

GSK Submission to the PMPRB Draft Guidelines Consultation



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INTRODUCTION

GSK is a science-led global healthcare company tackling some of the world's most pressing health challenges. We have a proud history in Canada, dating back to 1902. GSK has leading positions in respiratory disease and HIV, as well as a robust pipeline of new medicines, including candidate oncology medicines and antibiotics. GSK also has one of the broadest vaccines portfolios of any company in the world, helping to protect Canadians of all ages against vaccine-preventable illnesses.

It is from this perspective that GSK is writing to express our strong concerns regarding the PMPRB's proposed new pricing Guidelines, as they are currently formulated. As with any regulated party across virtually every industry sector, GSK requires **basic standards of regulatory predictability which are not met by the proposed new Guidelines**. If implemented as set out in the draft Guidelines, these new factors will inhibit access to medicines for Canadians and will hinder ongoing consultations on drugs for rare diseases and National Pharmacare.

It is a matter of public record that the innovative pharmaceutical industry is willing to help realize significant changes to drug pricing in Canada. But the new pricing Guidelines proposed by the PMPRB are badly flawed, and if implemented as proposed would completely destabilize the pricing and reimbursement landscape in Canada for innovative medicines. This is in no one's best interest.

There is, however, a better way. GSK is calling for real opportunities to engage in solutions-oriented dialogue with the Government of Canada, the PMPRB, provinces and territories, patient groups and other stakeholders to find a balanced approach to modernizing Canada's 30-year old pricing regime for drugs and vaccines. Through dialogue, we can find ways that meets the legitimate needs of manufacturers for predictability, while ensuring sustainability and access to innovation for patients.

It is with this spirit in mind that GSK is pleased to provide our comments and recommendations regarding the draft Guidelines that were published by the PMPRB. Thank you for your consideration.



Yoo-Seok Hong
President & GM, Canada Pharmaceuticals
GSK Pharmaceuticals Canada

Please note that key elements of our submission were researched and prepared by Canadian Health Policy Institute, to ensure that GSK's recommendations to Canadian policy-makers are accurate, and well-grounded in publicly-available data and evidence.

Recommendation #1

The PMPRB's proposal to set the Maximum List Price (MLP) to the Median International Price Comparison (MIPC) of the new PMPRB11 basket would lead to unsustainable pricing dynamics. These dynamics would significantly impact the availability of new medicines in Canada and undermine the Canadian environment for R&D investment, including clinical trials.

GSK recommends that the MLP should continue to be defined by a Highest International Price Comparison (HIPC) test. Maintaining an HIPC approach, particularly for so-called Grandfathered medicines, would seem to be more consistent with the government's policy intent.

Since its original announcement on PMPRB pricing reform in 2017, there has been much public discussion and debate around whether there should be changes to the basket of PMPRB reference companies. On principal, GSK does not support the new Schedule of International Reference countries and the removal of the United States and Switzerland. The new Schedule of Countries is unreflective of Canada's economic standing and aspirations regarding access to medicines.

For the new basket of comparator countries published August 2019, it remains unclear to us how and why this new set of countries was chosen. In particular, the methodology for adding and subtracting comparator countries appears inconsistent. For example, both Norway (5.2M people) and Sweden (9.9M people) which have far smaller population sizes than Canada have been added to the basket, whereas Switzerland which sits in between the two population-wise (8.4M) has been excluded.

Similarly, there has been a lack of consistency around *which pricing test* should be used to implement the PMPRB basket of reference countries, whatever that basket might happen to be.

For Canada, a key question is: should the PMPRB continue to rely on a Highest International Price Comparison (HIPC) test, or should it switch to a Median International Price Comparison test?

In May of 2019, Health Canada published a final version of the Cost-Benefit Analysis and Regulatory Impact Assessment (CBA), which suggested that the longstanding HIPC test would be preserved (at least for existing medicines). The CBA was used to inform the public discussions and debate surrounding the new pricing regulations that were put forward for consultation in the *Canada Gazette*. In her public statements about the proposed reforms, the former Minister of Health, as well as senior officials from her department and across government, generally referred to facts and figures that were drawn from that document. (The esteemed economist David Dodge was even engaged to offer a sober second look at the CBA, such was the weight given to it in the overall debate.)

It was the analysis contained in the CBA that undoubtedly would have informed the internal deliberations on the new rules by ministers leading up to their final publication in the *Canada Gazette* to ensure that on balance, the regulatory reforms were fair, reasonable and in the public interest.

In particular, looking at Page 20 of the federal government's published CBA/RIAS it reads: "Since the PMPRB uses a *Highest International Price Comparison (HIPC) test*, updating the schedule, especially removing the typically highest price (e.g. U.S.), could have impacts on existing drug revenue if *the Canadian price becomes the highest price among all comparators in the updated*

schedule (emphasis added by GSK). The cost-benefit analysis calculates that Canadians will pay \$788.5 million (PV) less for existing medicines over the next 10-years as a result of updating the schedule of comparator countries. This is the only instance in the cost-benefit analysis where prices of existing medicines are anticipated to be affected as a result of these Amendments.”

Considering the weight that was properly given to the CBA by ministers, elected officials, and senior civil servants across the Government of Canada, GSK respectfully submits that the CBA should be viewed as a clear reflection of the government’s policy intent. Again, the CBA formed the basis for public statements made by the government, and a foundation for key decisions made by ministers.

However, our review of the proposed new pricing Guidelines indicates that PMPRB is seemingly proposing to depart in a material way from the published CBA by applying an MIPC test to both new and existing drugs (i.e. the HIPC test used in the CBA is nowhere to be found in the draft Guidelines). Consequently, the net impact of these Guidelines would go well beyond the \$8.8 Billion (NPV) over 10 years cited by the Government in the lead up to the release of the Guidelines. If an MIPC test is applied, as proposed, by the PMPRB then the financial impact on the industry over 10 years would be considerably higher. In fact, according to one third-party estimate, the approach currently being proposed by the PMPRB could translate into over \$41 Billion (NPV) over 10 years.

GSK also has serious concerns that the PMPRB underestimated the impact on ceiling prices for new medicines from applying the MIPC to the PMPRB11. The cost benefit analysis (CBA) published with the CG2 regulations stated the following: “Updating the schedule of comparator countries is expected to lower patented medicine spending by \$2.8 billion (PV) over 10 years. The cost-benefit analysis assumes that new medicines first sold in Canada following the coming-into-force date of these Amendments will be tested against the median of the updated schedule of comparator countries (PMPRB11) at introduction. Prices of new high-priority medicines are estimated to be reduced by 4.5%, while prices of other medicines are expected to be reduced by 3.49%.” (CG2 p.5968.)

In fact, it is clear that applying an MIPC test to the PMPRB11, this would reduce ceiling prices for new medicines by at least 20% [TABLE 1], which could affect benchmarks used to regulate prices in other countries. Nine of the PMPRB11 countries use external price referencing (EPR) and commonly cross reference each other [TABLE 2]. (Canada is not currently used as a reference country among PMPRB11 countries, however, it should be expected that countries in the PMPRB11 will begin to formally or informally reference Canadian prices, as pending U.S. legislation now proposes to do.¹)

The MPIC vs. HPIC issue is crucial, because the consequence of getting this issue wrong will be delayed or deferred launches of new innovative medicines in Canada. Empirical research confirms the link between price level and launches. Using data from the PMPRB and the Organization for Economic Co-operation and Development, a 2018 study tested the statistical relationship between the number of new drug launches and the market price level for patented drugs across 31 countries. The analysis confirmed that lower priced markets experienced fewer new drug launches, and vice versa, that higher priced markets tended to experience more new drug launches (Skinner 2018).

¹ Consequently, this could induce perpetual deflationary pricing cycles. Recent studies published by The London School of Economics and the European Commission provide extensive evidence of the deflationary effect of External Price Referencing (EPR) in European markets (Kanavos et al 2019; Vogler et al 2015; Toumi et al 2014).

Finally, GSK is aware of concerns expressed by some interested parties that maintaining the HIPC to set price ceilings is “inflationary” over time. Perhaps there is evidence to support this having been the case in the past. However, this may not necessarily be the case depending on the basket selected.

For these reasons, GSK strongly recommends that MLP should continue to be defined by an HIPC test, regardless of which reference countries are identified by regulation as in the basket.

Recommendation #2

The new economic factors outlined in the August 2019 regulations are problematic in many ways, and the use of highly subjective Pharmacoeconomic (PE) tools and concepts, such as QALYs, to determine price ceilings is not an international best practice. If Canada’s pricing regulator were to use and apply the so-called New Economic Factors (including PE and the proposed Market Size Adjustment), on a regular and routine basis, this would create tremendous instability and uncertainty for drug and vaccine manufacturers such as GSK. There would be unintended consequences arising from this lack of pricing certainty and predictability, including decisions by manufacturers in some cases not to launch innovative new medicines in Canada. Consequently, the new economic factors should not play a role in price determination.

The so-called “new economic factors” do not allow for reliable prediction of an allowable ceiling price at product launch, or throughout a normal product lifecycle, due to their inherent subjectivity, as well as the broad criteria for reassessments after products are launched. This creates tremendous unpredictability in the Canadian pricing regime, which would clearly impact global launch decisions (i.e. whether or not to launch new products in Canada, and how long to wait).

One of the new economic factors involves the use of Pharmacoeconomics, which is still an emerging discipline. GSK recognizes the role that Pharmacoeconomics can play in certain circumstances, such as informing value-based discussions with HTA bodies and payers. But we disagree strongly with the notion that PE tools can be used to help establish a regulated price ceiling; at least not on a routine basis. Indeed, GSK and other members of the innovative pharmaceutical industry are not alone in calling into question the legitimacy of applying a pharmacoeconomic evaluation formula to set fixed price ceilings in regulation. The previously-mentioned Dodge review stated that, “*With respect to the pharmacoeconomic value factor... while there is widespread agreement that Cost Utility Analysis can be used as a flexible tool in payer/supplier negotiations, there is less agreement on the adaptations required to use CUA as a tool in price regulation*” (Dodge et al 2018 p. ix).

GSK is also concerned that the PMPRB has underestimated the impact on prices and revenues from the new economic factors in the Guidelines. According to the CBA published in CG2, “*The new price regulatory factors are expected to lower patented medicine spending by \$3.8 billion (PV) over 10 years. In calculating these benefits, only new high-priority medicines were assessed against the new price regulatory factors. The application of the new factors meant that the price of new high-priority medicines was reduced by 40% on average relative to the baseline forecasts. This would lead to a 5.4% reduction in projected patented medicine revenues by year 10.*” (CG2 p.5967)

However, a recent study (Rawson et al 2020) examined the proposed new Guidelines and applied them to a hypothetical case study of the decision-making process that the pharmaceutical manufacturer of a new medication for a rare disorder is likely to go through when assessing whether

to seek regulatory approval in Canada under the new rules. The Rawson case study demonstrated that the changes in the PMPRB Guidelines impose regulated price ceilings that could in some cases be up to 84% below existing levels. This is consistent with GSK's internal assessments as well.

Expected Impact of the Proposed New Rules on Canadian Patients

With this harsh pricing environment, the business case for launching the incoming pipeline of drugs is highly questionable in a country where our estimated MRP is so far below the OECD median. In fact, there becomes a vicious cycle associated with a country that sees their launch priority decrease globally. If it is not commercially viable to launch a product in a country, it then becomes difficult, from both a commercial and an ethical perspective, for a company like ours to sponsor clinical trials and enroll patients when the ultimate prospects for availability of the product in the Canadian market and public reimbursement are so vanishingly low.

Without these clinical trials being brought to Canada, the research community will likely endure reduced funding and academic opportunity, because they will lose the chance to work on and study the latest innovations in the pharmaceutical space. Furthermore, patients will feel the effects of reduced funding in the patient support programs by pharmaceutical companies, where historically our companies have been able to support patients to gain timely access, and through the creation of treatment infrastructure which previously was unsupported by the healthcare system.

To help assess the potential impacts on patients of the new PMPRB pricing regime (including the poorly devised new economic factors), on the availability for patented medicines in Canada, Life Sciences Ontario recently commissioned an independent research firm, to conduct a survey of pharmaceutical and other life sciences leaders. GSK participated in this anonymous survey. The survey, which drew on data from 46 respondents including leaders from Canadian and global pharmaceutical companies, revealed unanimity on the negative impacts of the new rules on patients.

In particular, respondents noted that there would be delayed new medicine launches in Canada (or in the case of some new medicines, no launches in Canada at all), particularly in regard to new biologics, including cancer medicines and medicines for rare disorders. Respondents also indicated that there would be reduced investment in clinical research, patient support programs, and compassionate access programs – all means by which patients have early access to new treatments. The LSO report is available here: <https://lifesciencesontario.ca/news/new-federal-drug-pricing-rules-are-already-delaying-medicine-launches-and-costing-jobs-in-canada-survey-reveals/>

While the new economic factors proposed by the PMPRB may be well-intentioned, these are the unavoidable downstream effects of curtailing prices so severely with an arbitrary tool like Pharmacoeconomics. Moreover, these new economic factors do not simplify the PMPRB's regulatory approach nor provide "bright-line" regulatory rules that are sufficiently straightforward for all parties to understand and apply. While they have been oddly positioned as a "streamlined approach," in fact, these new factors needlessly introduce far more complexity into an already complex system. The flawed MRP concept, underpinned by the proposed new economic factors, is disconnected from how drugs are negotiated with payers and reimbursed in the Canadian system. In light of this, the new economic factors should not play a role in price determination.

Recommendation #3

The PMPRB should work with industry to implement appropriate measures to limit the unnecessary administrative burden on manufacturers regarding publicly-tended vaccines.

GSK is proud to deliver over two million vaccine doses per day to people living in over 160 countries. We have one of the broadest portfolios of vaccines in the industry, offering innovative products to protect people at every stage of their life. Since we began producing and distributing smallpox vaccine in 1882, the vaccines in our portfolio have been helping to protect people from serious disease. Today, our vaccines continue to tackle and prevent some of the world's most devastating diseases, including pneumococcal disease, meningitis, hepatitis, shingles, whooping cough and influenza.

In December of 2017, Health Canada published for public consultation a draft set of amendments to the Patented Medicines Regulations published in the *Canada Gazette*. Those draft amendments included provisions specific to vaccines, which laudably proposed to modernize and simplify the way that vaccines are regulated by the PMPRB. Specifically, it was proposed that vaccines would be subjected to a different regulatory approach than patented drugs and biologics in recognition of the fact that, in the language used by Health Canada, vaccines have a “low risk of potential abuse of statutory monopoly.”

The approach proposed by Health Canada at the time made a great deal of sense because vaccine procurement in Canada is based on a competitive tendering process, whereby the lowest bidder is granted a majority share of the contract to supply the customer with a specific vaccine. This national tendering system ensures that patented vaccines are fairly priced within the Canadian marketplace. To help ensure equity, the federal system also limits price discrepancies for all provinces and territories.

The provinces and territories who leverage the federal tendering process to secure vaccines for their populations are sophisticated actors, and they have the purchasing power to negotiate contracts that provide optimal arrangements in terms of price, quality and volume. Consequently, GSK submits that strict PMPRB regulatory oversight is not necessary for vaccines given the competitive bidding process that covers the vast majority of doses dispensed in the Canadian market. Indeed, we would argue that vaccines are a perfect example of a grouping of patented products that belongs in a “low risk” category, which ostensibly would involve a reduced administrative burden on both industry and government (i.e. cutting “red tape”). Under such an approach, excessive pricing issues pertaining to vaccines (which are extremely rare) could potentially be managed on a complaint-driven approach, similar to OTC products.

Given all of this, GSK and other industry players were surprised that the above-mentioned regulatory carve-out for vaccines that had appeared in CG1 was absent from the final amendments published in August of 2019. GSK will continue to work with Innovative Medicines Canada, BIOTEC Canada and the Vaccines Industry Committee (VIC) to present an evidence-informed case to the federal government to revive the regulatory approach that was tabled for discussion in CG1. In the meantime, GSK is calling upon the PMPRB to work with industry to find and implement more appropriate measures to limit the unnecessary administrative burden on manufacturers (and on the agency) for public health vaccines.

Recommendation #4

Given the many issues set out above, the PMPRB should pause the implementation timetable and collaborate with stakeholders to take the appropriate time and consideration to work through highly technical amendments. As with previous PMPRB reforms undertaken over the years, proper implementation of any new Guidelines should be completed over a longer time horizon.

It is incumbent upon Canadian regulators to establish and maintain regulatory regimes that meet a certain standard: regulatory regimes must be practical, predictable, functional and comprehensible. Because the proposed new PMPRB Guidelines fall short of those basic regulatory expectations, GSK is respectfully calling for a pause on their implementation at this time.

As of this writing, many technical and highly substantive matters concerning the new Guidelines simply have not been adequately discussed or worked-out. There remains considerable confusion around these issues. For example, the new MRP concept, which is a cornerstone of the new Guidelines, is disconnected from how drug prices are actually negotiated with payers and reimbursed within the Canadian system. (i.e. at the time that PMPRB is assessing ceiling price, most manufacturers would not have product listing agreements in place with payers and therefore would have no rebated price to assess against an MRP. It can take upwards of two years to achieve formulary listings on government-sponsored plans and, in some instances, a listing is never achieved. Consequently, an MRP is not operationally feasible as proposed.)

For these and other substantive implementation details, it is encouraging that the PMPRB has proposed the establishment of technical working groups with industry to tackle these matters. GSK requests to be part of such working sessions, when they occur. But fact remains that the new Guidelines, as they stand, are simply not in a sufficiently advanced state of development to be implemented on July 1, 2020.

During previous substantive Guidelines changes, the PMPRB has taken appropriate time to work through highly technical amendments despite the fact that its powers were already specified in regulations (i.e. in situations that are highly analogous to the present one). So, the proper implementation of these Guidelines can and should be completed over a longer, more reasonable time horizon. Over that period of time, GSK continues to welcome any and all opportunities to engage with PMPRB to collaboratively generate a set of pricing rules that meet key principles like predictability, fairness, operational feasibility, and most fundamentally, continued access to new medicines for Canadians to a high global standard.

Recommendation #5

The Government of Canada, working with provincial and private payers and other health system stakeholders, should commit to engaging in discussions with the Canadian life sciences industry to identify and implement new approaches to shorten the time it takes to reimburse new medicines in Canada. This important work which would directly benefit Canadian patients should not be disconnected from the PMPRB pricing reforms, as is presently the case.

The PMPRB plays a longstanding role in enabling drug access for Canadian patients and ensuring affordability for Canadian payers. But needless to say, when it comes to the Canadian pharmaceutical policy space, the PMPRB does not operate in a vacuum. The PMPRB is one of several key players in a

complex and dynamic system, including Health Canada, CADTH, INESSS, private and public payers, and of course, the pCPA. The intricate balance surrounding the interrelationships between these various players should be considered when reforms are being proposed to any one component of the system.

Since the PMPRB pricing reforms began in 2017, there has been a singularly focused policy effort on lowering the prices of patented medicines, with little to no discussion around other adjustments or improvements that could be made to the broader ecosystem. For example, there has been almost no discussion about the woeful amount of time it takes to get innovative medicines listed on public formularies in Canada (ranging between an average of 252 days post-Health Canada approval in Quebec to over 500 days in the Atlantic provinces, per the latest IQVIA data).

As the PMPRB pricing reforms move forward, there is an opportunity for the federal government to convene relevant ecosystem players to explore ways to meaningfully shorten the time it takes to provide access to life-saving and life-changing new drugs and vaccines for Canadians. Perhaps certain objectives regarding time-to-listing could even be reflected in the mandate of the new Canadian Drug Agency.

Our made-in-Canada pharmaceutical reimbursement system is, in many ways, quite unique in the world. That in and of itself is not necessarily a problem – every developed country has its own approach to approving, pricing, reimbursing and prescribing medicines. Nevertheless, Canada could and should draw some inspiration from jurisdictions that are tackling pharmaceutical policy issues in a balanced and sustainable way, such as Germany, leading to better health outcomes for their populations.

Germany, like Canada, has a universal health insurance system. However, Germany does not have a government funded single payer system. Instead, medical and prescription drug insurance is mandatory, which is similar in principle to Quebec's universal compulsory prescription drug insurance system. The vast majority of Germany's population (90%) receive coverage from statutory health insurance (SHI). The other 10% are covered by private insurance or special schemes. Compulsory health insurance (statutory and private) covers 84% of the expenditure for outpatient medicines and patients pay the rest through co-insurance payments or consumption of OTC medicines. Medicines used in inpatient care are fully covered by health insurance (OECD 2019).

On average, according to a 2019 report by the Deloitte Centre for Health Solutions, the average length of time between market authorization and patient access to new life-saving and life-changing medicines in Germany is just 106 days. At the same time, the prices for medicines in Germany have been demonstrated to be highly consistent with the prices in Canada (PMPRB Annual Report 2017) This rapid access to innovative medicines is possible because the German pricing and reimbursement environment differs from Canada's in several distinct ways:

- All medicines entering the market are reimbursed by SHI unless included in a negative list;
- Manufacturers set the list price, and actual net reimbursement prices are negotiated;
- Government must negotiate the price within twelve months after market launch; and,
- Pharmacoeconomic Evaluation (PE) is used only to support price negotiations, not to set prices by regulation (this runs contrary to the PMPRB's effort to use PE as a price-setting tool, which is fraught with challenges).

Clearly, every system is different. But the fact remains that some OECD countries have been successful in finding ways to balance their necessary pharmaceutical policy cost-containment efforts with ensuring appropriate access to innovative new therapies for patients. As Canadians, let us draw inspiration from the way that other jurisdictions are tackling these issues as we work towards made-in-Canada solutions.

TABLE 1: Moving from PMPRB7 to PMPRB11 decreases the MIP and HIP.

PMPRB7	2014		2015		2016		2017
United States	2.21	United States	2.57	United States	2.91	United States	3.21
Switzerland	0.98	Germany	0.99	Switzerland	1.06	Switzerland	1.06
Germany	0.96	Switzerland	0.99	Germany	1.00	Germany	0.97
Sweden	0.87	Sweden	0.89	Sweden	0.89	Sweden	0.86
Italy	0.73	United Kingdom	0.82	United Kingdom	0.84	Italy	0.85
France	0.72	Italy	0.81	Italy	0.83	United Kingdom	0.83
United Kingdom	0.72	France	0.78	France	0.78	France	0.76
Canada	1.00	Canada	1.00	Canada	1.00	Canada	1.00
PMPRB11	2014		2015		2016		2017
United States	2.21	United States	2.57	United States	2.91	United States	3.21
Japan	1.04	Germany	0.99	Switzerland	1.06	Switzerland	1.06
Switzerland	0.98	Switzerland	0.99	Germany	1.00	Germany	0.97
Germany	0.96	Japan	0.91	Japan	0.92	Japan	0.92
Sweden	0.87	Sweden	0.89	Sweden	0.89	Sweden	0.86
Australia	0.80	United Kingdom	0.82	United Kingdom	0.84	Italy	0.85
Spain	0.73	Italy	0.81	Italy	0.83	United Kingdom	0.83
Italy	0.73	Australia	0.79	Belgium	0.80	Spain	0.80
France	0.72	Belgium	0.78	Spain	0.80	Netherlands	0.80
Belgium	0.72	Spain	0.78	Netherlands	0.79	Belgium	0.79
United Kingdom	0.72	France	0.78	Australia	0.78	Norway	0.78
Norway	0.69	Netherlands	0.75	France	0.78	France	0.76
Netherlands	0.66	Norway	0.73	Norway	0.75	Australia	0.74
Canada	1.00	Canada	1.00	Canada	1.00	Canada	1.00

SOURCE: PMPRB Annual Reports 2014-2017, Figures 10,10,13,21 respectively.

TABLE 2: EPR cross-referencing among PMPRB11 plus CA, CH, US, NZ.

Australia	Belgium	Canada	France	Germany	Italy	Japan	Netherlands	Norway	Spain	Sweden	Switzerland	United Kingdom	United States	NZ*
UK	FR	AU	DE	BE	BE	FR	BE	BE	BE	BE	FR			AU
NZ*	DE	BE	IT	FR	FR	DE	FR	DE	FR		DE			CA
	IT	FR	ES	IT	DE	UK	DE	NL	DE		NL			UK
	NL	DE	UK	NL	NL	US	UK	SE	IT		UK			
	ES	IT		ES	ES			UK	NL					
	SE	JP		SE	SE									
	UK	NL		UK	UK									
		NO												
		ES												
		SE												
		UK												

SOURCE: (Remuzat et al 2015), (Toumi et al 2014)

REFERENCES

- (CG1 2017). Regulations Amending the Patented Medicines Regulations. 2017-12-02 Canada Gazette Part I, Vol. 151, No. 48.
- (CG2 2019). Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements): SOR/2019-298. Canada Gazette, Part II, Volume 153, Number 17. Registration: SOR/2019-298, August 8, 2019. PATENT ACT: P.C. 2019-1197 August 7, 2019.
- (Kanavos et al 2019). Panos Kanavos, Anna-Maria Fontrier, Jennifer Gill, Olina Efthymiadou. Does external reference pricing deliver what it promises? Evidence on its impact at national level. The European Journal of Health Economics. <https://doi.org/10.1007/s10198-019-01116-4>.
- (OECD 2018) Martin Wenzl, Valérie Paris. Pharmaceutical Reimbursement and Pricing in Germany. OECD. June 2018. <https://www.oecd.org/health/health-systems/Pharmaceutical-Reimbursement-and-Pricing-in-Germany.pdf>.
- (Rawson et al 2020). Rawson, Nigel SB; Lawrence D. New Patented Medicine Regulations in Canada: Updated Case Study of a Manufacturer's Decision-Making about Regulatory Submission for a Rare Disorder Treatment. *Canadian Health Policy*, January 2020. Toronto: Canadian Health Policy Institute. www.canadianhealthpolicy.com.
- (Rémuzat et al 2015). Cecile Remuzat, Duccio Urbinati, Olfa Mzoughi, Emna El Hammi, Wael Belgaied and Mondher Toumi. Overview of external reference pricing systems in Europe. *Journal of Market Access & Health Policy* 2015, 3: 27675 - <http://dx.doi.org/10.3402/jmahp.v3.27675>.
- (Skinner 2018). Skinner, Brett J. Consequences of over-regulating the prices of new drugs in Canada. *Canadian Health Policy*, March 27, 2018. <https://www.canadianhealthpolicy.com/products/consequences-of-over-regulating-the-prices-of-new-drugs-in-canada.html>.
- (Toumi et al 2014). Mondher Toumi, Cécile Rémuzat, Anne-Lise Vataire, Duccio Urbinati. External reference pricing of medicinal products: simulation-based considerations for cross-country coordination. Final Report. European Commission, European Union. https://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/EPR_reimbursement_medicinal_products_en.pdf.
- (Vogler et al 2015). Sabine Vogler, Lena Lepuschütz, Peter Schneider, Verena Stühlinger. European Commission: Study on enhanced cross-country coordination in the area of pharmaceutical pricing. https://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/pharmaproductpricing_fre_p_en.pdf.
- (PMPRB 2018). Patented Medicine Prices Review Board. Annual Report 2017. July 24, 2018. <https://www.pmprb-cepmb.gc.ca/view.asp?ccid=1380>
- (CADTH 2016). CADTH. Common Drug Review Pharmacoeconomic Review report. [cited 3 February 2020]. https://www.cadth.ca/sites/default/files/cdr/pharmacoeconomic/SR0461_Nucala_PE_Report_e.pdf

Submitted by GlaxoSmithKline Inc.

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A submission pertaining to the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements): SOR/2019-298. Canada Gazette, Part II, Volume 153, Number 17. Registration: SOR/2019-298, August 8, 2019. PATENT ACT: P.C. 2019-1197 August 7, 2019; and the draft Guidelines published by the Patented Medicines Prices Review Board for public input, due by January 31, 2020.

Elements of this submission were researched and prepared by CHPI PolicyIntel, the consulting unit of the Canadian Health Policy Institute Inc. The opinions expressed herein are solely those of GlaxoSmithKline Inc.