October 31, 2016

Mr. Douglas Clark
Executive Director
Patented Medicine Prices Review Board
1400 - 333 Laurier Avenue West
Ottawa ON K1P 1C1

RE: Roche Canada Input on PMPRB Public Consultation

Dear Mr. Clark:

Enclosed, please find Hoffmann-La Roche Limited's (Roche Canada) response to the questions posed in the Patented Medicine Prices Review Board's (PMPRB) public consultation discussion document to aid in the revision of its regulatory framework as outlined in its *Compendium of Policies, Guidelines and Procedures*.

As you will note in our submission, we have provided our perspective on each of the questions proposed in the PMPRB Discussion Paper, but would also like to take this opportunity to share our views on the broader topic of value that should be considered in the PMPRB's evaluation of price for prescription pharmaceuticals, and particularly innovator biologic medicines.

As a key partner in the Canadian healthcare system, Roche recognizes that our country's growing healthcare spending places significant pressure on federal, provincial, and territorial budgets. In the face of these growing pressures, we also understand that payers and other stakeholders involved in the drug reimbursement process have a greater need to ensure they are getting good value from their investments in prescription medicines.

For this reason, we would be remiss not to offer our view on the value of our medicines, and the value of our business to society as part of this submission. In our view, the concept of value is a critical component to discussions around the price of prescription medicines as it offers a broader perspective on the impact our organization is making on the health of Canadians today, and well into the future.

Roche's Approach to Pricing

Roche has a long-standing commitment to partnering with key stakeholders within the current healthcare system to directly benefit Canadian patients. We are committed to working with regulators, policy makers, payers and healthcare providers to offer solutions that are sustainable for

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all. This includes our pricing strategy, which aims to balance the needs of our company with those of patients, their care teams, as well as other local stakeholders. We consider a number of key factors that we believe reflect the value of our innovations while keeping health system sustainability at the forefront. These include:

Degree of unmet medical need
As an innovation-driven company, Roche considers the impact the disease has on patients, their caregivers, as well as society. This includes evaluating the prognosis of the patient, severity of the disease, its impact on a patient's quality of life and his/her family, as well as the incidence and prevalence of the disease. We also evaluate what other treatment options (if any) are available; how effective they are; and how satisfied patients are with these existing options.

The science
We aim to develop innovative medicines that improve patient outcomes compared to the current standard of care.

Patient impact
We consider the resources required for the administration of our medicines, such as staff time, equipment, material investments, special premises, as well as any potential need for additional medicines, interventions, procedures or hospital stays. We also look at the healthcare costs that may be saved as a result of using our medicines.

Societal impact
We aim to develop medicines that allow patients and caregivers to go back to work and/or resume their roles within their families, thus returning key resources to society.

Quality of evidence
When designing our trials, we engage with external stakeholders, regulatory bodies, pricing and reimbursement authorities, as well as patient organizations, in an effort to address their evidence expectations around populations, endpoints and comparators. The number and size of trials, the methodology and homogeneity of the results and the representativeness of the patient population are crucial factors for the generation of robust evidence.

The pricing context
We also evaluate the external environment in which the new medicine will be used. We look at a number of elements, including the price of potential comparators or analogues, the results of cost-effectiveness analyses, the potential impact the new medicine may have on healthcare budgets, as well as the affordability levels across countries.

Value of Roche Medicines to Canadians

At Roche, we develop medicines and diagnostics that, we believe, significantly improve people's lives. For example, HERCEPTIN® (trastuzumab), our second monoclonal antibody approved for the treatment of a malignant condition and the first antibody approved for the treatment of a solid tumour, has redefined what it means to be diagnosed with HER2-positive breast cancer in Canada.

Since its approval in 1999, HERCEPTIN has offered HER2-positive breast cancer patients significant improvements in both overall survival (OS) and progression-free survival (PFS). A study published in the *Journal of Clinical Oncology* in 2014 demonstrated that, at 10 years after treatment, 84 per cent of women with early breast cancer treated with HERCEPTIN and chemotherapy were still alive as compared to 75.2 per cent of women who received chemotherapy alone (a 37 per cent improvement in OS for the HERCEPTIN treatment arm). In addition, 73.7 per cent of women treated with

HERCEPTIN and chemotherapy were alive without their cancer growing vs. 62.2 per cent of women who received chemotherapy alone (meaning that disease-free survival was 40 per cent better in women treated with HERCEPTIN).[1]

Despite HERCEPTIN's success in changing outcomes for women living with HER-2 positive breast cancer, Roche has continued to invest in the development of additional, more effective treatment options for this patient population. Our commitment to ensuring that we are always progressing science has been the backbone for our work to bring PERJETA® (pertuzumab) – a new standard of care for metastatic, HER2-positive breast cancer – to market. Data presented at the European Society for Medical Oncology (ESMO) annual meeting in September 2014 demonstrated that PERJETA, used in combination with HERCEPTIN and chemotherapy in the first-line setting, significantly improved OS for patients with HER2-positive metastatic breast cancer by providing a 15.7 month increase in the median values when compared to HERCEPTIN and chemotherapy alone. The median OS of 56.5 months was deemed to be unprecendented in first-line use, reinforcing our view that PERJETA is a new standard of care (replacing HERCEPTIN) in this setting.[2]

This focus on continuously advancing science and developing medicines that offer even more value than our existing therapies is not limited to the breast cancer setting. Roche has taken a similar approach with our hematology portfolio, which has been rooted in the value RITUXAN® (rituximab) has offered patients over the last 10 years, but is also being redefined by the improvements that GAZYVA® (obinutuzumab) has already provided to adult patients living with Chronic Lymphocytic Leukemia (CLL).

Impact of Roche Investments in Canada

In addition to delivering value to patients and the health system through our approved medicines, Roche also continues to invest in research to deliver innovative treatments and diagnostic solutions that meet the evolving needs of our patient and physician communities. Our commitment to the future of medicine hinges on our ability to invest and reinvest in countries, markets and communities that offer fertile ground for this research. This allows us to play an important role in supporting local, sustainable economies, with a focus on market needs, priorities and opportunities.

This approach to enhancing local economies has been the driving force behind our investment of more than $190 million into expanding our site in Mississauga, Ontario. In addition to serving as the home for the Pharmaceuticals division, the site also houses one of six Roche Global Pharmaceutical Development sites, which is responsible for managing company-sponsored clinical trials across the globe. The expansion project was supported by a $7.79 million investment from the Government of Ontario and brought close to 200 highly skilled and specialized jobs to the province.

In 2013-2014, Roche invested an additional $59+ million to continue expansion of our operations in Mississauga, making a sizeable impact to the Canadian economy by generating more than $60 million in Gross Domestic Product over the past two years.

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[1] Perez, EA, Romond, EH, Suman VJ, et al. Transtuzumab plus adjuvant chemotherapy for human epidermal growth factor receptor 2-positive breast cancer: planned joint anaylsis of overall survival from NSABP B-31 and NCCTG N9831. *Journal of Clinical Oncology*. 32.33 (2014): 3744-3752. Available online at: http://jco.ascopubs.org/cgi/doi/10.1200/JCO.2014.55.5730. Last accessed on October 23, 2016.

[2] European Society for Medical Oncology. ESMO 2014: Final overall survival analysis from the CLEOPATRA study in patients with HER2-positive metastatic breast cancer (September 28, 2014). Available online at: http://www.esmo.org/Conferences/Past-Conferences/ESMO-2014-Congress/News-Articles/Final-Overall-Survival-Analysis-from-the-CLEOPATRA-Study-in-Patients-with-HER2-Positive-Metastatic-Breast-Cancer. Last accessed on October 23, 2016.

Further to this, Roche invested over $38 million in clinical research in Canada in 2015, accounting for six per cent of our global research spending, and making Canada a key country in which we pilot new initiatives. Today, there are approximately 150 Roche-sponsored clinical trials currently underway in Canada, which offer people living with conditions like Alzheimer's disease, bladder cancer, lung cancer, skin cancer, breast cancer, and chronic obstructive pulmonary disease access to investigational medicines and diagnostics.

Recognizing that PMPRB aims to ensure the pharmaceutical industry invests in R&D within Canada, we believe our current footprint should be factored into our response to your discussion document. While these investments may not be captured in the current PMPRB system of measurement, which feeds data to the Scientific Research & Experimental Development Tax Incentive Program (SR&ED), they are important because they reflect our ongoing commitment to growing the life sciences ecosystem in Canada.

We hope you find our submission helpful in your assessment of the current regulatory framework for evaluating the price and value of medicines in Canada. We look forward to your feedback and would welcome a dialogue about the perspectives we have shared both in this letter and within our formal response.

Regards,

David Shum
Director, Market Access and Pricing
Hoffmann-La Roche Limited

Roche Canada Responses to PMPRB's Questions for Discussion:
Definition of Terms

To reduce the level of ambiguity in our responses, we have defined certain terms used within the Questions for Discussion. The terms, and their corresponding definitions, are presented below.

Table 1. Definitions

Term	Definition (Restricted to Drugs)
Drug Price	The public list price of a drug.
Drug Cost	The amount of money paid by a payer for a given drug over a given period of time.
Excessive (Drug Price) ***or*** **Excessively Priced (Drug)**	The average price paid for a given drug is greater than a predefined threshold, where the threshold reflects the value of the drug.
Potentially Excessive (Drug Price) ***or*** **Potentially Excessively Priced (Drug)**	A drug price that requires an assessment to determine whether it is excessive (i.e., at risk of having an excessive price).
Value	Established using a number of factors such as patient outcomes (mortality, morbidity, and quality of life), improvements in the efficiency of health care delivery, avoidance of unnecessary treatments and procedures, and improvements in drug administration and compliance in treatment.
Affordability	The ability of a payer with a defined budget to pay for the use of a drug.

Roche Canada Responses to PMPRB's Questions for Discussion

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

Roche's position

It is Roche's position that drug pricing should be based on the value offered by the drug in question. The prices of our products reflect the benefit that the innovation delivers to patients, their families, payers and societies, as well as the inherent risks in R&D required to sustain vital innovation, and to continue to meet unmet patient needs in the future.

For Roche, the word "excessive" as it relates to drug pricing means that the average price paid for a given drug is greater than a predefined threshold. The threshold used should reflect the value offered by the drug, with value being defined by factors such as patient outcomes, improvements in the efficiency of health care delivery, avoidance of unnecessary treatments and procedures, and improvements in drug administration and compliance in treatment.

PMPRB's past position

To date, the definition of "excessive" used by the PMPRB has been closely aligned with Roche's definition. The PMPRB currently uses the following factors from section C.6 of the Guidelines when recommending the level of therapeutic improvement of a new drug product:

Primary Factors
Increased efficacy
Reduction in incidence or grade of important adverse reactions

Secondary Factors
Route of administration
Patient convenience
Compliance improvements leading to improved therapeutic efficacy
Caregiver convenience
Time required to achieve the optimal therapeutic effect
Duration of usual treatment course
Success rate
Percentage of affected population treated effectively
Disability avoidance/savings

Primary factors are used to determine whether a new drug is a breakthrough or offers substantial, moderate, or slight/no improvement relative to other drugs available in Canada. Following assessment based on Primary Factors, an assessment based on Secondary Factors will occur; this can result in the drug being assessed as offering a moderate improvement. Based on this assessment of value, a specific price test is employed to determine the maximum allowable potential price of the drug.

Is redefining "excessive" appropriate?

Given that the Roche position on drug pricing incorporates both the value of the new drug and the R&D required to sustain innovation, we do not believe that a drug price should be viewed as

excessive if the drug in question costs exponentially more than other drugs that treat the same disease or costs more annually than a certain agreed upon economic metric.

When assessing whether a drug price that costs exponentially more than other drugs that treat the same disease is excessively priced, it is reasonable to expect that a decision maker will also assess whether the drug in question offers exponentially more value to the Canadian healthcare system, including stakeholders such as patients and their caregivers.

Should affordability influence a determination of excessive pricing?

In our view, when value drives the determination of drug price, neither the size of the population treated nor the impact on overall spending on drugs in Canada should be considered when assessing excessive pricing. Instead, issues of affordability such as how one should treat a drug that is 'very costly' and only treats a small group of patients such that it accounts for a very small proportion of overall spending on drugs in Canada or a non-excessively priced drug that accounts for a disproportionate amount of overall spending on drugs in Canada should be addressed at the budget holder (i.e., payer) level.

As was noted in the Discussion Paper, there are three distinct payer types in Canada: public payers, private payers, and cash customers. For each of these payer types, and for each unique payer within a given payer type, the definition of affordability differs.

In a system with multiple payers that have very different challenges, motivations, and levers for financial relief, it is difficult to arrive at a common definition of affordability. For this reason, it is important for the PMPRB to continue to assess "excessive" pricing by decoupling the price of a drug from its cost to payers.

Roche is prepared to work with stakeholders at all levels of the Canadian healthcare system to help Canadians access the medications they need when they need them.

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

Today, the PMPRB uses the following factors, taken from Subsection 85(1) of the Patent Act, to determine whether a drug is potentially excessively priced:

- The prices at which the medicine has been sold in the relevant market;
- The prices at which other medicines in the same therapeutic class have been sold in the relevant market;
- The prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
- Changes in the Consumer Price Index; and
- Such other factors as may be specified in any regulations made for the purposes of this subsection.[1]

These factors, in addition to including domestic and international drug prices, consider the

[1] The Patented Medicines Regulations (http://laws-lois.justice.gc.ca/PDF/SOR-94-688.pdf) do not outline any factors to be used in addition to the s.85 factors; however, they do include information regarding the countries that should be used for price comparisons.

economic measures of CPI and currency exchange rates. We believe that these factors should continue to be used to determine whether a drug is potentially excessively priced.

2. **Given that it is standard industry practice worldwide to insist that public prices not reflect discounts and rebates, should the PMPRB generally place less weight on international public list prices when determining the non-excessive price ceiling for a drug?**

   Roche believes that international public list prices should continue to play an important role in determining the non-excessive price ceiling for a drug for the following reasons:

   - As mentioned in the Discussion Paper, the standard industry practice worldwide is for public prices to be established and for discounts/rebates to be kept confidential. This practice is equivalent to establishing a non-excessive price ceiling (i.e., list price) from which the true local price can be established (i.e., discounted price). With all international public list prices representing price ceilings, it is appropriate to continue to use these values to determine a Canadian price ceiling.

   - The PMPRB's current Guidelines fit within the unique Canadian system of checks and balances for drug prices, which is composed of:

     - a national price control system (i.e., PMPRB),
     - health technology assessment organizations that recommend whether a drug should be reimbursed by regional public payers (i.e., Canadian Agency for Drugs and Technologies in Health, CADTH; *Institut national d'excellence en santé et en services sociaux, INESSS*),
     - a national system for negotiating visible and / or confidential pricing for regional public payers (i.e., pCPA),
     - public and private payers that are able to negotiate confidential pricing to meet their unique needs, and
     - patient assistance programs that support those individuals with access challenges (both logistical and financial).

     Any changes to the weighting of the international public list prices will require an impact analysis to determine how other stakeholders will be affected and if the desired results of such a change are likely to occur.

3. **In your view, given today's pharmaceutical operating environment, is there a particular s. 85 factor that the Guidelines should prioritize or weigh more heavily in examining whether a drug is potentially excessively priced?**

   The factors that are outlined in Subsection 85(1) of the Patent Act are:

- The prices at which the medicine has been sold in the relevant market[1];
- The prices at which other medicines in the same therapeutic class have been sold in the relevant market;
- The prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
- Changes in the Consumer Price Index; and
- Such other factors as may be specified in any regulations made for the purposes of this subsection.[2]

Schedule 8 (Application of Price Tests for New Drug Products) of the PMPRB Guidelines describes how the current value-based system uses the s. 85 factors to assess excessive pricing for newly launched products while Schedule 9 (CPI-Adjustment Methodology) provides guidance for in-market products. Table 2 summarizes how each of the s. 85 factors relates to the current guidance.

Table 2. PMPRB Price Tests

Subsection 85(1) factor	Therapeutic Class Comparison (TCC)	Median International Price Comparison (MIPC)	Highest International Price Comparison (HIPC)	CPI-Adjustment Methodology
The prices at which the medicine has been sold in the relevant market	✓	✓	✓	✓
The prices at which other medicines in the same therapeutic class have been sold in the relevant market	✓			
The prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada		✓	✓	
Changes in the Consumer Price Index				✓

Research conducted by Innovative Medicines Canada has demonstrated that Canadian prices for patented drugs that have no generic equivalent (i.e., the manufacturer can exercise monopoly power) are 43% below the PMPRB7 median prices. This suggests that the current application of the Subsection 85(1) factors from the Patent Act are being used effectively in the

[1] Historically, the term 'relevant market' has referred to four different customer classes (i.e., wholesaler, pharmacy, hospital, other) and the provinces and territories of Canada.

[2] The Patented Medicines Regulations (http://laws-lois.justice.gc.ca/PDF/SOR-94-688.pdf) do not outline any factors to be used in addition to the s.85 factors; however, they do include information regarding the countries that should be used for price comparisons.

PMPRB guidelines.[1] As such, a reprioritization or reweighting of the s. 85 factors cannot be justified at this time.

4. Should the PMPRB set its excessive price ceilings at the low, medium or high end of the PMPRB7 countries (i.e., the US, the UK, Sweden, Switzerland, Germany, France and Italy)?

The PMPRB does not establish the price of drugs but, instead, determines the ceiling price for patented drugs. The ceiling price of patented drugs is currently defined based on the Highest International Price Comparison (HIPC) Test, which is described in Schedule 6 of the PMPRB Guidelines. Although the PMPRB7 countries are noted as reference countries in this section of the Guidelines, they are dictated by the existing Patented Medicines Regulations.

Based on the Discussion Paper,

> *[m]ost developed countries engage in some form of international price comparison to limit drug costs, although increasingly as an adjunct to other forms of cost containment because of the worldwide practice of confidential discounts and rebates and the concomitant unreliability of public list prices.*

The most intuitive price point for excessive pricing is the high end of the PMPRB7 countries. As other forms of cost containment are currently being used in Canada, such as discounts and rebates, setting price ceilings below the high end of the PMPRB7 countries may have unintended domestic and international consequences without resulting in meaningful net price reductions in Canada. It also helps Canadian drug prices remain reflective of our entire peer group; this cannot be achieved by using the low or medium end of drug pricing from the PMPRB7 countries.

5. Does the amount of research and development that the pharmaceutical industry conducts in Canada relative to these other countries impact your answer to the above question and if so, why?

We believe that research and development that is based in Canada is important and should continue to be a priority in the pharmaceutical sector and elsewhere. When comparing R&D spending in Canada versus other countries, it is important to ensure that the methods being used across countries are the same; otherwise, the use of different methods may result in incorrect conclusions regarding R&D spending differences between countries.

In some cases, investment by a company is handled at the Global headquarters level rather than at the affiliate level. Current accounting for R&D spending in Canada is restrictive and does not consider investments made by foreign headquarters. To develop a fair assessment of the R&D investment in Canada that is being made by the pharmaceutical sector, both local and Global spending should be considered.

Nonetheless, the amount of research and development that the pharmaceutical industry

[1] Source: Form 2 Block 5 data submitted to PMPRB, July-December 2015, Innovative Medicines Canada members.

conducts in Canada relative to these other countries does not impact our answer: we believe that the excessive price ceiling should be based on the high end of the PMPRB7.

6. What alternatives to the current approach to categorizing new patented medicines (based on degree of therapeutic benefit) could be used to apply the statutory factors from the outset and address questions of high relative prices, market dynamics and affordability?

At Roche, we believe that the therapeutic benefit of new patented medicines is of paramount importance when evaluating how a patented medicine should be priced. The fact that the Canadian system has evolved to have a minimum of three clinical evaluations of the clinical impact of a drug (at Health Canada, at the PMPRB and during the health technology assessment process) highlights the importance of therapeutic benefit in the Canadian context.

In addition, there is a need to encourage innovation in this industry. Pricing based on therapeutic benefit is an effective means of achieving this, while a move away from categorizing new patented medicines based on degree of therapeutic benefit will undermine local efforts to support innovation in this sector.

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

The PMPRB should consider different levels of regulatory oversight for patented drugs based on indicators of risk of potential for excessive pricing, provided doing so:

- improves the effectiveness of the PMPRB (as per the PMPRB Strategic Plan),
- reduces regulatory burden (as per the Government of Canada's Red Tape Reduction Action Plan), and,
- addresses the needs of stakeholders in a fair manner.

For example, as noted in the PMPRB Guidelines Modernization Discussion Paper, according to the Supreme Court, the PMPRB's mandate "includes balancing the monopoly power held by the patentee of a medicine, with the interests of purchasers of those medicines".[1] In situations where the manufacturer can no longer exercise its monopoly power due to the existence of generic competition, the need for regulatory oversight by the PMPRB could be eliminated.

8. Should the price ceiling of a patented drug be revised with the passage of time and, if so, how often, in what circumstances and how much?

Roche supports the PMPRB's existing guidance regarding the annual revision of the price ceiling of patented drugs based on changes in the Consumer Price Index. We support this as it allows for the price of Canadian drugs to be adjusted based on economic factors that are at play in the Canadian landscape.

[1] Celgene Corp. v Canada (Attorney General), 2011 SCC 1, [2011] 1 S.C.R. 3 para. 29.

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

Price discrimination between provinces/territories and payer types should not be considered a form of excessive pricing. This is because variations in pricing can occur as a result of business/policy decisions made by customers or governments. For example, one Canadian province does not currently permit drug price increases, which can lead to different prices in different provinces.

It is Roche's position that payers are uniquely responsible for their budgets and should have the ability to establish their governing policies based on their specific needs. For this to be possible, price differences between provinces/territories and payer types must be permitted.

10. Are there other aspects of the Guidelines not mentioned in this paper that warrant reform in light of changes in the PMPRB's operating environment?

Three aspects of the Guidelines that warrant reform in light of changes in the PMPRB's operating environment are:

- the recent change to drug launch pricing,
- the impact of exchange rates on drug prices, and
- the method of evaluating R&D investment

Recent change to drug launch pricing

The PMPRB recently changed the Guidelines, adding additional restrictions to drug launch pricing. It is unclear why changes to the Guidelines were made during a period of consultation. Action on another change was postponed in light of the ongoing consultation. Roche recommends that this recent change be delayed until after the consultation.

Impact of Exchange Rates on Drug Prices

A challenge posed by the current Guidelines is the way in which it has integrated differences in the relative value of the currencies of PMPRB7 countries. At present, 36-month averaged exchange rates are used, with the 36-month time period being used to reduce the impact of exchange rate fluctuations over time. The current Guidelines allow for exchange rates to force manufacturers to lower the price of their drugs as a result of a stronger Canadian dollar. In a system that is fair to all players, the opposite should also be permitted (i.e., increasing prices based on a weaker Canadian dollar); however, this is currently not the case. The PMPRB should take this opportunity to ensure the fairness of its system of evaluation.

Method of evaluating R&D investment

If the original intent of the PMPRB was to ensure increased R&D investments by the pharmaceutical industry in light of increased patent protections, it is important to acknowledge

that investments are currently happening, with millions of dollars being invested in the Canadian life sciences ecosystem that are not being captured by the PMPRB's current system of measurement. It is important for the PMPRB to be transparent about the limitations of the current criteria used to define qualifying investments; without such context, the level of investment made by the pharmaceutical industry will not be fully understood by policy makers and the Canadian population. We recommend that the value of SR&ED credits in this context be reviewed and revised to reflect the current environment. As well, the PMPRB needs to establish and leverage a link with both the Minister of Innovation, Science and Economic Development and government of Canada's innovation strategy, especially as the life sciences represent a critical sector within the knowledge based economy.

11. Should the changes that are made to the Guidelines as a result of this consultation process apply to all patented drugs or just ones that are introduced subsequent to the changes?

It is not possible at this time to state that changes to the Guidelines should be applied to all patented drugs or just ones that are introduced subsequent to the changes. A final decision on this question should aim to improve the effectiveness of the PMPRB at controlling monopoly power, reduce regulatory burden and redundancy, and be fair to all stakeholders. Without knowing the changes that will be made to the Guidelines, such a decision cannot be made.

We look forward to having the opportunity to explore this question further with the PMPRB during the later phases of the consultation process.

12. Should one or more of the issues identified in this paper also or alternatively be addressed through change at the level of regulation or legislation?

We support the use of the fairest and most efficient method to modernize the PMPRB's operations.

Roche Canada Responses to PMPRB's Questions for Discussion:
Additional Questions for Discussion

While reflecting on Question 1 from the list of Questions for Discussion, a number of questions were raised that we were unable to address based on the content of the Discussion Paper alone. We have listed those questions below. We look forward to the opportunity to discuss these questions with the PMPRB to support it in its effort to modernize its Guidelines.

PMPRB Questions	Roche Questions
1. What does the word "excessive" mean to you when you think about drug pricing in Canada today? For example:	• The Discussion Paper refers to "excessive" drug pricing, while the Questions for Discussion refer to "potentially excessive" drug pricing. As noted in Table 1, we view these terms as being different. Is this use of different terms intentional?
a. Should a drug that costs more annually than a certain agreed upon economic metric be considered potentially excessively priced?	• How is value to be factored into this decision? • What economic metric(s) would be considered to be valid? • How would the appropriate economic metric be determined? • What parties would need to agree to the economic metric? • Is the threshold set by this economic metric a range or a fixed value? • If the PMPRB does not have access to confidential pricing information, how will it assess annual drug costs? • How will the use of an economic metric impact the work done by stakeholders who currently hold responsibility for assessing Canadian drug costs using their own economic metrics?
b. Should a drug that costs exponentially more than other drugs that treat the same disease be considered potentially excessive?	• How is value to be factored into this decision? • How is "exponentially more" defined? • If the PMPRB does not have access to confidential pricing information, how will it identify drugs that cost exponentially more than other drugs that treat the same disease?

PMPRB Questions	Roche Questions
c. In considering the above two questions, does it matter to you if a very costly drug only treats a small group of patients such that it accounts for a very small proportion of overall spending on drugs in Canada?	• How is value to be factored into this assessment? • What is the role of budget holders in this assessment? • Who would determine the meaning of the term “small group of patients”? • Who would determine the meaning of the term “very small proportion” with respect to spending?
d. Conversely, if a drug’s price is below an agreed upon metric and in line with other drugs that treat the same disease, should it be considered potentially excessive if it accounts for a disproportionate amount of overall spending on drugs in Canada?	• How is value to be factored into this assessment? • Question 1d) refers to a drug’s price, while Question 1c) refers to a drug’s cost. Prices and costs, as noted in Table 1, are not the same. Is the use of different terms intentional? • Who would determine the meaning of the term “disproportionate”?