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June 28, 2017

VIA EMAIL (PMR-Consultations-RMB@canada.ca)

Patented Medicines Regulations Consultations
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Pfizer Canada Inc. Response to Patented Medicines Regulations Consultations

Introduction:

Pfizer Canada Inc. ("Pfizer") is pleased to have the opportunity to contribute to the consultations on the proposed modernization of the Patented Medicines Prices Review Board (PMPRB) Regulations in the consultation document "Protecting Canadians from Excessive Drug Prices", released by Health Canada on May 16, 2017.

Pfizer is a leading biopharmaceutical company with a wide-ranging portfolio of innovative medicines, consumer products, vaccines and multisource products. We have extensive experience in the Canadian health care sector. In addition to this submission, Pfizer has contributed to, and supports, the submissions of our industry associations, Innovative Medicines Canada, BIOTECanada and the Vaccine Industry Committee.

Pfizer acknowledges the Minister's mandate related to the current PMPRB reform and we want to support this policy review with our contribution. After 30 years, we agree that the PMPRB needs to be reviewed and reformed to address the realities of 2017 including, but not limited to, the significant role now played by provincial governments in drug price controls; our industry's evolution; your Government's innovation strategy for the future; and the Government's legitimate interest in using the PMPRB's regulatory oversight over patented medicines in the most relevant manner. Pfizer has been actively involved in the consultations. We are working with PMPRB to provide clear and meaningful information that can only lead to a better understanding of the current pharmaceutical market.

While we understand the objectives of the proposed reforms, we are concerned that they will lead to serious unintended consequences where Canada could become a de-prioritized market to launch new innovative medicines. They will reduce predictability and stability for the business environment; introduce unnecessary regulatory duplication with existing Federal, Provincial and Territorial governments (FPT) and provincial programs; and move into areas not supported by the PMPRB's mandate over "excessive" price. The proposals for positive regulatory change, to adopt a risk-based approach, do not go far enough.

The proposals do not meet important standards for proposed regulatory initiatives. There is very little, to no, policy rationale provided to support the proposed changes, nor any assessment of the impacts on other Federal government priorities related to innovation and life sciences, and on provincial drug programs. As an example, it takes on average 731 days[1] to get a new drug reimbursed on public formularies across Canada. The PMPRB has also reported that Canada's median lag time for launch of innovative therapies compared to first global launch is 11 months[2]. Therefore, a rudimentary and conservative combination of these two metrics point to the fact that it can take as many as three years from the first country that launches an innovative treatment anywhere in the world to most Canadians having access to this treatment through provincial public drug programs. If changes are made they should address these gaps that have a direct impact on the accessibility of innovative medication to Canadians.

We hope that this consultation is the first step in a broader and more comprehensive dialogue with all stakeholders over drug pricing and the future role of the PMPRB. Multi-stakeholder dialogue is the only way to ensure sound evidence-based policy in such an important and complex area. Considering the scope of the proposed changes and considering the more rigorous Health Canada consultations on less impactful matters, this consultation on proposed amendments to the Patented Medicines Regulations appear to be rushed and vague, thus making it difficult to fully assess all of the potential implications.

Economic Factors:

Pharmacoeconomic analysis

Pfizer Canada supports the submissions by our industry associations that Health Canada should not incorporate a pharmacoeconomic analysis in regulations intended to set a non-excessive ceiling price. The QALY analysis is used nationally and internationally as a tool in negotiating an appropriate reimbursement price with budget holders; it is not suitable in establishing a

[1] M. Rover , B. Skinner, Coverage for new medicines in Canada's public drug plans, 2015, http://www.canadianhealthpolicy.com/products/coverage-for-new-medicines-in-canada---s-public-drug-plans--2015-.html

[2] PMPRB, Meds Entry Watch, 2015, http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1307

regulated maximum non-excessive price. Affordability is best evaluated by the payers and not by the PMPRB as it is not a payer and has no mandate to attempt to act in their place. By definition, a QALY is a measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life.[3] Cost per QALY is a formulaic economic measure used by payers along with other factors in making reimbursement decisions, including local health priorities and trade-offs among competing demands on the payers' budgets. Keeping that in mind, a cost per QALY threshold is inappropriate as a tool to define "excessive" price as the willingness to pay of Canadians may vary considerably as a result of differing values and constraints.

This activity is well beyond PMPRB's role defined by the *Patent Act* and would duplicate and overlap with existing programs used by CADTH, INESSS and pCPA.

Market size

One of the new factors introduced in the consultation document is the anticipated size of the market for the drug. It is relevant for payers to take market size and budget impact into account when negotiating prices and other terms and conditions of listing. It is not relevant in assessing whether a given price may, or may not, be excessive. Payers currently take market size and budget impact into account when negotiating listings, so to add these factors as a determinant of "excessive" price will duplicate existing processes and create an unnecessary regulatory burden that may result in additional delays for patients.

Gross Domestic Product

Similarly, questions about the "affordability" or willingness to pay for a treatment are questions for payers to address. There is no single ability-to-pay threshold in Canada; public and private payers currently make their own determination and use it when negotiating listing agreements. Consideration of Canada's GDP relative to other countries may be appropriate as a criteria in selecting countries for international price comparisons, but not as a factor in determining "excessive" price.

Basket of countries:

The consultation document is proposing to change the current basket of countries used by the PMPRB for price comparison purposes.

[3] National Institute for Health and Care Excellence, Glossary, June 20, 2017
https://www.nice.org.uk/glossary?letter=q

Canada should be compared to countries that reflect similar economic conditions and public policy objectives for patient access to important new therapies. The economic ties between Canada and comparator countries form part of "similar economic conditions". For many reasons, the United States (U.S.) should be part of the basket.

Pricing in the U.S. is complex because there may be a range of prices available to different payers and they are often not transparent – however, this is no reason to exclude Canada's most important trading partner. The PMPRB already uses prices from the U.S. government's Federal Supply Schedule – transparent, negotiated and heavily-discounted prices – as part of its calculation of a U.S. price. The consultation paper has not provided any analysis of options for identifying appropriate U.S. prices for comparison purposes such as different price sources and, or, methodological adjustments.

Canada and the U.S. have mixed private/publicly-funded systems with multiple payers; utilization and prescribing patterns are comparable. Geographic proximity and an extensive economic relationship support a high degree of scientific and clinical integration and patient movement.

As a result, Canada is more closely aligned with the U.S. than any other country in the medicines available to treat patients. The PMPRB has reported that in terms of availability of new active substances (NASs) launched in recent years, "Canada has the greatest similarity to the United States." Of the 128 NASs launched in Canada, 123 were also launched in the U.S., a higher number than the other PMPRB7countries. By contrast, only 76 were available in France.[4] As many as 10% of products under current PMPRB jurisdiction are only available in Canada and the U.S., and are not sold in the European Union or other countries.[5] While we understand the rationale here, we suggest that the Government place more focus on wait times and on percentages of drugs not launched in Canada based on the recent report (39%)[6].

Providing information related to third party rebates:

Proposed amendments to the Regulations would require the reporting of all forms of indirect price reductions, including rebates, discounts and free goods and services. It is unclear how this information will be used by the PMPRB.

Most of these third-party rebates are likely paid to governments pursuant to Product Listing Agreements (PLAs) that may include several conditions specific to the product, such as criteria and conditions of coverage, how the rebate is calculated and accrued, and the frequency of payments. These agreements are confidential. We do not have enough information to consider

[4] PMPRB, Meds Entry Watch, 2015, http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1307
[5] Source: Form 2 Block 5 data submitted to PMPRB, July-December 2015, Innovative Medicines Canada members
[6] PMPRB , Meds Entry Watch, 2015, p. 8, http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1307

how the requirement to report them to the PMPRB will be applied and whether it can be done in a manner that is consistent and fair to all parties. At a minimum, this requirement will create a considerable regulatory burden.

We are also concerned that it will have unintended consequences. Provincial governments first introduced PLAs to take advantage of their buying power to obtain the best possible prices. If the PMPRB were to use the rebate information to affect its calculation of "excessive" price in any market in Canada, the impact would be to reduce the ability of a manufacturer to accept the level of rebates sought by public payers.

Today, many manufacturers have agreements with different jurisdictions to address affordability and ensure optimal access to medications for their constituents. The public payers who benefit the most from these agreements are largely responsible for insuring the most vulnerable populations in Canada.

For their part, the private, for-profit, insurance companies are also able to negotiate with the pharmaceutical manufacturers to achieve the best value for the health benefit plans they offer. A variety of formularies and plan designs are available including multi-tiered formularies, prescribing appropriateness and cost-sharing mechanisms, case management programs, adherence programs, preferred provider networks, and industry-level pooling mechanisms.

The forced disclosure of the rebate information appears designed to allow the PMPRB to force an equalization of prices in the market – an outcome that is most likely to harm public drug programs and could limit products being launched in Canada. The only beneficiaries of such regulation would be the private for-profit insurance companies and due to the nature of that industry, there is no guarantee that any savings achieved would be passed along to plan sponsors and patients in the form of lower premiums or added benefits. In fact, numbers show that in 2011, Canadians paid near $6.8 billion more in premiums than what the private payers paid as benefits.[7]

Modernization of PMPRB Regulatory Framework:

The PMPRB regulatory framework has been largely unchanged since it was established almost 30 years ago. Reform is overdue. The nature of drug research and development and the pricing and reimbursement framework have changed dramatically since 1987. The consultation paper leaves the impression that Canada has somehow not kept pace with developments in other countries. On the contrary, and led by the major provincial public payers, Canada was an early adopter of health technology assessment and CADTH has long been considered a global leader

[7] Michael R. Law et al, The increasing inefficiency of private health insurance in Canada, CMAJ, 24 March 2014, http://www.cmaj.ca/content/early/2014/03/24/cmaj.130913.full.pdf

in this area; in order to benefit from their joint buying power, governments created the pan-Canadian Pharmaceutical Alliance to negotiate optimal listing conditions for new drugs and to obtain lower prices and annual rebates leading to annual savings currently estimated to be about $1 billion.[8]

The PMPRB has been part of Canada's performance, creating an environment where maximum prices for patented drugs are in-line with other major developed countries and price increases have been essentially non-existent for 25 years. According to the PMPRB, Canadian prices for the top new patented drugs introduced between 2010 and 2014 were below the median of the PMPRB7 countries. In fact, Canada was tied with Italy for fifth spot, lower than Germany, the United Kingdom, Switzerland and the U.S., and only one percent above Sweden. Not only are Canadian prices for patented drugs not excessive, they have been stable for the past two decades, with annual average changes ranging between minus 2.2% and plus 0.7%. These results provide evidence that the system in place has generally been effective in determining non-excessive prices. Yet, the current rules of engagement may present opportunities for modernization in areas where innovation has been most disruptive.

We are concerned about inappropriate overreach on the part of the Federal government with some of its proposed PMPRB reform measures. By creating new price factors that are inherently open to a range of interpretations it may actually weaken the ability of the PMPRB to achieve voluntary compliance and disrupt the policies of public and private payers to ensure value in their coverage decisions for drugs.

We are also concerned that some measures will impact Canada's standing as one of the first countries to benefit from the availability of important new therapies.

Proposed Risk-based Approach to Regulation:

The consultation paper proposes a risk-based approach to the PMPRB program:

> Drugs with higher potential to exert market power would face a higher degree of regulatory scrutiny while drugs with medium or lower risk of excessive prices would face respectively lower oversight.

We support this approach as it is consistent with good regulatory policy, reduces the risk of undue regulatory burden and minimizes the risk of unintended consequences.

[8] The most recent information published by the Council of the Federation estimated annual savings of $712 million as of April 1, 2016. http://www.canadaspremiers.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance. In response to questions at a CORD conference on June 14, 2017, the pCPA Senior Manager stated the savings are now about $1 billion annually.

Potential PMPRB reform could help shape policy in a cooperative non-judicial way, with a set of criteria tailored to Canadian consumer priorities, while still providing the necessary parameters to foster innovation and protect Canadian consumers. A risk-based model could provide clear regulations that encourage access to innovation through market-based forces rather than rely on duplicative, redundant or burdensome regulations. A balanced risk-based model would allow for efficient achievement of the policy objectives stated by the Minister.

The proposed regulatory change to reduce reporting requirements for patented generic drugs, is a step in the right direction, but only goes part way.

These drugs face greater competition because they are multisource drugs, as in because they compete with interchangeable products, brand-name and generic. To be consistent with the objective, the proposed regulatory change should be to reduce reporting requirements for ***all*** patented multisource products. The consultation paper acknowledges that such drugs have medium or low risk of excessive prices and the market does not require a high degree of PMPRB oversight. To treat patented generic multisource drugs differently from patented brand-name multisource drugs is unjustified and unfair and will likely lead to market distortions. To regulate the prices of some drugs in a therapeutic class and not others would be inconsistent and unreasonable.

The risk-based approach could be extended to several other areas such as vaccines, tendered blood products and other therapeutic areas where market forces are effective and heavy competition prevails.

PMPRB Legal Framework: The Need for Alternative Dispute Resolution

Modernization of the PMPRB program needs to respect the quasi-judicial nature of the PMPRB and the legal processes and remedial powers provided by the *Patent Act*. We note that the PMPRB has obtained a high degree of voluntary compliance with its guidelines, and therefore a limited need to take formal quasi-judicial proceedings, because it has relied on "bright guidelines" (defined as clear and specific rules that patentees can understand and follow[9]).

Significant changes to the regulatory framework as proposed will endanger the voluntary compliance policy. By their nature, factors such as health economics and affordability are dependent on many variables and subject to different interpretations. There is no reason to believe that the PMPRB will be able to develop "bright guidelines" that will be suitable for voluntary compliance purposes.

[9] The PMPRB Guidelines elaborate specific price tests and how they are performed which allow patentees to calculate maximum non-excessive prices at launch and on an ongoing basis. See PMPRB Compendium of Policies, Guidelines and Procedures, http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492

It appears that PMPRB anticipates there will be a greater need for formal proceedings to resolve pricing issues in the future. Such an outcome should be avoided. The legal process provided under the *Patent Act* is cumbersome and not suited to a dynamic market. Hearings before a Hearing Panel of the PMPRB typically take several years and are often followed by appeals to the Federal Court. If lengthy and costly legal proceedings become the norm for important new therapies, two outcomes can be predicted: (a) patients and drug plans will be left waiting for the determination of a maximum price, and (b) manufacturers will be reluctant to bring the drug to market in Canada due to the pricing uncertainty.

If the proposed reforms are adopted, we propose that the PMPRB adopt an alternative dispute resolution (ADR) option to allow disputes to be addressed promptly and at less cost. The efficiencies achieved by adopting a more streamlined approach to conflict resolution will benefit all parties involved, including by reducing burden on the PMPRB itself. In our view, if the government decides to reform the PMPRB in the manner proposed, it needs also to address the legal framework of the PMPRB and ensure mechanisms exist to provide appropriate remedies and processes.[10] Ultimately, faster resolution can only serve better patient outcomes, which is in the overarching interest of all parties involved.

Reporting on Research & Development Investments:

We regret that the consultation paper does not address the question of PMPRB reporting on industry Research & Development (R&D) expenditures. We believe there is considerable consensus that the current reporting by PMPRB is out-of-date as it is based on definitions and tax rules from 30 years ago; it does not recognize the significant evolution in R&D in today's global biopharmaceutical industry.

Furthermore, we are not aware of why this role should be performed by the PMPRB. Under the *Patent Act*, the information is not used in any way by the PMPRB in its price regulation functions. To the extent that the Government would wish to collect information on industry investments in R&D, we will welcome the opportunity to discuss the appropriate mechanism and agency to perform that role and definitions that are relevant and useful to the Government.

[10] Several federal agencies use ADR or mediation mechanisms, e.g., Competition Tribunal, http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/04053.html; Canadian Transportation Agency, https://otc-cta.gc.ca/eng/publication/resolution-disputes-through-mediation-a-resource-tool, Canadian Industrial Relations Board, http://www.cirb-ccri.gc.ca/eic/site/047.nsf/eng/home, Canadian Radio-television and Telecommunications Commission, http://www.crtc.gc.ca/eng/industr/rddr/

The Minister's proposals for PMPRB reform provide an ideal opportunity to open a dialogue on this question with the Minister of Innovation, Science and Economic Development and other stakeholders.

Closing comments:

We agree that any reform of the PMPRB must consider the significant changes in the pharmaceutical sector during the past 30 years. Those changes include the adoption by all governments in Canada of more sophisticated and effective mechanisms for the pricing and reimbursement of prescription drugs similar to policies in other developed countries.

We are supportive of a modern, risk-based approach that will allow the PMPRB to focus on the most important innovative therapies, but we question if the proposed regulatory changes strike the right balance. They would continue unnecessary detailed oversight of multisource patented drugs and add unwarranted regulatory overlap and duplication. Many of the measures proposed, especially those based on pharmacoeconomics and ability- and willingness-to-pay thresholds, are currently performed by FPT governments and public and private drug plans; the proposed measures are not only duplicative but also inappropriate for the PMPRB model of regulation. The PMPRB's role is to ensure prices of patented medicines are not excessive – a role it has been carrying out in the vast majority of cases effectively for many years. The proposed amendments would establish a new regulatory framework that goes beyond the "excessive" price mandate of the *Patent Act* and would duplicate existing and effective programs across the country.

The PMPRB uses a quasi-judicial approach. Rather than a nimble and flexible approach that is needed in drug pricing. The PMPRB structure necessitates lengthy and expensive legal proceedings to resolve disputes. The proposed regulatory changes are likely to create market uncertainty and discourage voluntary compliance. Unless mitigated by an ADR approach, the lengthy, costly and contentious legal proceedings are likely to lead to significant delays in Canadians' access to innovative new treatments and act as a disincentive to manufacturers to bring important new treatments to Canada as quickly as possible.

Thank you once again for the opportunity to contribute to the consultations on the proposed modernization of the PMPRB Regulations. If you have any questions about our comments, or require any clarifications, please do not hesitate to reach out to me.

Sincerely,

John Helou
President, Pfizer Canada Inc.