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Re: Protecting Canadians for Excessive Drug Prices

Executive Summary:

In the 30 years since PMPRB was established to regulate the prices of medicines set by patentees, the environment has shifted. While there is no denying that an evolving environment warrants a modernization of PMPRB, the original mandate remains relevant and unique; "to ensure that patentees do not abuse their patent rights by charging consumers excessive prices during [the] statutory monopoly period".[1] In contrast, cost-effectiveness, affordability, willingness and ability to pay, price negotiations and reimbursement decisions are the purview of provincial governments, drug plans, and other agencies and organizations.

The Consultation Document highlights that PMPRB is looking to move towards a risk-based approach and while we agree with the premise that more focus on those products with a higher potential for excessive pricing is appropriate, we do not believe the current proposals on the whole, achieve that objective. The proposals appear to suggest a large increase in regulatory burden; if applied to all medicines and this is in stark contrast to the PMPRB's stated objective of moving to a risk-based approach. Therefore, until further clarified, we must assume the proposed changes will be applied to all patented medicines which seems highly unnecessary and impractical. Also as the consultation process currently stands, constructive feedback is limited by the sparse information that has been provided Consultation Document and we would encourage a more robust follow up consultation period be initiated.

GlaxoSmithKline strongly supports the notion that PMPRB, Canadians and innovators will benefit most from simple "bright line" regulations which decrease regulatory burden and unnecessary reporting and yet at the same time focus efforts on those products which have the highest potential for excessive prices. In specific cases, where this approach does not provide sufficient control, PMRPB has the power to request additional information to help determine if a price is excessive as per Section 85 (2b) of the Patent Act. Therefore, additional regulations, which affect all products and cause unnecessary regulatory burden, such as the proposals outlined in the Consultation Document, are not required.

GSK firmly believes the innovative pharmaceutical industry is more than just a supplier in the health eco-system and that discourse and collaboration between industry, governments and other relevant stakeholders, working towards a robust strategy to ensure stability and predictability, is the best way to ensure the future health and wealth of our country.

[1] Protecting Canadians from Excessive Drug Prices, Health Canada, May 2017

Introduction:

The consultation document entitled "Protecting Canadians from Excessive Drug Prices" (Consultation Document) identified that "In January 2016, federal, provincial and territorial Ministers agreed to work together to improve the affordability, accessibility and appropriate use of prescription drugs to better meet health care system needs....". As an innovative pharmaceutical company which has been a part of the Canadian fabric for 115 years, GSK is fully aligned with that goal and is committed to ensuring Canadians have access to the right medications at the right time for the right price. We recognize that this is an important and integral component in achieving a sustainable healthcare environment and the critical role the pharmaceutical industry plays. We welcome the opportunity to provide a written submission to the PMPRB consultation document. More importantly, we welcome the opportunity for an open and ongoing dialogue and subsequent commitment with the all relevant payers and governments to ensure that Canadians can optimally benefit from innovative medicines.

The premise of the current consultation revolves around updating the PMPRB regulations to ensure Canadians do not pay excessive prices, by today's standards. We agree that regulatory reform is important and necessary to modernize the current regulations. However, if we do not pay attention to the limits of PMPRB's authority, the broader health ecosystem, and the ever-changing environment, Canada will soon find itself over-regulated and out of date once again. Therefore, to produce real and effective reform, we must not only simplify and modernize the regulations but ALSO consider additional eco-system approaches which allow us, as a nation, to be flexible and responsive to the evolving environment. Across Europe, governments and the pharmaceutical industry are developing sectoral agreements that balance access to medicines with support for innovation. As of January 2016, nine European countries had voluntary agreements or memoranda of understanding with three more undergoing negotiations.[2] There is significant value when payers, regulators and innovators collaborate on binding agreements. As experienced in these markets, this can create the real time ability to address excessive pricing and sustainability without unnecessarily limiting Canadians nor Canada's access to the innovations which are important to health and wealth of the nation.

Addressing the Requirements for Regulatory Changes:

In the Consultation Document, Health Canada is proposing a number of changes to the Patented Medicines Regulations to "ensure" that the prices of patented medicines in Canada are not excessive. Before we address the merits of each of the individual proposals, it is important to consider the overall suggested approach in light of the specific requirements the Federal Government imposes on regulations as a test of their appropriateness/relevance.[3] We will briefly address this in the following section and then specifically address the five proposals of the Consultation Document and the next section.

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[2] European Federation of Pharmaceutical Industries and Association Publications, https://www.efpia.eu/publications/data-center/collaborative-solutions/stability-agreements/

[3] Guide to Making Federal Acts and Regulations: Part 3 – Making Regulations, Privy Council Office, Government of Canada

Requirement #1: Federal Government intervention is justified and regulation is the best alternative

The Federal Government has the constitutional authority to ensure that there is no abuse of patents (non-excessive prices); the provincial governments have the constitutional authority to address pricing -*vis a vis* affordability. Consequently, for PMPRB to move towards addressing affordability would be overstepping its bounds. Furthermore, when one reviews PMPRB annual data there is significant evidence that the regulations are working well to control excessive prices, as Canadian prices are already below the international median established by PMPRB.

With respect to alternative solutions, regulations already exist and, while there may be some need to modernize them, it is not clear that other alternatives have been explored. GSK, and indeed the pharmaceutical industry, is fully prepared to sit down and negotiate stability and predictability agreements with Governments/payers for individual products and/or for the pharmaceutical sector as a whole. Such an approach, which would be in addition to reasonable pricing regulations, would be flexible, responsive, and generate the most value for Canadian patients and the healthcare ecosystem.

Therefore, we believe Federal government intervention on "affordability" is not justified and there is no evidence that better alternatives have been explored to date.

Requirement #2: Canadians are consulted and have an opportunity to participate in developing or modifying regulations

A consultation period of 30 business days has been established for interested parties to provide a written response to the proposals put forward by Health Canada. These proposals are short on detail and therefore very difficult to properly assess and comment on, especially since it is based on a complex, existing process which has worked well for 30 years. In addition, Health Canada reached out directly to select parties (including our Industry Association but no individual members) to participate in a two-hour engagement session within 14 business days of publication of the Consultation Document.

Therefore, while Health Canada can claim they have consulted with Canadians, this minimal approach provides little opportunity for credible discourse and calls into question how well Canadians are served through this process.

Requirement #3: The benefits outweigh the risks to Canadians, their governments and businesses

The narrow focus on reduction in spending on pharmaceuticals without reference to other parts of the health ecosystem runs the risk of significant unintended consequences. For example, while Canada may spend more per capita on pharmaceuticals, we spend commensurately less per capita on hospitals.[4] The question becomes which health expenditure provides the most benefits for Canadians?

[4] 2015 International Profiles of Health Care Systems, Commonwealth Fund, January 2016

Is it necessarily a bad thing to spend more/capita on pharmaceuticals than hospitals when in fact many medications are designed to keep patients out of hospital - this may be the difference between healthcare and illness care. To focus exclusively on reducing expenditure on pharmaceuticals without regard for its impact on outcomes and health system utilization may prove to be folly.

We are not downplaying the government's position that prices in Canada are too high and that the current system is unsustainable. We support the assertion that there is a need to address sustainable pricing and that the pharmaceutical industry has an important and responsible role to play, but regulation is not the only way. Nonetheless, achieving sustainable pricing should not be done at the expense of access or it runs the risk of undoing the very benefit it is trying to. According to Health Canada's own data, released weeks before the Consultation Document, the proposed new comparator countries all have delayed market entry for new products relative to Canada.[5]

By focusing exclusively on drug prices and ignoring the broader elements of the health ecosystem, we are exposing ourselves to a number of significant unintended consequences which will directly impact the health of Canadians. We believe the benefits of such broad sweeping changes do not outweigh the risk.

Requirement #4: No unnecessary regulatory burden

The Consultation Document purports to apply a "risk-based approach to modernizing the regulations", yet as far as can be ascertained it proposes adding significant unnecessary regulatory burden for all product submission/monitoring (increased country reporting, provision of pharmacoeconomics, etc.). A true risk-based approach would focus only on the small percentage of products which put Canadian prices at risk and for which there are few or no domestic comparators such as orphan drugs, cell and gene therapies, or other specialty pharmaceuticals for rare diseases. Similarly, the vast majority of other products such as those with direct comparators (generics, multiple therapeutic options) require significantly less regulation since today's market forces are successful in keeping prices down.

We believe that as the Consultation Document proposals currently stand, significant regulatory burden will be added to both innovative medicine manufacturers and PMPRB and that this additional encumbrance will not add any incremental value to the determination of excessive price.

Requirement 5: Intergovernmental agreements are respected and full advantage is taken of opportunities for coordination with other governments and agencies

As previously discussed, the Federal Government has the constitutional authority to ensure there is no abuse of patents and moving towards affordability and pricing ignores the powers given differentially to the Federal and Provincial authorities through the constitution. Furthermore, for PMPRB to pursue an "affordability" mandate ignores not only the established purpose of the PMPRB, but the broader ecosystem which currently regulates cost-effectiveness, affordability and

[5] Meds Entry Watch 2015, NPDUIS, April 2017

reimbursement in Canada. None of the other organizations which are integral to our pharmaceutical ecosystem today (Common Drug Review (CDR), pan-Canadian Oncology Drug Review (pCODR), Institut National d'Excellence en Sante et en Services Sociaux (INESSS) and the pan-Canadian Pharmaceutical Alliance (pCPA)) existed at the time PMPRB was established but they have developed in the ensuing years to effectively fill gaps in the Canadian pharmaceutical system. The duplication of processes which are already addressed by the above organizations increases the potential for contradictory recommendations which would serve to add complexity rather than simplify.

To step beyond federal authority (preventing abuse of patent rights) or to attempt to address mandates of other government bodies and agencies which are now an effective part of the broader ecosystem would not be respectful of, nor seen as taking full advantage of opportunities for coordination.

In summary and based on the Federal Government's own principals for regulatory reform, we believe the case for significant regulatory modernization is weak. Therefore, we would suggest that any reform must remain focused within the mandate of the PMPRB, and it must serve to reduce regulatory burden by using a practical risk-based approach to address those products at greatest risk of excessive prices. Notwithstanding this position, we recognize the specific proposals contained within the Consultation Document and have attempted to address each one in the section that follows.

Addressing the Specific Proposals:

<u>Proposal #1: Introducing new factors to help determine whether a price is excessive</u>

a) *The pharmacoeconomic evaluation for the medicine and other medicines in the same therapeutic Class in Canada and in other Countries other than Canada:*

The concept of introducing pharmacoeconomic (PE) evaluations to help ascertain "cost-effectiveness" has merit and is an established standard in health technology assessment (HTA) but not for determination of excessive prices. These evaluations compare the cost and benefits of one pharmaceutical intervention to alternative treatment options and are combined with a variety of other considerations in the HTA process to help inform drug funding decisions. But even in this area they have limitations as the authors of the Consultation Document point out: "a drug can be considered cost effective yet still be priced at a level that may result in short term rationing by payers because of the prevalence of the condition it is indicated to treat." If the utility of such analyses are questionable at times for determination of cost-effectiveness (for which they were developed), how much less useful are they for determinations of excessive price? It should also be noted that as the complexity of future innovations increases, such as cell and gene therapy products and other monoclonal antibodies, traditional valuation processes, such as cost-effectiveness analyses, will be detrimental. For example, a singular focus on price rather than clinical outcomes in the UK has effectively reduced access to novel cell and gene therapy products for rare diseases. The Consultation Document also proposes the use of these analyses for international comparisons of cost effectiveness. Results of PE analyses have generalizability and transferability restrictions across different populations and settings, as well as in the type of drug being evaluated, and as such

international comparisons would provide little value to the determination of excessive price in Canada. The Consultation Document further states that this proposal has stemmed from international best practices; however, we were unable to identify other jurisdictions which use incremental cost-effectiveness analyses to regulate prices.

The Consultation Document is quite vague on how these CUAs would be used and, given their limited and at times questionable use in HTA, it is difficult to understand how it could bring value to an excessive price exercise.

b) *The size of the market for the medicine in Canada and in countries other than Canada:*

It is unclear what exactly PMPRB is seeking through the addition of the market size information and how it would relate to the monitoring of excessive prices. Manufacturers currently provide market size information in their budget impact analyses but it seems, based on the following excerpt, that the government is suggesting manufacturers should establish their price based not on the current predicted market potential but on what the market potential could possibly become:

> *"Since monopolies are protected from new entrants, prices tend to remain unaffected from subsequent fluctuations in market size. Seeing that firms are assumed to set their introductory prices at a profitable level to recoup initial investment, a subsequent exponential growth in the market size should align and correct prices downwards to a comparable level. Failure to do so could suggest that the original price for an expanded market is now excessive". (pg. 10, section ii, para 3)*

It would appear the rationale for this proposal is based on the following two assumptions:

1. New entrants in the market have no natural competitors to drive the prices down:

While this may be true for a small class of new entrants in the market, the vast majority of products approved by PMPRB have natural therapeutic competitors (in 2015; 84.2% of products reviewed were assigned to "little to no improvement" therapeutic category) implying that, according to PMPRB, there are viable alternatives in the market. These viable alternatives, while important for patient choice, are considered by both HTA bodies in making reimbursement recommendations and payers in making reimbursement decisions. Therefore, the prices of these medicines are directly controlled by payers through the mere presence of these alternatives in the market and there is little/no risk of abuse of patent rights (excessive pricing). The corollary to this is that 15% of the medicines that went through PMPRB during the same time period were assigned "breakthrough" status and, therefore could be at greater risk of being excessively priced as they have limited/no direct competitors. However, even in these cases as the market develops and competitors evolve payers take the new entrants into considerations to challenge prices – as seen with the Hepatitis C products at pCPA. These natural controls need to be able to develop.

In a true risk-based approach, the system would focus on addressing this 15%. In 2015, this would have represented 13 products of the 86 new drug products submitted to PMPRB and a

customized and focused approach would be a more appropriate use of resources resulting in a more impactful outcome for Canada and Canadians.[6]

2. Regulations must be put in place to control growth beyond that which is projected by the manufacturers at the submission date:

It is understandable from a payer's perspective that uncontrolled market growth, due to unpredicted increased utilization and/or "indication" creep, is of concern. However, it does not make sense to regulate based on fear or "what ifs". Again we are living in an age where bilateral dialogue and agreements between stakeholders can provide a more flexible and appropriate approach to: trade price for volume, cap expenditures, and create pay for performance initiatives to name a few. This is happening today (with both pCPA and private payers and where each new indication generates new negotiations) on top of pre-existing pricing regulations. The potential for these types of flexible arrangements to expand at an industry or manufacturer level is unlimited. Through these arrangements, manufacturers [would] commit to pricing/performance contracts which would permit reasonable and appropriate revenue and growth, payers would be protected from uncontrolled growth and Canadian patients would not be inappropriately denied access to the medicines they need.

In summary, PMPRB is looking to take a risk-based approach to preventing excessive prices. The majority of products reviewed and monitored by PMPRB represent little risk due to the competitive environment and market forces. Therefore, requiring additional PE and market size information for every product, would not only provide no value but would be an unnecessary additional regulatory burden for both the manufacturer and PMPRB.

A more prudent approach would be to deal with the "high risk" products (those with no real competitors) in a more customized and flexible manner requiring PE, market size, or any other data on an "as needed basis". In such instances the requirement to provide these additional data does not need to be regulated since PMPRB already has the ability to require this information under the current regulations as identified in Section 85 (2b) of the Patent Act: "Such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances"

c) Gross Domestic Product in Canada

The final factor proposed in the consultation document is that of Gross Domestic Product (GDP). Though not outlined in the document itself, it is clear that this factor could have possible uses in both the initial price determination as well as price changes over time. PMPRB already has strict limits placed upon price increases through the use of CPI-based adjustments, which incorporates GDP. In fact, Canadian patented drug prices have increased far less than CPI in almost every year since the creation of

[6] PMPRB Annual Report, 2015

PMPRB.[7] Based on this analysis, it remains unclear if PMPRB is seeking to add this factor to control an element of the system which is already controlled, or if GDP will be applied in another fashion.

Regardless of how GDP will be used by PMPRB to determine whether a medicine is priced excessively, if the purpose of this consultation is to provide predictability for Canadians payers on the prices of pharmaceuticals, the addition of GDP is not a suitable solution. GDP varies by province making a single national GDP irrelevant to inform payer decisions and to aid in determining whether a price is excessive. There is also a certain amount of unpredictability associated with the fluctuation of GDP – is it to be expected that pricing would fluctuate over time with GDP?

With a lack of information from the consultation document as to how GDP would be applied to determine if a price is indeed excessive, it is difficult to make an assessment on how this factor would be relevant. Further to this point, the fluctuation associated with GDP makes it unclear how the addition of this factor would benefit Canadians by providing predictability. For these reasons, we recommend that GDP not be utilized as a factor to determine whether a drug is priced excessively.

Proposal #2: Amending the list of countries used for international price comparisons

In the Consultation Document, the authors correctly identify that "*the selection of countries [for pricing comparisons] can have a significant impact on the price ceiling for patented drugs in Canada.*" The authors claim that the original comparator countries (PMPRB7) were chosen because they had a level of R&D investments Canada sought to emulate but that we have never been able to achieve. It should however be understood that, at that time, six of the seven comparator countries already had a well-established innovative pharmaceutical base and each were home to large multi-national pharmaceutical firms which created significant home grown R&D investment. *(The only other PMPRB7 comparator country without a significant domestic presence at the time was Italy, and their PMPRB reported R&D investments remain similar to those of Canada and below the rest of the PMPRB7.)*[8] Canada was, as a result of the legislation of the day, coming out of an extended period of compulsory licensing which effectively drove any innovative R&D out of our country and instead gave birth to "Canada's homegrown pharmaceutical industry"; the generic pharmaceutical manufacturers. Over the past three decades, the Canadian Government has largely been unsuccessful in attracting "R&D" investment on the scale of the PMPRB7 in part due to Canada's lagging IP regime relative to most western nations. [9] Despite this, innovative pharmaceutical companies operating in Canada have been able to attract significant investment in both R&D and infrastructure & capacity building. This has led to the establishment of a world class Biosciences and Life Sciences sector which, as recently as this spring, was identified as one of the six key superclusters our Federal Government is banking on for the new economy. Pharmaceutical companies in Canada continue to invest at around 10% of sales.[10]

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[7] PMPRB Annual Report, 2015

[8] PMPRB Annual Report, 2015

[9] Fraser Institute, Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measures Up, January 2017

[10] Summary of 2013 R&D Spending and Investments by Rx&D Members, KPMG Report, June 2014

Nonetheless, based on historic definitions, the PMPRB challenges whether or not the investments are considered R&D. In many ways this seems to be a moot point because it is clear that investments in Canada continue and benefit to Canadians is derived from them. As PMPRB looks to modernize their regulations, it can be argued they should also modernize their definition of pharmaceutical investment. The world is changing and these extramural and venture capital investments are important contributors to the economy and should be considered as such.

Our industry has continued to invest in Canada and we have maintained our prices at or below the international median of the PMPRB7 since the establishment of the PMPRB.[11] Indeed, in 2015, Canadian drug prices were on average 18% below median international price of the PMPRB7 - the highest difference in over 15 years. Furthermore, when comparing only the prices of patented drugs for which there is no generic equivalent Canadian prices are even lower (43% below the PMPRB7 median prices).[12] Finally, in a recent report by NPDUIS, the PMPRB has reported that Canadian launch prices of new active substances (NAS) are among the lowest in the PMPRB7, slightly higher than only Sweden and France.[13] Thus based on all standards to date our prices in Canada have been deemed to be non-excessive since the inception of the PMPRB. Beyond these controls, pCPA themselves leverage the negotiated net prices to further drive down launch prices of subsequent market entries to achieve a new low cost alternative (LCA).

Despite this evidence of compliance and PMPRB's effectiveness, the authors of the Consultation Document have still argued for the establishment of a new basket of international comparators (PMPRB12) by adding the following new countries which, in their opinion more closely reflect Canada from an economic and consumer protection standpoint: Australia, Japan, Belgium, Spain, Norway, Netherlands and South Korea. It should be noted that all of seven of the proposed comparators have average published drug prices below Canada, and also have delayed market entry of new medicines relative to Canada.[14] The proposal also includes removing Switzerland and the United States from the basket but the reasoning behind this is unclear, except that they are the countries with the two highest average prices of new active substances (launch prices) of the PMPRB7.[15] From a market dynamics and geographic proximity perspective the U.S. is probably our most relevant comparator. At same time that Health Canada (in their capacity as a price regulator) is proposing removing the U.S. from the PMPRB7 basket, Health Canada (acting as a product regulator) is considering revising their cost-recovery framework benchmarked to a number of jurisdictions including the U.S.[16] At a minimum this seems to be a significant inconsistency in approaches.

What at first glance might appear to be a random selection of comparator countries in reality may be a carefully selected group of countries in which the median prices are approximately 20% below

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[11] PMPRB Annual Report, 2015

[12] Source from IMC Analysis of Form 2 Block 5 data submitted to PMPRB, July-December 2015, Innovative Medicines members

[13] Meds Entry Watch 2015, NPDUIS, April 2017

[14] Meds Entry Watch 2015, NPDUIS, April 2017

[15] Meds Entry Watch 2015, NPDUIS, April 2017

[16] Health Canada Stakeholder Webex, Health Products Cost Recovery Renewal Initiative, May 26th 2017, 9-11 am

published Canadian prices. This will serve effectively lower the price of pharmaceuticals as per the Federal government's stated objective, thus creating a self-fulfilling prophecy; Canadian prices WILL BE demonstrated to be excessive by these NEW standards – *sort of a decision-based evidence making scenario.*

Health Canada may opt to change the basket of comparator countries if they so choose (subject to regulatory approval) but is it appropriate to "randomly" choose a collection of OECD countries? Canada is an OECD economy for sure, but more than that we are a G10 or better yet a G7 economy and we should act like it. PMPRB appropriately defines itself as a "counterweight to and reasonable check on the exclusive rights afforded to pharmaceutical patentees"[17] and it should be remembered that the purpose of the granting of patents is to encourage and support innovation in the first place. [18] Therefore, we should be compared to countries with a similar interest in driving innovation and an aligned respect for intellectual property (IP).

One very specific example of this interest is the focus on cell and gene therapy – an exciting new area in therapeutics. Many countries, including Canada have declared a strong interest in stem cell research and Prime Minister Trudeau has specifically called this area out as one of Canada's burgeoning strengths. Clearly these products, which are one time treatments, can completely change the life of a child with a rare genetic disorder have a unique pricing model. To try to regulate its price first before addressing access will i) decrease the ability to make it available to the patients who need it and ii) eliminate Canada's ability to be competitive in attracting this type of investment. This contrast can be seen today in the way the UK is approaching orphan drugs (let alone stem cell therapies) by trying to establish an ICER without regard for access. This is in comparison to the progressive approaches in Germany and France in which access is encouraged, a reasonable price is established and investments are made. This is not to suggest that pharmaceutical manufacturers should be given free-reign in their pricing, rather it is to point out that other factors, including, affordability, access and research investment must be taken into consideration. Regulations are not sufficient.

GSK recommends that the PMRPB uses the countries in the G10 as comparator countries to determine excessive price. Canada has been included as a member of the G10 countries to consult and co-operate on economic, monetary and financial matters based on economic standing. For this reason, these countries would be appropriate comparators to determine the price of innovative pharmaceuticals. According to the OECD data provided in (Figure A) of the Consultation Document changing the basket from the PMPRB7 median to the G10 median would result in in a 10-12% decrease in average published prices in Canada. This would represent an appropriate basket of international comparators by which to establish excessive price determinations, achieve a reasonable decrease in published prices and be an effective springboard for bilateral negotiations on a sectoral agreement with the appropriate stakeholders.

[17] PMPRB Guidelines Modernization Discussion Paper, June 2016, page 14
[18] PMPRB Guidelines Modernization Discussion Paper, June 2016, page 14

Proposal #3: Reducing regulatory burden for generic drugs with a patent:

While the recommendation to remove the systematic reporting for patentees of generic drugs and replace it with a complaint basis is a good way to reduce regulatory burden and ensure a risk-based approach, we challenge if this is going far enough. This proposal is a result of a situation in which the product is subjected to significantly "*greater competition and [therefore] the risk of excessive pricing due to market power is generally not cause for concern*" (page 13). We suggest there are other opportunities for similar consideration in the basket of products PMPRB monitors. As identified earlier, patented medicines can fall into one of two categories: those for which there are no real competitors, those for which there are direct competitors (other therapeutic alternatives or generics). We have previously argued those for which there are no competitors should be subjected to appropriate regulations but similarly we would argue that those for which there are competitors should have proportionally reduced risk-based regulations.

Under the current PM(NOC) regulations some medicines that have been genericized are still compelled to systematically report to PMPRB even though they are subjected to generic competition, and consequently significant market force restrictions. We recommend that this "complaint basis exclusion" also be extended to patent holders of drugs for which a generic NOC has been granted. This would significantly reduce the regulatory burden on manufacturers while having minimal, if any negative impact on pricing. **In the event that the PM(NOC) regulations change we would reserve the right to revisit this recommendation.**

Another important area for consideration would be vaccines that are publicly procured through combined federal and provincial tenders which create a unique set of market forces. In Canada, the tendering process provides government payers a significant amount of control over prices and aids in the establishment of a healthy and competitive price point. However, because the production of vaccines is more complex, it can at times result in unpredictable and constrained global supplies. When vaccine supply is restricted, its global allocation naturally becomes price-related. In these situations, regardless of the willingness of Canadian payers to pay a premium for these vaccines, procurement may not be permitted due to the established price cap set by PMPRB. In reality, PMPRB's intervention does not serve any relevant purpose in this space, rather it creates unnecessary administrative burden (due to resulting investigations) and has potential for limiting or preventing supply of vaccines to Canadian patients.

In summary, we support the PMPRB proposal to remove the systematic reporting for patentees of generic drugs and replace it with a complaint basis but we further suggest they do the same for other product categories in which significant market forces (competition, tenders) exist to reduce or eliminate the risk of excessive prices. This includes, genericized products, products with multiple therapeutic comparators and tendered vaccines.

Proposal #4: Modernizing reporting requirements for patentees

Coinciding with the proposal for the addition of new factors for which PMPRB will use to assess excessive price, the consultation document proposes the addition of reporting requirements to support these new factors. Specifically, filing requirements as they relate to PE and market information have been proposed. As highlighted above, GSK believes that adding these additional factors and, consequently, new reporting requirements, is exceptionally burdensome and provides no value to the determination of excessive prices.

GSK proposes that instead of adding these requirements into regulation, PMPRB should use the power bestowed on them through Section 85 (2b) of the Patent Act which allows for them to ask for additional information from innovators should the board deem it relevant to the discussion of potential excessive price. Using this methodology would allow for PMPRB to adopt a truly risk-based approach for the limited number of products that would be impacted.

Proposal #5: Providing information related to third party rebates

Pharmaceutical manufacturers in Canada had historically operated with a single transparent price across virtually all payers. It was the public payers themselves (beginning with the Province of Ontario with Bill 102 in 2006) that introduced confidential negotiated agreements. The industry complied and this has now grown into the pCPA which negotiates confidential agreements on behalf of virtually every public payer (including the Federal Government) resulting in reported savings of $712 million in combined savings annually (These savings, reported by pCPA, which annually equate to 5.65% of the forecasted $12.6 billion public pharmaceutical spend in 2015.[19,20] are 14 months old and likely a significant under-estimate). Any interference with this process, which is clearly working will over-step the mandate of PMPRB and enter into the pricing realm of the provinces.

The Consultation Document argues that without information concerning the reduced net price to third party payers resulting from confidential bilateral agreements "*the PMPRB is left to set its domestic price ceilings on the basis of information that only includes list prices and does not reflect the actual prices paid in the market" (page15 para 2)*. It also states that access to this information (which they would consider confidential) "*would be taken into consideration by PMPRB when determining whether a patentee is compliant with ceiling set to determine excessive price*." (page 15, para 3). Such an argument makes little sense from the perspective of the regulator because either the patentee is compliant or not. If they are deemed compliant based on published prices than clearly they would be "more than compliant" if one were to consider additional discounts, rebates, etc. Nonetheless, it is unclear just how PMPRB would use this information in their determinations given that the information would be privileged and therefore the findings could not be published. Furthermore, a growing number of these confidential agreements involve the determination of value over and above pricing with each

[19] "The pan-Canadian Pharmaceutical Alliance", Council of the Federation, April 2016
[20] National Health Expenditure Database, 2015, CIHI

being unique to different jurisdictions. This adds an additional layer of complication which may make the utility of these data to any "excessive price" determinations questionable. From an international comparator perspective, almost every other jurisdiction around the world publishes prices that exclude confidential discounts, rebates, etc. and therefore transparent published prices remain the most legitimate comparator.

Perhaps the most significant issue of all is that in 2009 the Federal Court ruled these confidential prices do not need to be reported to PMPRB and it validated that PMPRB's responsibility is to consider ex-factory pricing to customers of manufacturers.[21] This ruling further reaffirmed the role of the Federal Government (via PMPRB) as a regulator of excessive prices and the role of the provinces as responsible for determining what they can and will pay.

We do not understand how PMPRB would make use of these confidential data, nor do we see the relevance to their determination of excessive price as we suggest published prices remain the best international comparator. Finally, we respect the confidentiality of any agreements we have with payers and the Federal Court's determination that these data are not relevant for PMPRB to do their job of monitoring excessive ex-factory prices.

Conclusion:

For thirty years the PMPRB has maintained a stoic presence in ensuring that pharmaceutical prices in Canada were not excessive based on valid international comparators. In fact, during this timeframe, Canadian innovative medicine prices have remained at or below the established international median. At the same time, the pharmaceutical environment in Canada has seen a significant evolution with the development of active HTA and payer components which add significant regulation to market prices and therefore further mitigates the role of PMPRB. Given these changes PMPRB has recognized that it needs to modernize its regulations to ensure that it continues to meet its mandate and yet evolve to remain relevant with the changing environment and new innovations.

As has been suggested throughout this response, PMPRB has the opportunity to commit to a new risk-based approach which could decrease regulatory burden and unnecessary reporting for those products where the risk of excessive pricing is low (due to significant market forces). In turn PMPRB should focus efforts on those products where the "potential" for excessive pricing is high and we call on Health Canada and the PMPRB to simplify the regulations to do so. Furthermore, we submit that while there may be some perceived need to alter the basket of comparator countries, more rigour should be taken in making this determination and that the G10 may be a more appropriate comparator. Finally, and perhaps most importantly we urge the PMPRB to recognize the limits of their mandate and recognize that there are other elements of the ecosystem whose job it is to consider cost-effectiveness, affordability and economic impact. So while the PMPRB must ensure that ex-factory prices in Canada are not excessive, there are other government bodies and agencies that pick up from there to determine

[21] Pfizer Canada Inc. v. Canada (Attorney General), 2009 FC 719

what they can and will pay for. Therefore, we suggest minimal, non-burdensome, and effective regulations to create a springboard for effective and binding sectoral discussions involving a collaboration between industry, governments and other relevant stakeholders. This would ensure greater stability and predictability for all sides, while promoting appropriate consumer protection and overall Canadian competitiveness for investment attraction, minimizing regulatory burden and providing risk-based assurances.

Sincerely,

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Josée Gravelle

General Counsel