by some of the most well-resourced and sophisticated corporations in the world. An argument could likely be made that any additional resources dedicated to a more active and effective PMPRB would be more than recouped through lower drug prices.

9. Should price discrimination between provinces/territories and payer types be considered a form of excessive pricing and, if so, in what circumstances?

The PMPRB's mandate is to protect Canadians from excessive patented drug prices. This applies to all Canadians in all provinces and territories and to all Canadians regardless of their coverage or lack thereof under a public or private drug plan. It is the reality of the current Canadian system that drug prices paid can be vastly different from one type of payer to another and from one jurisdiction to another. Those who pay the highest prices are usually the middle-income uninsured who are too young to qualify for public plans. This is a zero sum game from an economic and public policy perspective with those paying less effectively being subsidized by those who pay commensurately more.

In common with almost every other developed country, Canadian drug prices are not purely a function of market dynamics but rather are the product of a state-imposed regulatory scheme. This regulatory

scheme sees Canadians pay sometimes radically different prices for drugs depending on their income, employer and province of residence and results in some Canadians going without the drugs they need due to their exorbitant cost. A state-created regulatory scheme that results in such differential outcomes is arguably discriminatory.

10. Are there other aspects of the Guidelines not mentioned in this paper that warrant reform in light of changes in the PMPRB's operating environment?

When the PMPRB determines that a drug has been excessively priced, the typical remedy is an order to pay an amount to the Crown. While governments are obviously large purchasers of drugs, private payers account for approximately 40% of the market. A mechanism should be developed so that non-government payers including plan sponsors, plan members and private individuals can be appropriately compensated where they have paid excessive prices.

11. Should the changes that are made to the Guidelines as a result of this consultation process apply to all patented drugs or just ones that are introduced subsequent to the changes?

Any changes as a result of this consultation process should apply to all patented drugs. The purpose of the Board is to protect Canadians from excessive drug prices, not only excessive prices on drugs approved after this exercise. Changes made in the wake of this consultation will be tantamount to an acknowledgment that previous practices were not sufficient to protect Canadians. To essentially "grandfather" pre-existing drugs would be to condone these previous practices and leave Canadians paying an excessive price for a number of drugs potentially for years into the future.

12. Should one or more of the issues identified in this paper also or alternatively be addressed through change at the level of regulation or legislation?

As has been mentioned previously, it may not be possible to address all of the issues raised, or indeed to fully realize the objective of protecting Canadians from excessive prices on patented medications by way of a review of the Board's Guidelines. While we are entirely supportive of this process and compliment the Board on the quality of the Discussion Paper, we urge the Government of Canada to undertake a thorough review of the PMPRB and associated legislation and regulation as soon as practicable. It is demonstrable that a regulatory mechanism conceived in the mid-1980s, no matter how well-intentioned or designed at the time, is simply no longer fit for purpose. This also suggests that as part of any review, consideration should be given to insertion of a sunset clause in the PMPRB's enabling legislation in hopes of avoiding another situation where Canada's drug pricing system is 30-years old and out of date.

The work of the Board is important to all Canadians. As an insurer serving more than 12 million of our fellow citizens, and an organization with a corporate goal of improving the well-being of Canadians, we feel that we have an important voice in this discussion. We look forward to the continuation of this process and further consultation.

Yours,

Stefan Kristjanson
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