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October 31, 2016

Patented Medicines Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
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Dear Sir/Madam:

Unifor is pleased to offer the following comments to the Patented Medicines Prices Review Board (PMPRB) in respect of the public consultation regarding prospective reform of the Compendium of Policies, Guidelines and Procedures (Guidelines) in the context of the broader reform and renewal initiative set out in the Strategic Plan 2015-2018.

In 2013, Unifor was formed as a new union resulting from the merger between two of Canada's most influential and progressive unions: the Communications Energy and Paperworkers' union (CEP) and the Canadian Auto Workers' union (CAW). Unifor is now the largest union in the private sector with 315,000 members across Canada.

Unifor also holds to a vision of a sustainable pharmaceutical system that provides Canadians with effective and affordable drugs as are essential to live healthy and productive lives. Our recent 2nd Convention this summer in Ottawa affirmed our demands on the Liberal government of Canada to support and renew Canada's public Medicare system; and to expressly work with the provinces and territories to create a national public drug program to ensure equal access to life-saving medication.

Unifor holds that a robust social infrastructure - providing universal access to basic education and health care - is critically essential for Canada to succeed in a global economy. Ironically, every other developed country with a universal health care system also has universal prescription drug coverage, but for Canada. Why is Canada competing with one arm tied behind our backs?

Canadians (and often employers on their behalf) pay more for pharmaceuticals than almost any country in the world, with drug spending on a per capita basis 30% above the OECD average and second amongst OECD countries after the United States. This is clearly unsustainable in the longer term and workplace drug plans are under enormous pressure to contain, if not shift costs.

When it comes to prescription drug coverage, Canadians face a bewildering patchwork of programs and plans, with charity often the last resort. An estimated 38 percent of spending on prescription drugs is through publicly-funded plans providing coverage for the elderly, disabled and/or low income Canadians. More than one third, or 34 percent, is funded by private insurance, with the remainder including another 22 percent that is paid out-of-pocket by Canadians.

Prescription drug spending in the private sector has increased nearly fivefold in only 20 years, from $3.6 billion in 1993 to $15.9 billion in 2013. The lack of universal access often results in real harm - non-adherence or drug interactions result in hospital admissions and additional public costs. It is estimated that private drug plans reimbursed for $5.1 billion in 2012 alone without evidence of that spending yielding any therapeutic benefits in return.

A national pharmacare plan for Canada would improve access and affordability through bulk purchase and negotiated pricing with drug manufacturers; it would eliminate duplication and cost-shifting amongst existing payers while promoting integration amongst health care providers.

A universal pharmacare plan that includes an evidence-driven drug assessment process could also help distinguish between drug products in order to ensure the quality, safety, and cost-effectiveness of prescription drugs. A universal pharmacare plan is not only a way to compensate for or reimburse drug expenses, it is essential as means to control costs through efficient pharmaco-economic assessment of new drugs and by developing bargaining power when dealing with large transnational drug companies.

Previous studies have demonstrated that Canadians could save between 10% and 42%—up to $10.7 billion—of total drug expenditures. Can we continue to afford not to implement such a plan?

As far back as 1964, the Royal Commission on Health Services recommended that a universal drug insurance plan be established for all Canadians. The National Health Forum, under Jean Chrétien in 1997, recommended universal drug coverage. The Romanow Commission in 2002 recommended catastrophic drug coverage as a first step towards universal Pharmacare.

A universal Pharmacare has even more pharamcare champions today such as Ontario's Health Minister Eric Hoskins; a passionate advocate willing to state the obvious case that access to prescription medicines must be more equitable in Canada; and would improve health outcomes; but also that such a plan would generate savings for all Canadians of up to $10.7 billion in prescription drugs. Unifor intends to remain such a champion and we offer the following comments in respect of the topics reviewed in the Guidelines.

Yours truly,

Jerry Dias
National President

cc: Katha Fortier, Corey Vermey

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UNIFOR RESPONSE'S TO THE 'GUIDELINES' QUESTIONS Patented Medicines Prices Review Board Guidelines Modernization Discussion Paper

Patented Medicines Prices Review Board
(Rethinking the Guidelines)

UNIFOR RESPONSES TO THE 'GUIDELINES' QUESTIONS

Patented Medicines Prices Review Board Guidelines Modernization Discussion Paper

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

The Merriam-Webster dictionary meaning of "excessive" is "*going beyond what is usual, normal, or proper*". That definition suggests that both comparative (usual or normative) and ethical (proper) considerations are equally inherent in assessing 'excessive'. Within the context of drug therapies and technologies that save lives and are measured in quality adjusted life years (QALYs), pricing and excessive pricing can have similarly varied connotations when viewed from the perspective of either pharmaceutical corporation; health care providers or patient with constrained resources and declining health.

In the end, 'excessive' drug pricing is certainly a comparative and inherently an ethical matter related to the perceived balance of benefits as between patients and pharmaceutical companies. We agree with the current leading candidate for the Office of the President of the United States; who states "[i]*t's wrong when drug companies put profits ahead of patients, raising prices without justifying the value behind them.*" Recent events involving most notably Turing Pharma and its former CEO Martin Shkreli, or Mylan EpiPens have added a further dimension to the debate around social licencing and monopoly patent exclusivity; as they have compromised the legitimacy and credibility of Pharma more generally. Exploiting patent exclusivity to transform the market potential or capitalization of a corporation is to transform the altruistic social mission of tending to the sick into a selfish commercial opportunity.

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

Certainly a drug should be considered excessively priced if the agreed upon economic metric incorporates specific criteria that involve more than just:

i) average transaction price above 5% of average potential price for new products; or
ii) cumulative revenues greater than CAD 50,000 or more over the life of the patent.

For instance, there is a consistent failure resulting from the limited scope permitted under the PMPRB legislation to consider drug pricing more generally in relation to the net budgetary impact of newly patented drugs or technology or comparative health technology assessment. It would be relevant to consider drug pricing in relation to broader comparative drug and health system spending; i.e., budget impact analysis, and an assessment of net cost or efficiency of the drug in relation to other drug and non – drug alternatives such as through determining the incremental cost effectiveness ratio (ICER).

Relying simply on measuring pricing against classes of drug purchasers within Canada for existing drugs and/or measuring global prices within only seven domestic markets for new drugs is a major hurdle in determining whether the drug is 'excessively priced'.

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

The Human Drug Advisory Panel (HDAP) change in guidelines in 2010 provided a more formal review process with 'break through' drug products being measured against PMPRB's assessment guidelines involving increased efficacy, reduction in incidence or grade of important adverse reactions. Newer drugs that cost exponentially more than current drugs will essentially have higher ICERs. However, the framework essentially fails the needs of our country since there is no uniform adoption within Canada. Many provinces do not list drugs with high ICERs even though the Common Drug Review (CDR) may issue positive recommendation or may list drugs in spite of obtaining negative recommendations. As well, additional provincial/territorial expert reviews may further delay listings that inadvertently forces Canadians to pay more for medications.

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?***

For decades Canada has been viewed as a nation that embraces innovation and offers among the best in health and technology that the developed world has to offer. In our view, a very costly drug treating only a small group of patients that accounts for a very small proportion of overall spending on drugs within Canada should be of no material significance, although, it should be of material significance to the nation on how the drugs are being procured which can ultimately determine the price.

For instance, adopting a common national formulary strategy within the landscape of equal access to all drugs and technologies or a more rigorous national pharmacare strategy can ultimately result in the efficient allocation of drug spending within the global health budget of all Canadians.

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?***

Surely, sales mix and/or sales volume of any drug has a critical role to play especially where and if the drug accounts for a disproportionate amount of the overall spending in Canada. A drug's price could be deemed excessive in relation to volume even if it is below any agreed upon per unit metric within the same therapeutic class.

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

A methodology that assigns proportionate weight to the sales volume generated towards the same drug within several indication categories, across different payor markets and within a benchmark of OECD pricing, should be the priority economic consideration relevant to the

determination of whether a drug is fair or potentially excessively priced. An exhaustive search for therapeutically equivalent products licensed by the brand name drug manufacturer to a generic manufacturer in other countries should be simultaneously conducted in negotiating any market-specific transaction price.

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?***

International public list prices serve as but one, among other reference points, when determining the non-excessive price ceiling for a drug. In the consultation paper, the PMPRB acknowledges that the current reality is that actual prices being paid in European countries, for example, are below the public prices that the PMPRB is constrained to use for international purposes. Since confidential discounts and rebates are common practice around the globe, the consultation paper appropriately points out the unreliability of public list prices, which at best, serves as an adjunct to other tools and factors in determining excessive drug prices.

As such, the PMPRB should place international public list prices in this context by still incorporating, albeit limiting the impact of international public list prices in determining price ceilings, while also examining other important international factors. This includes looking at more appropriate or relevant comparator jurisdictions – placing more weight on those jurisdictions with national drug programs and less weight on those that have less regulation – and looking at the low end of drug prices in comparator regions, among other factors.

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?***

Subsection 85(1) of the *Act* stipulates those factors that must be taken into consideration when determining whether a patented medicine has been sold or is being sold at an excessive price in any market in Canada. Those factors include the prices at which the medicine (as well as other medicines in the same therapeutic class) is being sold in other relevant markets; a form of market-based reference-based pricing. The remaining factors that must be considered include inflation and any other specified regulatory factors.

The *Act* at subsection 85(2) also provides that the Board may also consider the actual production and marketing costs of the medicine. We would submit that a critical additional relevant factor in any determination of whether drug pricing is 'excessive', moving beyond simple reference-based pricing is assessing the value proposition offered by the pharmaceutical product.

Value-based pricing policies, according to the publication, "*Investigation and Analysis of Options to Enhance Canada's Patented Medicine Price Ceiling Regulatory Regime*", by the Institute of Health Economics (IHE) are viewed as a "potential means to resolve existing tension across competing policy objectives that have not been resolved through reference-based policies; namely, to create maximum health benefits for consumers, opportunities for health system sustainability and clear incentives for future producer innovation."

Value-based pricing would also be inherent for the vast majority of OECD countries with universal pharmacare coverage schemes that allow for price negotiation/regulation connected to the public insurance reimbursement and/or direct purchasing of patented medicines. Any new entries into existing therapeutic classes should only be 'priced' in relation to their value proposition - the extent of therapeutic improvement above or beyond that provided by existing generic drugs in that therapeutic class.

Comparative effectiveness is also a relevant criterion - examining how well a health technology works under routine ("real world") conditions as compared with one or more different technologies that are or could be used for the same purpose. To operationalize this criterion, we would as a country across all jurisdictions need to become far more consistent and determined to report and capture adverse medical events or patient safety incidents involving prescribed medications.

Certainly we need a system of pricing and reimbursement for pharmaceutical products that fosters spending on R&D but more importantly that leads to R&D that discovers 'new' medicines that are indeed safe and truly innovative and/or truly required - that provide a true value to both patients and producers.

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)?***

The PMPRB should set excessive price ceilings in relation to a value standard rather than simply anchor to reference prices by way of explicit comparison to existing external price standards. At the very least, the PMPRB should discount and adjust for prices set in external markets that are not comparable and not themselves subject to any regulation; permitting producers to charge whatever that market will bear.

Alternatively, the PMPRB should incorporate internal reference prices to analogous chemical, pharmacological or therapeutic properties and/or effects. By benchmarking the price ceilings at the low end of the PMPRB7 countries, the PMPRB would be addressing one of the most important elements of the discussion: the high cost of badly-needed patented medicine products in Canada.

At the same, the PMPRB should consider the marginal costs of production (costs of research, production, promotion, and distribution) in any determination of 'excessive price', and the benefit potentially or actually realized as a result of the therapeutic innovation resulting from the patent. The resulting operational definition of 'excessive price' would then bear direct relation to the societal value of permitting exclusivity through patent monopoly in relation to the therapeutic benefits of treatment by the pharmaceutical relative to complimentary and/or alternative treatment modality.

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 should set its excessive price ceilings no higher than at the low end of the PMPRB7 countries. The amount of research that the pharmaceutical industry in Canada conducts relative to

these other countries does not significantly impact this position and therefor is separate and apart from consideration directly of the comparative reference for establishing the excessive price ceiling.

As mentioned in the discussion paper, Canada's growth in patented drug expenditures as a share of GDP has outpaced the PMPRB7 since 2000 and has increased by 184%. This reflects the fact that Canadian drug prices are now 35% higher than the OECD average for the same drugs. Given that R&D investment simultaneously declined over the last three decades and has reached record low-levels, it is evident that the patent exclusivities or monopolies that have been afforded to such companies have simply led to higher consumer prices and not to the desired R&D investment.

The level of R&D conducted within Canada – as a relevant metric for consideration of industrial strategies - is simply overwhelmed by the pharmaceutical industry's desire to maximize shareholder value and profit. Canada's approach of benchmarking prices against countries with R&D levels it sought to emulate has not worked and should be revised.

There is no evidence to suggest that using lower excessive price ceilings would significantly impact the level of R&D investment (especially in a negative way). By benchmarking the price ceilings at the low end of the PMPRB7 countries, the PMPRB would be addressing one of the most important elements of the discussion: the high cost of badly-needed patented medicine products in Canada. As the discussion paper reveals, consumers would have saved nearly $3.6 billion if Canadians paid the OECD average for these products.

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?***

We understand that the PMPRB presently categorizes newly patented medicine sold in Canada according to recommendations provided by the expert advisory committee (Human Drug Advisory Panel or HDAP) into four distinct categories of therapeutic improvement:

i. Breakthrough Improvement
ii. Substantial Improvement
iii. Moderate Improvement
iv. Slight or No Improvement

The extent of therapeutic benefit relative to other drugs within the therapeutic class remains relevant but there should be a parallel categorization in respect of the dimensions of health needs addressed in terms of the significance of the patient population. There would then be a distinct consideration of the extent to which the therapeutic benefit was socially relevant in terms of 'depth' - relevant to rare medical conditions or diseases not otherwise commercially attractive; and 'breath' - relevant to the scale or population of patients that would be treated.

If it was intended as a component policy objective for the PMPRB through the enforcement of the Patented Medicine Regulations (SOR/94-688) to strengthen rewards and incentives for prospective patentees, it becomes essential to acknowledge when the patentee has indeed acted altruistically or beyond mere commercial interest. If the patentee has expressly limited their commercial ambitions in expending R&B dollars in search of a therapeutic solution for rare medical conditions or diseases, the

balance in terms of reward or incentive may fall closer to the patentee than when commercial advantage is sought through only moderate improvement in an otherwise crowded therapeutic class.

The related issue is whether it is merely an issue of pricing when the extent of therapeutic benefit relative to other drugs is in the nature of a 'breakthrough improvement'. We need to ensure that federal and provincial regulatory bodies are acting in synchronicity in drug evaluation and review to ensure that the opportunity to reduce treatment cost is realized not merely in relation to complimentary pharmaceutical products, but other existing treatment modalities as well.

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

While every effort should be made to ensure safety and efficacy of drugs prior to public launch within Canada should be of paramount importance, federal and provincial regulatory bodies offer frameworks that discourage faster launches and evidently slower adoption within provincial drug review boards even after the patented drug has received a positive recommendation.

Cockburn, Lanjouw and Schankerman in their seminal paper "*Patent and the Global Diffusion of New Drugs*" noted that the observed timing of market entry reflects both the decision of the patentee firms and the efficiency of a country's regulatory process; for instance, adopting a national formulary or an Essential Drug List. One of the main conclusions drawn from the study is that the long duration of product patents have a powerful effect on limiting the diffusion of pharmaceutical innovation.

Recognizing that stronger patent rights and the absence of price regulation promote faster launch and that in itself an environment that raises prices, it is clear that much work needs to be done in terms of offering a streamlined approach within the fragmented framework of Canadian approval and listing processes without sacrificing the safety of Canadians. The paper itself offers an approach towards introducing multilateral recognition of drug trials and regulatory approval, thereby lowering launch costs and speeding up drug diffusion.

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?

Considering the many studies in Canada that have discussed the issue of cost related non-adherence, price ceilings on patented drugs should undergo frequent periodic reviews. Price ceilings can be influenced by a number of factors: approval for an increased number of indications or off-label use, or emergence of competitive drugs/technologies within the same therapeutic class or whether the affordability of the entire Canadian health budget is proxied by a percentage of the GDP.

A periodic reassessment should have been a natural approach from the start. A prescriptive study (CMAJ Law, Cheng, Dhalla et al– 2012) suggests 9.6% of Canadians who had received a prescription in 2011 reported cost-related non-adherence. Furthermore and quite tragically, the study found that patients in poor health; without drug insurance and those who lived in BC were more likely to report cost related non-adherence.

It is quite clear from these observed findings that not re-assessing patented drug pricing periodically within the broader context of affordability is causing an unnecessary burden on patients and the health system. Stuart, Doshi and Terza (2009) found that outpatient prescription drug expenditures create "cost savings for Medicare beneficiaries" once reduced hospital costs are considered.

However, it is observed that PMPRB's current practice of reviewing patented price increases annually relative to just CPI is a woefully inadequate approach and creates an environment of unaffordability for low-income Canadians and those without health insurance plans.

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

Excessive pricing in relation to the PMPRB mandate is a matter of 'consumer protection' from the capacity of a provider to exploit patent monopoly 'unduly' in regards to therapeutic benefit. Clearly, in respect of the public health system, large purchasers including public purchasers have the capacity to combine in response to the monopoly provider to balance or level the market dynamic through negotiations.

To illustrate, collaborative negotiations through the pan-Canadian Pharmaceutical Alliance (or pCPA) may have yielded an estimated $490 million in combined annual savings as of March 31, 2015 on 63 brand name and 14 generic products. The pCPA is a critical element or component of any prospective universal pharmacare program in Canada - allowing the public provider to combine the negotiating power of public drug plans across multiple provinces and territories, and to leverage that power in furtherance of pCPA aims to increase access to drug treatment options; achieve lower drug costs and consistent pricing, and improve consistency of coverage criteria across Canada.

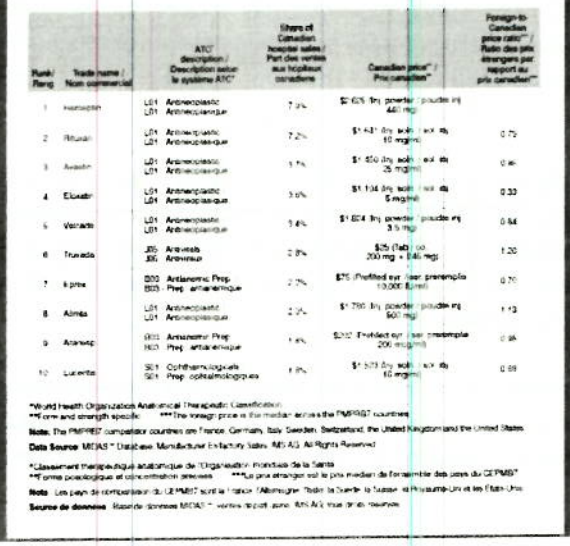
Obviously in the absence of a national pharmacare program, other jurisdictions or purchasers not part of the Alliance have to make tougher choices on whether they should or should not list these products in their respective plans. What of the other drug products that are not cancer related given that pCPA's predominant area of focus has been oncology.

A case in point is a recent Quebec Auditor's value for money (VfM) audit in 2015 that examined the cost of medications for five different hospital groups. The audit found a price variance of more than 10% for the same drugs and illegal kickbacks being paid to local health board pharmacies. To quote another example, PMPRB's successful $60 million ratiopharm settlement strongly illustrates that absent a national pharmacare strategy, our country remains subject to drug price inflation that is neither necessary nor sustainable.

As the data in the *Cost Pressures in the Canadian Hospital Drug Market, 2006–2014* table below indicates, hospital prices on top selling drugs in Canada are typically higher than PMPRB7 counterparts. We strongly recommend the PMPRB give consideration to categories or types of payer/sub-markets as well in considering whether there is evidence of 'excessive pricing'.

6. The hospital prices for top-selling drugs tend to be lower in foreign markets than in Canada.

The table lists the 10 top-selling drugs for the hospital market in Canada, which account for 36% of hospital sales. For many of these drugs, the median foreign price is below the Canadian level (a ratio lower than 1).



6. Les prix d'hôpitaux pour les médicaments les plus vendus ont tendance à être plus bas dans les marchés étrangers qu'au Canada.

Le tableau présente les dix médicaments les plus vendus sur le marché hospitalier au Canada, ce qui représente 36 % des ventes aux hôpitaux. Pour bon nombre de ces médicaments, le prix étranger médian est inférieur à celui du Canada (ratio inférieur à 1).

Price and volume (market share) also operate in tandem as the PMPRB *Market Intelligence Report 1st Edition: Biologic Response Modifier Agents, 2015* demonstrated. That report identified that Remicade accounted for nearly 40% of the Canadian market for biologic DMARDs for the treatment of rheumatoid arthritis and cost close to 50% more per patient than the class average based on 2015 public drug plan data.

The Report acknowledged the market share for Remicade was much lower in the PMPRB7 countries, ranging from 12% to 23% in 2015, with a median list price 25% less than in Canada - a price differential that translated into $224 million in drug sales or 1.0% of the entire Canadian pharmaceutical market.

Another study (Heinsohn and Flessa) from Germany published in the BMC Health Services Research in 2013 on pharmacy competition proves the same point. Even after 10 years of reforms and deregulation, public payers (hospitals), private payers (employer sponsored plans) and individuals are powerless by themselves to force even pharmacies to offer price discounts on pharmacy fees and drug mark ups.

It is also common knowledge that patentees routinely provide discounts and rebates to their largest paying customers which in itself accounts for 80% of drugs under PMPRB jurisdiction. It should be self-evident that the case for a unified Canadian entity negotiating prices with drug manufacturers is stronger under a national pharmacare program for all Canadians.

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?

The Guidelines speak to two issues of particular interest to Unifor in respect of changes in the PMPRB's regulatory environment. The first matter is the notice that at the time of the creation of the PMPRB little was empirically known in regards to the relationship between drug pricing, IP protection and R&D investment. In that context, it was a matter of trust that brand name Pharma (Rx&D) would respond in view of the legitimacy granted to extended patent exclusivity with further innovation and a steadfast and relevant commitment to R&D in Canada.

The PMPRB should re-consider the Guidelines expressly in view of the repeated and prolonged failure of brand name Pharma (Rx&D) to achieve R&D spending as a percentage of sales in Canada anywhere near the 10% the industry committed to when their periods of market exclusivity were increased in 1987.

The PMPRB's latest annual report notes that in 2015 member companies of Innovative Medicines Canada (formerly Rx&D) spent only 4.9% of their Canadian revenues on research and development in Canada, marking the 13th consecutive year they have failed to meet the 10% percent threshold. At the same time, the aggregate ratio for R&D spending to domestic sales for all comparator countries was 22.8%, five times greater than Canada.

The presumption that pharmaceutical companies would generally seek to avoid abusing their newly strengthened patent rights has been a quaint fiction for too long. Given that shortening patent duration is 'not on the table', the issue of excessive pricing needs to consider pricing throughout the duration of patent exclusivity.

We would also suggest that the Comprehensive Economic and Trade Agreement (CETA) and Trans Pacific Partnership (TPP) trade agreements are factors that should be considered by the PMPRB. There is a general consensus that proposed further extension of patent protections under CETA will drive up drug costs for millions of Canadians – increasing by between $850 million to $1.6 billion, annually (based on CCPA study estimates). Not only will this make Canadian health care less affordable for citizens, this will place additional strain on negotiated workplace benefit plans for active and retired members.

Another detailed study of this issue by two of Canada's leading health economists, estimated the EU trade proposals would delay the availability of generic drugs by an average of 3.5 years at a cost to Canadians of $2.8 billion annually. That study, *The Canada-European Union Comprehensive Economic & Trade Agreement: An Economic Impact Assessment of Proposed Pharmaceutical Intellectual Property Provisions*, authored by Hollis and Grootendorst has not been successfully rebutted by CETA advocates.

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?

The changes that are made to the guidelines as a result of this consultation process should apply to all patented drugs. Applying the changes only to the ones introduced subsequent to the changes would have a limited impact on drug pricing since they would make up a small proportion of the market.

The PMPRB has a crucial role in protecting consumers from excessively priced patented medicines. In order to make an impactful change on the accessibility of such medicines – and subsequently the health of Canadians – any change in policy needs to have the largest scope possible. This includes tackling the prices of patented drugs that Canadians and insurance companies have been historically overpaying for and will continue to rely on.

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?

The largest issue that needs to be addressed through legislation is fundamentally how to provide universal access to medications for all Canadians. It is Unifor's view that this can only be achieved through a national drug program that is funded and administered by the federal government and in partnership with the provinces and territories.

Like other jurisdictions where a national drug program does not exist, when drug prices are left to the market and a fractured consumer base, drug companies are allowed to charge excessive prices for their products, leaving many people without the medicines they need. In the longer term, establishing a national program provides Canadians with universal access to medicines in the most cost-effective way that also ensures the safe and appropriate use of medications. Creating such a framework would require federal leadership given its role and jurisdiction over health care in Canada.

We already have the fundamental infrastructure in place to create a national program and transitioning to such a program can be done in a sensible manner. Canada already has a universal public health care system – however, it is the only country in the world with such a system that does not include access to prescription medication. We have a pan-Canadian framework for elaborating public health policy, approving medicines for safety and efficacy and for collecting and disseminating health data, among other functions. The PMPRB already plays a relevant role in protecting Canadian consumers and supporting consumer access to affordable drugs.

While public drug plans already exist, they are but a patchwork of different federal, provincial and territorial plans that cover approximately 30 per cent of the population. In some jurisdictions, public plans only cover seniors, people on social assistance or those suffering from certain illnesses. Provinces and territories already participate in common drug formularies and bulk-buying arrangements. However, there is no consistency between these jurisdictions with regard to coverage, consumer cost and drug lists, which results in differential access to medications across the regions of Canada.

With a national program, negotiations on drug prices can be done at the national level, which would provide the public payor with considerable leverage when negotiating drug prices with multinational corporations. This greater balance in bargaining power would fundamentally reduce the cost of medications for all Canadians. This buying power combined with reducing administrative costs and relieving pressure on the health care system through better access to medications, could save Canadians an estimated $10.7 billion annually on health care costs.

It is clear that the most sensible solution to the drug pricing problem – and more broadly the accessibility and affordability of medications for all Canadians – is the creation of a pan-Canadian universal public pharmacare program within our federal health care framework.

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