



June 28, 2017

Attention: Patented Medicines Regulations Consultations
70 Colombine Driveway, Tunney's Pasture
Mail Stop 0910, Floor 10, Building Brooke Claxton Building
Ottawa, Ontario
K1A 0K9

Dear Sir or Madam,

We are writing to provide the views of Bayer Inc. ("Bayer") on the consultation of proposed amendments to the Patented Medicines Regulations (the "Regulations"). We appreciate the opportunity provided by Health Canada for stakeholders to contribute their knowledge and insight on proposed changes which will have far-reaching effects on the lives and well-being of all Canadians.

Bayer, an innovative company that provides life-saving and life-altering medications, also delivers important value to the Canadian health & regulatory system. We are hopeful that our comments will be duly considered to form appropriate regulations that will be beneficial and fair to all stakeholders, but most importantly do not impede patient access to innovative medicines.

While we understand the circumstance surrounding this consultation, we are nevertheless greatly concerned that proposed changes to the Regulations and subsequent changes to the Patented Medicines Prices Review Board ("PMPRB") Guidelines are based on the misconception that patented drug prices are excessively high. In the following pages of this letter, we will demonstrate that drug prices are not excessively high and have remained relatively stable over time. Although the proposed changes to the Regulations may have the immediate effect of lowering prices, they could lead to negative unintended consequences that pass costs onto other parts of the healthcare system, resulting in suboptimal health outcomes and decreased quality of life for Canadians. We ask that Health Canada examine the implications of lowered drug prices through an objective lens and consider impacts beyond just lowered drug prices. Canada's health system is complex, and any regulatory change that is implemented without proper due diligence can have a long-lasting and potentially irreversible effect on patient access to innovative medicines to Canada.

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Bayer, as a proud member of Innovative Medicines Canada (“IMC”), encourages Health Canada to extend the consultation timeline for the proposed Regulations amendments. IMC will be working through the pan-Canadian initiative to propose changes to the pricing and reimbursement model of innovative medicines and will be sharing details on its plans at the Council of the Federation in July. We believe that Canada has one of the best healthcare systems in the world, where the majority of patients get access to life-saving and life-altering innovative medicines. It is our core belief that every Canadian should have access to these innovative drugs. All Canadians should be able to access innovative medicines based on their medical need. However, this vision can only be achieved through the joint efforts of all stakeholders including industry, government, payers and patients.

The following pages provide Bayer’s detailed feedback specific to the consultation questions, and also includes Bayer’s perspective on PMPRB’s mandate of non-excessive pricing.



Summary of Bayer's Recommendations and Comments

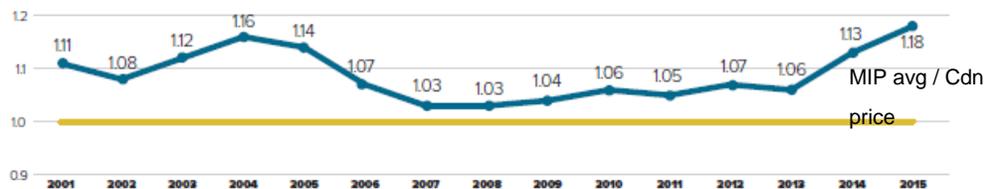
- **Extend the consultation process until the proposals by IMC are communicated.** IMC is developing plans to address price, affordability and access to medicines and will be introducing this concept in July at the Council of the Federation. These proposals are expected to address the specific areas of concern that Health Canada is attempting to address in this consultation. Only a collaborative approach will be able to address this elusive solution. Extending the consultation period to allow for consideration of IMC's proposal will increase the potential range of solutions.
- **PMPRB should release how the proposed regulatory changes will be translated into PMPRB Guidelines prior to the publication of these proposed changes in Canada Gazette I.** This is necessary in order to have a fulsome and transparent discussion. Uninformed decision-making increases the probability of unintended consequences.
- **Any regulatory change should enable PMPRB to carry out their mandate to ensure that patented drugs are not excessive in price. PMPRB should avoid duplicating efforts & roles of other agencies.** Any changes to the Regulations should be aimed at *supplementing* the tools that the PMPRB currently have to ensure that the PMPRB delivers on its mandate of ensuring that innovative drugs are not excessively priced. The proposed price tests do not assist in this endeavor. Duplicating efforts of other Canadian institutions such as CADTH, INESSS or pCPA is discouraged as this decreases predictability, increases regulatory burden, and may result in delayed innovative drug launches, or, in some cases, no drug launch in Canada at all. It also blurs the line of responsibilities between agencies.
- **Any new Pricing factors should be optional tools used only upon the investigation of a drug rather than a blanket application to all patented drugs**
- **The reference countries should not change.** The current PMPRB7 is a fair representation of reference countries as the Canadian price has been shown to be 18% below the median international price. The only other objective choices would be the G7 or G10 countries. Trade and geographical proximity to Canada should be major factors in determining the reference countries.
- **Regulatory burden reduction should be applied beyond patented generics.** Regulatory burden should be reduced by eliminating the need to report data for generic, multi-source or any other patented product that undergoes a competitive RFP process paid for by the provinces such as blood products and vaccines. It is also critical to ensure equity in reporting requirements and treatment for generic and branded manufacturers.
- **Confidential rebates should not be reportable to the PMPRB.** Confidential rebates should not be used to determine excessive pricing as the net prices would become evident over time as described in a subsequent section.



Section 1. PMPRB’s Mandate of Non-Excessive Pricing has been effective

PMPRB’s regulatory mandate is to “ensure that patentees do not abuse their patent rights by charging consumers excessive prices during their statutory monopoly period.”¹ In the consultation document, Health Canada has stated that PMPRB’s current regulatory framework does not provide it with adequate tools to effectively protect Canadians from excessive prices, or for optimal price setting in today’s pharmaceutical environment. In contrast to PMPRB’s and Health Canada’s critical evaluation, we believe that PMPRB has been effective in achieving its mandate. For instance, PMPRB has indicated that at introduction, Canadian drug prices are in line with international levels.² Additionally, the PMPRB Strategic Plan 2015-2018 document clearly indicates that Canadian prices remain 18% below that of the median of the PMPRB7 (Figure 1).^{3,4}

Figure 1. Average Ratio of Median International Price (MIP) to Canadian Price, at Market Exchange Rates, 2001-2015



Source: PMPRB

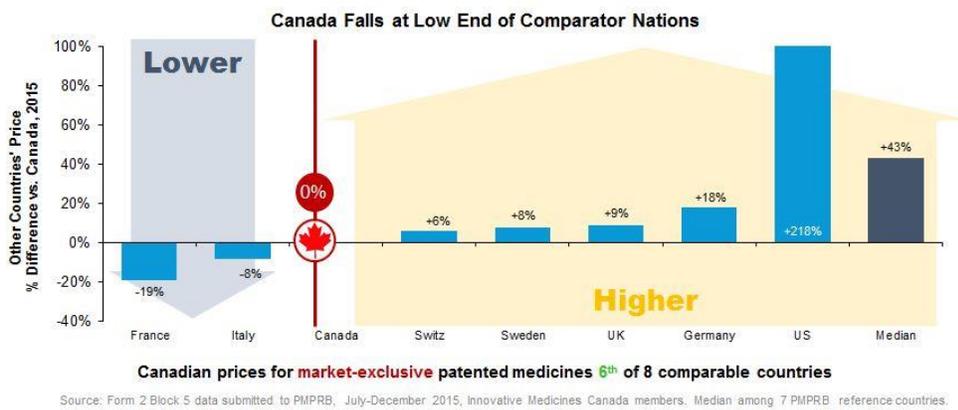
While the 2015 PMPRB Annual report indicates that Canada is priced below the U.S. and Germany, and is tied for third with Switzerland,⁵ we encourage Health Canada to focus squarely on the segment that will be the most affected by the

¹ Health Canada, Protecting Canadians from Excessive Drug Prices, Consulting on Proposed Amendments to the Patented Medicines Regulations
² Meds Entry Watch, 2015, Patented Medicine Prices Review Board
³ Strategic Plan 2015-2018, Patented Medicine Prices Review Board
⁴ Patented Medicine Prices Review Board Annual Report 2015
⁵ Ibid.



proposed Regulations amendments: patented medicines with marketing exclusivity, known as single-source patented medicines. A study commissioned by IMC and conducted by a third party, utilizing the same data provided by patentees to PMPRB, discovered that Canadian prices of patented drugs that have market exclusivity are actually 43% below the PMPRB7 median prices, putting Canada third lowest ahead of only France and Italy, and below the U.S., Germany, Switzerland, the U.K. and Sweden (Figure 2). This analysis is based on international and domestic List Prices, which may be flawed due to confidential rebates. However, the sheer magnitude of the difference between Canadian list prices and the PMPRB7 median should provide sufficient evidence that Canadian net prices are in-line with or lower than what we see internationally for market-exclusive patented drugs.

Figure 2. Single-source patented drugs are actually ranked 6th Highest after removing Patented Generics & Multi-Source Patented Drugs



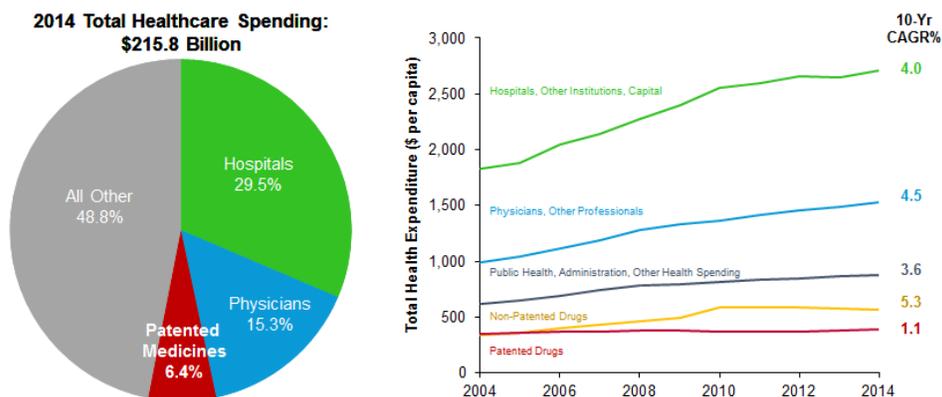
Section 2. Innovative Drugs are an investment in healthcare that can reduce overall costs

Patented Medicines represents only 6.4% of total healthcare spending with its cumulative annual growth rate over the past 10 years leading up to 2014 at 1.1%



(Figure 3).⁶ More recent data published by the PMPRB in the 3rd Edition of its Compass Rx report, illustrated that while public drug costs grew by 12% in 2015/16, 8% of that growth was due to direct-acting antiviral (DAA) drugs for the Hepatitis C virus (HCV)⁷. However, the competition in the DAA market for HCV drugs has increased substantially over the past few years resulting in at least three pan-Canadian Pharmaceutical Alliance (pCPA) negotiations which have likely led to significant savings for public payers.

Figure 3. Patented Drugs Represent only a fraction of Total Healthcare Spending and is growing slower than other Healthcare costs



Source: Skinner, BJ (2016). Spending on patented drugs in Canada 1990 to 2014. Canadian Health Policy, February 22, 2016. Toronto: Canadian Health Policy Institute

A siloed perspective of innovative drugs that only considers drug budgets only can lead to erroneous conclusions. The value that the innovation of patented drugs brings to the broader health system is underestimated. While the cost of patented drugs tends to receive the headlines, the benefits that these drugs bring to the

⁶ Skinner, BJ (2016). Spending on patented drugs in Canada 1990 to 2014. Canadian Health Policy, February 22, 2016. Toronto: Canadian Health Policy Institute

⁷ CompassRx, 3rd edition: Annual Public Drug Plan Expenditure Report, 2015/16, Patented Medicine Prices Review Board



healthcare system including the reduction of emergency and primary care visits, and reduced surgical interventions, are largely ignored. For example, while there is no question that the DAA's have contributed to the burden on drug budgets, there should also be no question that the >80% cure rates on HCV have led to substantial reductions in downstream health system costs. The average direct lifetime costs of HCV was estimated to be \$64,694 per person, but varied substantially depending on the stage of the disease, with the highest per-patient costs attributable to liver transplantation at approximately \$328,000.⁸ The curative nature of these drugs will result in a natural reduction in the prevalence of HCV over time providing additional opportunity for cost savings to the healthcare system.

Section 3. Proposed Amendments to the Regulations

The three new price tests proposed by Health Canada are intended to incorporate cost effectiveness, affordability, and willingness to pay or budget impact in order to assess whether a drug is excessively priced. These tests are already being used by payers and agencies within Canada. The Canadian Agency for Drugs and Technology in Health (CADTH) and Institut national d'excellence en santé et en services sociaux (INESSS) assess cost effectiveness while the pCPA and each payer assess affordability and budget impact. Thus, if PMPRB undertakes to re-evaluate these factors, it will be engaging in a duplicative effort that only serves to increase administrative burden. Furthermore, as explained below, such factors do not help determine whether drug pricing is excessive. These changes can decrease pricing predictability and put patient access to innovative medicines at risk.

A fulsome and transparent discussion is not possible without clarity on how PMPRB will interpret any Regulation amendments in forming their Guidelines. While the consultation document recommends that PMPRB should apply 'bright line' rules that are consistent with international best practices and provide **predictability** to stakeholders, the lack of a 'bright line' on how these factors would manifest itself in PMPRB Guidelines is notable in its absence.

⁸ RP Myers, M Kraiden, M Bilodeau, et al. Burden of disease and cost of chronic Hepatitis C virus infection in Canada. *Can J Gastroenterol Hepatol* 2014;28(5):243-250.



Bayer is well versed in health technology assessment and its associated tools (like cost-effectiveness and budget impact analyses), but we do not understand how PMPRB proposes to use them in practice in regulating ceiling drug prices. Cost-Effectiveness Analyses (CEA) and Budget Impact Analyses (BIA) are intended to answer the policy questions of value for money and affordability, respectively. However, they do not answer the policy question of whether a product is excessively priced in the market. We are unclear on how these proposed measures would facilitate achievement of the PMPRB mandate given that they answer fundamentally different policy questions. Moreover, we are concerned about the duplication of assessments that would now be done by different agencies that have different policy goals and mandates. We believe this will lead to unnecessary administrative burden for manufacturers and PMPRB staff, confusion amongst stakeholders regarding the intended policy questions the submitted information is expected to answer (and therefore confusion within the policy ecosystem about how to use the data being requested) and an inefficient use of taxpayer-funded PMPRB staff time.

We believe Health Canada should not proceed to make Regulation amendments without a complete and clear understanding of the risks these changes pose to the Canadian healthcare system, which can only be accomplished with an open discussion with stakeholders. As such, we propose that Health Canada provide clarity on how its Regulations amendments would be implemented in the PMPRB Guidelines.

We provide our comments on the Proposals questions below.

Proposal #1: Introducing new factors to help determine whether a price is excessive

- 1. Do you agree that a pharmacoeconomic evaluation is an important factor for the PMPRB to consider when determining whether a drug is priced excessively? If so, how should the evaluation be considered**

No. We believe that pharmacoeconomic (PE) measures should not play a role in determining whether a patented drug is excessively priced. First and foremost, excessive price and cost effectiveness are two distinct concepts. A PE analysis



compares the incremental cost and benefits of a pharmaceutical intervention to alternative treatment options in order to determine whether the intervention provides sufficient value to a given payer relative to the incremental cost. It is not designed to determine whether drugs are excessively priced. Using these two metrics as interchangeable will inevitably lead to poor decision-making resulting in greater ambiguity due to potentially diverging results from the different price tests, increased regulatory burden as the patentee will need to collect and interpret this data and a potential to stifle innovation.

Furthermore, there are many issues inherent in the use of cost-effectiveness analysis for helping the PMPRB determine that prices are non-excessive. These include:

- The value of a drug is different from its budgetary impact. Drugs that have a large impact on a drug budget is often misconstrued as being less valuable. This is irreconcilable with the fact that drugs that treat a large patient population and/or are highly effective are the ones that offer the biggest benefit to society⁹.
- PE models are laden with assumptions and are not necessarily consistent amongst those who conduct them. For example, one PE analysis using omalizumab, an asthma drug, found a ~50% difference in the drug's cost effectiveness because of differing assumptions made in different PE analyses¹⁰. PE models can be useful tools to consider when deciding between differing investment options; however, they are not definitive and highly subject to a user's perspective.
- Cost utility analyses (CUA) submitted to CADTH are conducted from a public healthcare system perspective, which generally disregards productivity in the workplace¹¹. Patients who are covered on a private plan, which constitutes most of the population, have different metrics and value assessments from the aged and those on social assistance.

⁹ <https://www.statnews.com/2017/06/08/value-based-drug-pricing/>

¹⁰ <https://www.ncbi.nlm.nih.gov/pubmed/24559022>

¹¹ Cost Utility Analyses conducted from a society perspective could address productivity costs. INESSS prefers economic assessments conducted from a societal perspective.



- The results of CUAs – measured using cost per Quality-Adjusted Life Year (QALYs) – are not an appropriate metric for excessive pricing. There is no clear consensus on what constitutes an acceptable threshold for cost per QALY. A single cost per QALY measure would penalize specialty drugs and does not always capture patients' needs or preferences. QALY measures will favour therapies that have overall survival data, and show bias against newer agents, those that treat short-term disabilities, and those interventions that treat the pediatric population¹².
- Potential inconsistencies may arise when comparators used for CADTH differ from that identified by the Human Drug Advisory Panel yet highlighting another difficulty when a clear delineation of mandates is not established.
- Even within the Health Technologies Assessments (HTA) world in which CEAs are used, there are limitations and challenges. For example, the validity of using of CEA and their accompanying ICER thresholds depend on a set of underlying conditions that are not met in the real-world environment in which CEAs are actually used.
- PE analyses from other countries are not generally not made available to Canada

The consultation document indicates that other developed countries rely to some degree on cost per QALY in determining whether and how much to pay for a drug. In countries that use this approach, pricing regulations and HTA's are often conducted by the same body. To our knowledge, only Canada has the unique infrastructure of having a quasi-judicial body determining whether a drug is excessively priced. We are unaware of any other country that regulates prices through PE analysis. Because the Canadian infrastructure for drug pricing is so different from other jurisdictions, processes that work well in other jurisdictions may not work as well if they are simply transplanted into the Canadian environment.

Evaluating PE measures with other countries will pose additional challenges. Differences in comparators, prescribing patterns, legal framework, indications, criteria, reimbursement structures, confidentiality laws and language barriers are just some of the variables that will pose significant challenges for comparative purposes. In addition, adding price factors will increase the complexity for all stakeholders. The Copaxone legal ruling (*Teva Canada Innovation v. Canada (Attorney General)*, 2013

¹² IMC Regulatory response to the Proposed Amendments



FC 448) indicated that PMPRB needs to consider all factors in determining whether a drug is excessively priced. Additional factors will likely to lead to divergent results and lead to increased uncertainties. This will only serve to cause a significant increase in investigations and hearings.

Based on the rationale provided, we do not agree with utilizing a PE factor. Utilizing a PE evaluation on every drug would be significantly onerous on both the patentee and the PMPRB and increase uncertainty for all parties as it does not assess whether a drug is excessively priced. We would also recommend against providing PE analyses of other countries as these are generally not made available to Canada.

A pharmacoeconomic pricing factor such as \$/QALY does not inform whether a patented drug is excessively priced. Non-uniformity and subjectiveness of PE analyses between products, companies and internationally makes it an unreliable metric.

2. Do you agree that the size of the market for the drug in Canada and other countries is an important factor for the PMPRB to consider when determining whether a drug is priced excessively? If so, how should the size of the market be considered?

No. Market size, which we presume would be used to assess budget impact, is a different construct from excessive pricing. Moreover, even if market size could inform whether a product is non-excessive in price, there are inherent difficulties in estimating the market size of a product at launch. A population size estimated through prevalence data vs. actual diagnosed/treated patient groups may and often ends up being significantly different. In addition, estimating market sizes may be difficult for therapeutic areas with little epidemiology.

When additional indications are obtained from Health Canada, the size of the market re-evaluation is already being conducted by both public and private payers. Patentees engage with CADTH or INESSS and negotiate through pCPA when seeking public coverage on new indications. This process automatically adjusts for



changes in the market size and is more relevant for a payer as opposed to a price regulator.

It is also inherently difficult to obtain market sizes outside of Canada. The information required would be onerous for a patentee to obtain and fraught with complications given the potential for different indications, criteria, reimbursement, and prescribing habits.

The current PMPRB Guidelines provide a significant degree of predictability once the patented drug has been evaluated by the Human Drug Advisory Panel (HDAP) and PMPRB Staff. Aside from foreign price changes and exchange rate variations, patentees can predict their compliance with the Guidelines with a high degree of accuracy. Knowing that the price ceiling does not fluctuate allows patentees to direct maximum savings towards pCPA and Product Listing Agreement (PLA) negotiations with public and private payers. If the price ceilings were to change unpredictably due to changes in market size, manufacturers would be forced to maintain a buffer to cushion any future price concessions they need to make and potentially even forego opportunities to expand indications of the drug with Health Canada.

The unfortunate implication of this potential Regulations amendment is that patentees may choose to forego additional indications or line extensions that would benefit the lives of Canadians.

Estimates of market size and actual market size often differ. Market size changes are already being re-evaluated by HTA's, the pCPA, and payers upon each new indication. Obtaining market sizes for other countries would be extremely difficult and fraught with difficulties given differences in reimbursement designs. We would be supportive of utilizing market size as a secondary, optional factor only upon the PMPRB investigation of a drug, but only upon understanding how market size determines whether a drug is excessively priced.



3. Do you agree that Canada's GDP and GDP growth are important for the PMPRB to consider when determining whether a drug is priced excessively? If so, how should GDP be considered?

While we generally agree that countries with greater wealth can absorb more of the economic burden associated with patented drugs, GDP measures cannot be used in isolation and need to be 'normalized' with differences in healthcare systems. International differences in co-pays and deductibles, criteria, indications, time to reimbursement and market potential are just a few variables that need to be considered.

It has been found that GDP fails to correlate tightly with public health measures in that per-capita GDP is an average, and does not capture the distribution of wealth. In the U.S., for example, the infant mortality rate is high because the wealth is concentrated in the hands of a few; the contributions to high infant mortality come from poor subsets of the population living at an economic level that is lower than the rest of the nation¹³.

In addition, there are technical issues with relying on GDP figures as a factor in drug pricing. Canadian GDP is published with an original estimate and is revised, often significantly. Statistics Canada publishes a first estimate of GDP data two months after the respective reference period and is subject to a revision process to allow the integration of new information such as new surveys, taxation data, public accounts, and updates to benchmark data. Because this measure fluctuates significantly, it should not be used to evaluate drug launches. Even quarterly data is generally revised covering data up to three years back. Changes in new international standards may also result in a historical revision.

The lack of details in the consultation document also limits the response that we are able to provide. There should be clarity on the application of this pricing factor before we can advise Health Canada on the appropriateness of its use. In any case, while GDP and GDP per capita are measures of ability to pay, we do not see this as an effective measure on whether the drug is excessively priced.

We generally believe that countries with high GDP or GDP/capita should absorb more of the economic burden. However, without clear knowledge of how the GDP measure will be used, it is not possible to provide detailed analyses on whether the GDP would be an effective measure. The GDP measure should only be used as an optional tool when the patented medicine is under PMPRB investigation, but only upon clarification on how GDP measures will be used in determining whether a drug is excessively priced.



4) Are there any other factors that should be considered by the PMPRB when determining whether a drug is priced excessively? How should the factor(s) be considered and what information should be required from patentees?

As was demonstrated earlier, the current price factors have been highly effective in keeping patented medicines at or below the international median. Introducing additional price factors will only add to the ambiguity of determining the excessive price. Any additional factors should be limited as optional tools to be used by the patentee upon a PMPRB investigation. As was seen with the Copaxone legal case, PMPRB needs to consider all factors in determining whether a drug is excessively priced. As such, additional factors should only be included if it will aid in achieving this objective. Adding pricing factors that measure anything else will likely lead to divergent results and lead to increased uncertainties.

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

- 1) Are there other countries that should be considered in revising the schedule?**
- 2) Are there other criteria that should be considered in revising the Schedule?**
- 3) Please provide any other comments you may have on the Schedule of comparator countries.**

It is our recommendation that the current basket is a fair representation of comparator countries and should not be changed. The PMPRB7 includes countries that share geographic proximity, trade relationships, prescribing patterns, and private-public reimbursement structures. Health Canada has not provided the specific rationale on the inclusion and exclusion of countries using the relevant considerations which would have been useful for this consultation. Although the three factors of consumer protection, economic standing and pharmaceutical market characteristics were used, why these 12 countries were selected (and why other countries were not selected) is not clear.



Even with the current seven comparator countries, most of the correspondence between Bayer and PMPRB are due to discrepancies of international prices in our Form 2 Block 5 reporting. This issue is likely widespread as international prices are contracted out to specialized consultants who have significant experience and knowledge of appropriate PMPRB pricing sources and the appropriate application of PMPRB guidelines. Increasing this list to 12 will cause an unreasonable burden on patentees to further obtain and validate pricing from additional countries and will contribute to the uncertainty of establishing a non-excessive price ceiling.

Statistics Canada indicated that C\$47.0Bn of pharmaceuticals and medicinal products were exported from Canada in 2016 and C\$49.0Bn imported¹⁴. Pharmaceuticals are listed as the 10th largest export category and the 7th largest import category for Canada.¹⁵ In 2016, Canada had a \$2.1Bn trade surplus with the United States for pharmaceutical and medicine manufacturing¹⁶. Lowering drug prices in Canada will only increase this trade deficit further at a time when trade deals with our NAFTA partners are being renegotiated. The impact of significant price reductions on pharmaceutical products needs to evaluate the impact on trade, especially with the US. The complex trade risk surrounding the importation of cheaper Canadian drugs into the US is an ongoing issue. While laws have been passed at the national level prohibiting this practice, individual states have passed legislation to allow the importation of cheaper Canadian goods. Far and away, the United States is our major trading partner. Given that the US is the most similar to Canada in almost all respects, the consultation document did not clearly outline why the U.S. was removed from the list of comparator countries.

In addition, companies who have substantial sales in the U.S. may reconsider launching their products in Canada for fear that cross-border trade may significantly impact their sales. The Meds Entry Watch 2015 published by NPDUIIS indicated that of the PMPRB7, the US dominates in both sales and quantity. Out of all brand-name

¹⁴ <http://www5.statcan.gc.ca/cansim/a26?lang=eng&id=3800070>; for the 4 quarters ended 2016

¹⁵ Trade Data Online. Industry Canada. March 3, 2017.
<http://www.ic.gc.ca/eic/site/tdo-dcd.nsf/eng/Home>

¹⁶ https://www.ic.gc.ca/app/scr/tdst/tdo/crtr.html?timePeriod=5%7CComplete+Years&reportType=TB&hSelectedCodes=%7C3254&searchType=KS_CS&productType=NAICS¤cy=CDN&countryList=specific&runReport=true&grouped=INDIVIDUAL&toFromCountry=CDN&areaCodes=9&naArea=9999



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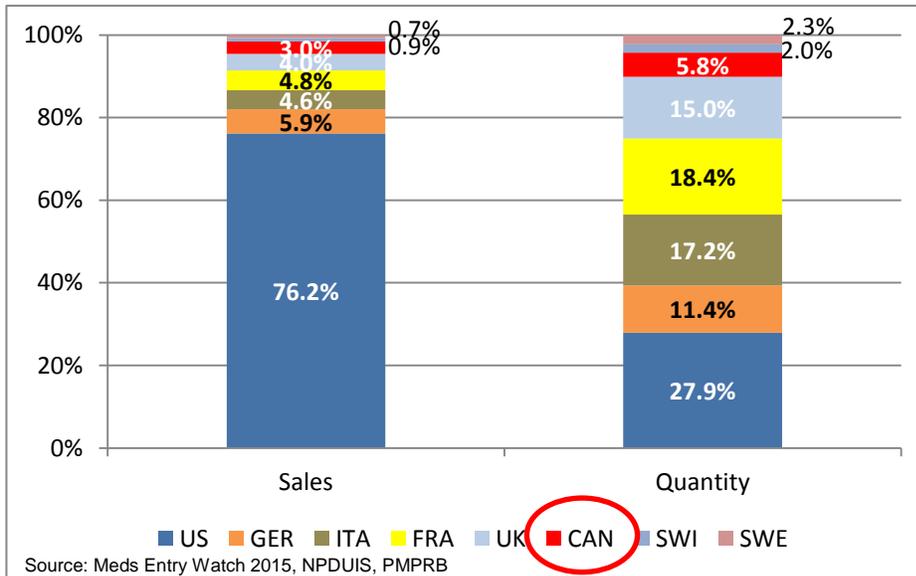
drugs sold within the PMPRB7, the US generated 76.2% of the sales while Canada only generated sales of 3.0% (Figure 4)¹⁷. The sheer importance of the US generating sales for an innovative drug is clear and anything that could jeopardize sales in the US could be viewed as too risky by patentees. As pricing has also come into focus in the US, significant list price differences between Canada and the US may give pause to many companies from launching in Canada should the price differential increase from current levels. Consequently, it is our belief that major trading partners need to be included as comparators.

The list of 12 countries proposed by the PMPRB, aside from adding an administrative burden, would also pose many challenges. We have attempted to obtain ex-factory prices for Japan, South Korea and Norway utilizing the same general principles utilized by the PMPRB and have not been successful. In many instances, we see that only the Consumer Prices or Pharmacy Prices are regulated with no maximum upcharges mandated by governments. This makes it difficult, or if not impossible, to back-calculate to the ex-factory prices and thus these prices would ultimately be excluded from the PMPRB assessment. Indeed, in many of these countries, the patentee establishes confidential contracts with wholesalers causing the ex-factory price to vary. This provides additional rationale for abandoning any change to the PMPRB7.

¹⁷ Meds Entry Watch 2015, NPDUIS, PMPRB



Figure 4. Market share by country for brand-name drugs, by volume of sales and units, Q4 2015



The PMPRB7 list of countries fulfills the criteria outlined by Health Canada. Trade relationships and geographical proximity should be additional factors that are included in the criteria for selecting the basket of countries. The US should also be kept as a comparator country given that a valid rationale has not been provided to exclude it and given that it is a major trading partner whose geographic proximity could lead to parallel trade/importation issues and potentially Canadian drug supply challenges. Should changes be insisted upon, Bayer would be supportive of changing the reference basket to the G7 or at most the G10, but Health Canada should provide a rationale of how these would be preferable to the PMPRB7.

For countries that do not have a publicly available list price or cannot be derived by means identified by the PMPRB, signed letters by a signing officer from the country in question attesting to these prices should be an acceptable pricing source.



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

- 1) Do you agree that patentees of generic drugs, i.e. drugs that have been authorized for sale by Health Canada through an ANDS should only report information about the identity of the drug and its price in the event of a complaint or at the request of the PMPRB?**

Bayer is in full support of reducing regulatory burden when the risk of excessive pricing is low. Consequently, we are in full support of allowing patented generic drugs not to have to submit pricing data except when a complaint is lodged or at the request of the PMPRB.

In order to create an even playing field, however, patented branded drugs with multi-source competition should be granted the same reporting requirements as patented generic drugs. Should generic drugs be removed from the market either due to supply issues, patent infringement or any other reason, Bayer would be in support of reinitiating the reporting of prices.

The regulatory burden should also be reduced in areas where the patentee engages in highly competitive, publicly funded RFP environments. Our recommendation is to exempt blood products and vaccines from reporting to the PMPRB unless there is a complaint or is requested by the PMPRB. The competitive nature of these therapeutic areas tendering to national, inter-provincial and Quebec governments, who wield significant market power, makes the potential for excessive pricing extremely remote.

Bayer is in full support of reducing the regulatory burden by not requiring the reporting of price when the risk of excessive pricing is low. This should apply to therapeutic areas with intense competition such as RFP's conducted by public payers and areas where there is multi-sourced competition. Health Canada also needs to ensure that any regulatory change ensures that there is an even playing field between competitors.



Proposal #4: Modernizing reporting requirements for patentees

- 1) Is the information sought in relation (to) the new factors relevant and sufficient?**
- 2) Is this information generally available to patentees?**

Bayer is in support of providing data to demonstrate that prices are not excessive. However, data should be only required when it does not cause undue administrative burden on the patentee and on the PMPRB. We do not support data collection that will evaluate factors outside the purview of PMPRB's mandate. Areas that are focused on the areas of cost-effectiveness, ability and willingness to pay are objectives and measures owned by other agencies and would result in an unnecessary duplication of duties adding to the administrative burden of patentees who will need to collect, understand and submit the data to the PMPRB. The reporting of this information would not help to facilitate PMPRB's achievement of its stated mandate of ensuring that patented drug prices are not excessive.

In addition, much of the data that is recommended under this consultation would be difficult, if not impossible, to obtain. Pharmacoeconomic analyses may not be conducted for all medications and PE analyses are generally not available from other countries. Even if they are, different market dynamics, standards of therapy, reimbursement criteria, indications and label will serve to complicate the comparison. Significant resources would be required from both the patentee and the PMPRB to analyze, comprehend and interpret the additional information. Language barriers will also make it difficult to analyze foreign data and would add an additional administrative burden and cost to patentees and the PMPRB. Given that these measures will address areas outside of excessive pricing, we do not feel that the benefits of these price factors justify the additional cost and resources.



Bayer supports price reporting requirements when it does not create excessive administrative burden and when the information required serves to address the policy objective of ensuring patented drugs are not excessively priced. In addition, obtaining data for additional cost factors are not always available and will result in an onerous task for a patentee to collect, analyze and interpret. In some cases, we would not be able to obtain many of the international pieces required by these proposed Regulatory changes. Any additional reporting should only be used as an optional tool during a PMPRB investigation.

Proposal #5: Providing information related to third party rebates

- 1) Are there any reasons why patentees should not be required to disclose to the PMPRB information...[on indirect price reductions, given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit in Canada]?**

We are deeply concerned about how the confidential rebates will be utilized by the PMPRB. The consultation document indicates that the information would be considered privileged as per section 87 of the *Patent Act* and would be taken into consideration by PMPRB when determining whether a patentee is compliant with price ceilings. Although there are typically no rebates for New Active Substances (NAS) during the first year of launch due to the delays seen through CADTH, INESSS and pCPA, the launch price will be benchmarked against existing therapeutic comparators who will likely have confidential rebates in place. The net effect is that if the confidential rebates are incorporated to assess price ceilings, the competitor net price would in effect become transparent. Such a move could jeopardize patentees from entering into confidential negotiations with pCPA and may undermine the entire innovative drug ecosystem. This could result in patentees not being able to negotiate confidential rebates resulting in significant delays or not launch in Canada. This flies in the face of amendments proposed to the *Patent Act* that would encourage manufacturers to file for marketing authorization within a



prescribed time period after a foreign filing in order to be eligible for extension of patent term.

Canada is typically able to launch relatively early within the context of global launches as its list prices are the only ones that are generally publicly available. NPDUI's Meds Entry Watch 2015 edition indicated that Canada was the second country of launch for approximately one-third of the 30 top-selling drugs¹⁸. The existence of confidential prices offered within product listing agreements (PLA's), which are available to both public and private payers, allow Canadians to access these drugs relatively early and at a negotiated cost that are often below the list price. Canadians gain timely access to new drugs through early drug launches, while PLA's support this access at discounted prices. Should list prices of Canadian drugs fall due to a combination of Regulatory and PMPRB Guideline changes, we risk significant delays in the launching of innovative drugs in Canada. Indeed, the launch sequence of the 30 top-selling NASs, indicated that while Canada had a lag time of 9.4 months, Italy and France had lag times of 14.8 and 15.4 months, respectively¹⁹. As stated above, Italy and France were the two countries that had lower prices for single-source patented medicines within the PMPRB7 (Figure 2). In addition, while Canada had launched all 30 of these NASs, Italy and France did not launch 3 and 8 of the NASs, respectively.²⁰

The announcement by Minister Philpott that Health Canada and HTA's can be conducted in parallel may not have the intended impact on the timing of new innovative drug launches. Any potential savings of time due to these parallel reviews would likely be offset by decisions to delay launches in Canada due to International Price Referencing.

Aside from the legality of sharing this confidential information, there is a large technical challenge of reporting these rebates. There is often a significant delay before a province invoices patentees for confidential rebates. We have seen some provinces invoice years after the reimbursement event. In order for companies to follow proper accounting guidelines, accruals are put into place which can

¹⁸ Meds Entry Watch, 2015, Patented Medicine Prices Review Board

¹⁹ Ibid.

²⁰ Ibid.



occasionally be substantially different from the actual invoice and will fluctuate from company to company which adds another layer of uncertainty and complexity.

It is critical to understand how confidential rebate information will be utilized. If future patented products will be benchmarked against the confidential net prices of comparator products, many innovative products will either have significantly delayed launches or not launch at all as the magnitude of the rebates will become self-evident over time. The elimination of PLA's could undermine the entire pCPA process and force innovative drugs to be sold at a publicly available list price to all payers. Payers and patients need to be aware that this will result in highly curtailed discounts and that the cost to the public payer may in fact be higher than what they may receive through confidential rebates. The impact of disclosing rebates requires further discussion as this requirement has the greatest potential to affect patients' access to innovative drugs in Canada. Aside from the legal ramifications, there is also a technical challenge in reporting rebates as there is often a delay in receiving and paying the invoices.

Conclusion

Bayer is aligned to revisit PMPRB regulations with the caveat that changes to the regulations should only occur if PMPRB's mandate is not being met. As Canadian patented drug prices are below the median prices, we believe that the PMPRB has the appropriate tools to ensure that prices are not excessive. Other factors such as cost effectiveness, affordability and willingness to pay, do not address the policy question (PMPRB mandate) of whether an innovative drug's price is excessive. Regardless, implementation of any new price factors should be optional and used only during an investigation. To do so otherwise would create an unnecessary administrative burden and also decrease predictability for all stakeholders.

We are concerned that the proposed amendments to the Regulations are vague and duplicate roles conducted by other agencies in Canada. Should PMPRB decide



to include these factors despite the significant concerns raised both in this document and by the IMC, we suggest that these factors only be used as a last resort during an investigation, and with transparency, publicly-stated clarity on how these measures would further facilitate achievement of the PMPRB's goal. The proposed Regulations amendments, without context on how these changes would be implemented in the PMPRB Guidelines, makes us particularly concerned that decisions are being made without understanding the full implications to patients, patentees and payers.

We ask that this consultation on the regulatory process be extended. We ask that Health Canada work closely with PMPRB and other stakeholders, including patentees and patients, to clearly elucidate the full impact of any Regulation amendment. How Regulations will manifest itself in PMPRB Guidelines is important to allow all parties to provide meaningful feedback and make this process relevant and transparent. During this time of rework, it will give time for IMC to share their reform proposals to the pan-Canadian initiative so that Health Canada can consider several additional options, which will likely result in the best solution for the patient. This initiative focuses not only on price, but addresses a broader, more positive policy in order to facilitate sustainable access for Canadian patients to innovative medicines. Industry and government can then work together to bring the best options forward to ensure that patients continue to have access to the most innovative medicines.

In order to mitigate potential significant impacts to Canadians who are benefitting from innovative medicines, we ask that any Regulation amendment be applied only on new product launches. This would serve to avoid the deluge of needless investigations on existing patented products and would ensure that patients who are receiving the benefits of innovative medicines continue receiving the treatment unabated.



Conclusion: Regulations and Guidelines are working given that patented drugs are below the median international price. Canadians deserve to understand how these regulatory proposals will be adapted into PMPRB Guidelines and how this will affect their access to innovative medicines. Only informed discussions between all parties can make this possible. In order to minimize the impacts of these regulatory changes, they should only apply to future drug launches. We ask that the regulatory consultation be extended to allow Health Canada to work with the PMPRB on how these changes will be reflected in the PMPRB Guidelines. This will give an opportunity for the IMC to share proposals through the pan-Canadian initiative. Any action that could affect Canadian access to innovative medicines must be handled with caution and after all alternatives have been considered. Any change, be it positive or negative, will have a long-term and lasting impact on the well-being of Canadian patients.

We wish to thank Health Canada on this opportunity to reflect on the proposed regulatory changes. Only with all stakeholders working together, can patients continue receiving the innovative medicines that work best with them when they need them. Regulations should help facilitate this process rather than hinder it. We look forward to working with Health Canada and PMPRB to make this a reality.

Yours sincerely,

A handwritten signature in black ink that reads "Dale Toki".

Dale Toki
Director, Pricing and Contracts
Bayer Inc.