October 20, 2016

Patented Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
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Re: CLHIA response to PMPRB Guidelines Modernization Discussion Paper

The Canadian Life and Health Insurance Association Inc. (CLHIA) appreciates the opportunity to provide comments on the PMPRB's Guidelines Modernization Discussion Paper.

The Canadian Life and Health Insurance Association (CLHIA), established in 1894, is a voluntary trade association that represents the collective interests of its member life and health insurance companies. The Association's membership accounts for 99 per cent of the life and health insurance in force in Canada. The industry provides a wide range of supplementary health insurance products and services to 24 million Canadians. In 2015, insurers paid out $32.2 billion in supplementary health benefits, including $10.7 billion in prescription drugs.

The CLHIA commends the PMPRB for embarking on a modernization program review. This is very welcomed by Canada's insurers given the rapidly evolving prescription drug landscape and the importance of ensuring our regulatory framework is keeping pace. While we recognise the importance of innovation and ensuring that Canadians continue to have access to needed medications, the pricing of prescription drugs needs to be fair and set at a level that is sustainable for consumers going forward. The CLHIA strongly believes that Canada's approach to pricing regulation should be narrowly focused on what is in consumers' best interests which is to reduce prices to the degree possible while ensuring continued access to needed medications.

We understand that the scope of this review is limited to potential changes to the PMPRB Guidelines. While there are changes to the PMPRB guidelines that will be helpful, ultimately, we would urge the PMPRB to move quickly to a broader review of both its legislative and regulatory frameworks so that even more fundamental reforms can be assessed and implemented.

CLHIA Responses to Questions posed in PMPRB Consultation Document

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

In the current context where many countries are fixing prices of new drugs based on "pay for performance" schemes, the trend is for governments to actively incorporate several measures to determine whether a proposed price is excessive, including more value/benefit kinds of assessments as well as measures of ability to pay.

For example, in the United States the Institute for Clinical and Economic Review (ICER) uses a value-based price benchmark which combines cost-effectiveness assessment and budget impact to determine whether a new drug's price is acceptable.[1] ICER has developed two metrics for this purpose:

1) Long-term cost-effectiveness assessment:

This review is similar to what Canadian Health Technology Assessment (HTA) agencies are currently doing. If a new drug's incremental cost-effectiveness ratio exceeds a pre-determined threshold, the price of the drug would be considered excessive.

[1] http://icer-review.org/wp-content/uploads/2016/02/Value-Assessment-Framework-slides-for-July-29-webinar-FINAL.pdf

2) Potential short-term budget impact: set up an affordability threshold:

The ICER has also developed a budget impact (affordability)threshold beyond which a drug is deemed to be excessively priced. They have effectively stated that any new drug whose aggregate cost would contribute to growth in overall health care spending greater than the anticipated growth in GDP + 1% would trigger a flag for excessive pricing.

We would note that in the US, since the launch of ICER, three new drugs (alirocumab, evolocumab and sacubitril/valsartan) exceeded the ICER's affordability threshold. PMPRB did not consider the price of these drugs as excessive.

Given this, we would recommend that

a) the PMPRB work more closely with CADTH to incorporate a value for money metric into it's assessment criteria. Drugs that have an incremental cost-effectiveness ratio exceeding a pre-determined threshold would be considered excessively priced, and

b) the PMPRB develop a Canadian-specific, affordability threshold. Drugs whose aggregate costs exceed that threshold would be considered as 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?

The CLHIA believes that, in the near to medium term, the PMPRB should no longer explicitly target prices against a select group of comparator countries. Rather the PMPRB should increase its use of market-based approaches to strive for the lowest possible price for Canadians. To the degree it continues to be used, international price referencing should only be one input into what a non-excessive price should be. To the extent that

international price comparisons continue to be used over the long-term, we would strongly suggest that the basket of countries be changed so that it is more representative of worldwide drug market. The use of only seven countries to determine a median price provides an insufficient sample size for determining normal pricing. This is particularly true when the US and Germany, both recognized as high price outliers, are included. Ultimately, the CLHIA strongly believes that Canada's prices should be closer to the median of the OECD prices on an ongoing basis.

In the interim, until a more fulsome review of the PMPRB's approach to regulating prices is undertaken, we would support the PMPRB placing less weight on international public list prices when determining the non-excessive price ceiling for a drug. We would, however, also strongly encourage the PMPRB to broaden and deepen its relationships globally with other national pricing regulators to ensure Canada is learning from existing and evolving best practices in this regard globally.

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?**

Within the scope of the current Section 85 tests, we recommend that the PMPRB consider some reform to its application of Paragraph 85(1)(b) and place more weight on 85(2)(a) than is currently the case.

With respect to sections 85(1)(b) we note that the PMPRB does seek to reward breakthrough drugs with higher pricing by applying the following pricing framework which is based on a therapeutic assessment of each new drug as follows:

- Breakthrough – Median of International Price Comparison (MIPC)
- Substantial Improvement – Higher of top of Therapeutic Class Comparison (TCC) and the MIPC
- Moderate Improvement – Higher of mid-point between top of TCC test and the MIP, and top of TCC
- Slight/No Improvement – Top of TCC.

However, the net result of applying these criteria is that each subsequent drug to the market in a particular therapeutic class can price at the top of the TCC. In practice, this means that, over time, drugs classed as providing a "Slight / No improvement" over existing therapies can price up to the median of the PMPRB7 at the time of launch of the first drug to market in that class (plus CPI over time). In our view, a better approach would be to impose some market pressure on prices over time such that a new drug in a therapeutic class, that offers little to no therapeutic improvement, can only price at a discount off of the relevant TCC. Should additional drugs in that same class come to market with little to no therapeutic improvement, they should in turn be required to price at a discount off of the price that was established by the second new drug in that class. This would cause the market for prescription drugs to function more like those in other markets, where each new entrant competes for market share through, amongst other initiatives, lowering prices to consumers.

We would also recommend that Paragraph 85(2)(a) become a more important factor in the PMPRB's determination of excessive price levels. We want to reiterate that the CLHIA strongly supports innovation and believes it is very important that Canadians continue to have access to new medications. We would, however, support the PMPRB establishing benchmark returns on investment that would represent a reasonable return for manufacturers and could help inform decisions around what price levels may or may not be excessive for a new drug. The benchmark return could also potentially be calibrated to whether a drug is "breakthrough", "substantial improvement", "moderate improvement" or "slight/no improvement". During this evaluation, it is likely the PMPRB will have to required manufacturers to provide an accounting of their investment costs related to the new drug. As part of this, particular attention should be paid to what, if any, amounts of research are done through public institutions versus private sector research. We would also support not including marketing, regulatory and legal fees as cost of development of a new drug.

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)?**

As noted in Question 2, the CLHIA believes that, over the longer term, the PMPRB should no longer explicitly target prices against a select group of comparator countries. However, in the interim, until a more fulsome review of the PMPRB's legislative framework is conducted, the Canadian life and health insurance industry believes that the PMPRB's approach to assessing whether a drug's price is "excessive" should be to strive for prices that are at the lowest level of the PMPRB7 countries.

There are several reasons why we feel this is appropriate. Such an approach would be more in keeping with the overall consumer protection goal of the PMPRB. It also recognizes that

the PMPRB7 country list is made up of generally high priced jurisdictions within the OECD with some, like the US and Germany, being outliers in terms of pricing relative to the OECD in general. The CLHIA continues to believe that Canada should be striving for prices to be, on aggregate, at the median of the OECD. Setting prices at the lowest of the PMPRB7, therefore, would move Canada closer to this target level. We would also note that the comparator list prices in the PMPRB7 do not reflect the confidential pricing that each of those countries has negotiated and so using a comparator pricing approach necessarily results in an inflated price in Canada. Choosing the lowest public price from within the PMPRB7 would help to mitigate this. Finally, a lower PMPRB list price that is closer to what the actual market price will be for the drug (after negotiated pricing), would reduce many of the distortions and inequities currently in the market that result from artificially high PMPRB price ceilings that then incent the proliferation of confidential listing agreements.

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?**

As noted, in the PMPRB consultation document, "the empirical evidence does not support the idea that price and Intellectual Property (IP) are particularly effective policy levers for attracting pharmaceutical R&D. Other factors, such as head office location, clinical trials infrastructure and scientific clusters, appear to be much more influential determinants of where pharmaceutical investment takes place in a global economy."

Accordingly, the CLHIA does not believe pricing policy should be used as an indirect tool to try to encourage research and development in the Canadian market. Canada's approach to

pricing regulation should be narrowly focused on what is in consumers' best interests which is to reduce prices to the lowest possible while ensuring continued access to needed medications.

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?**

The CLHIA would support adoption of the following alternatives to categorizing new patented medicines to help in the determination of what an excessive price level may be:

- Benchmark investment return: As noted in Question 3, the CLHIA would support the establishment of benchmark returns on investments for manufacturers. Such an approach would determine what a reasonable return on investment is for manufacturers and could be an important anchor in the analysis around what an excessive price may be.

- Develop an Affordability Threshold for Canada: As noted in Question 1, the CLHIA believes that the PMPRB should develop a Canadian-specific, affordability threshold. Recently there have been drugs launched into the Canadian market whose impact on overall budgets and spending have strained the sustainability of drug coverage for both public and private payers, even if it is considered a breakthrough drug. A good example of this was the launch of Sovaldi and Harvoni to treat Hepatitis C. We do not believe that any one manufacturer should make a windfall return on a new drug to the point where it undermines the sustainability of the entire system.

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

The CLHIA supports the general concept of risk-based regulation and so would support the PMPRB focusing its compliance and oversight efforts on those classes of drugs that represent the greatest impact on the system and / or greatest risk of excessive pricing. Areas where there may be greater risk include those classes of drugs for which there are limited or no competitors as well oncology drugs and very expensive drugs for rare diseases. For those classes of drugs with greater risk of excessive pricing, there should be expert consultation (e.g. from CADTH/ INESSS) on the appropriate category of the pricing framework: breakthrough, substantial improvement, moderate improvement. Ultimately, the assessment of category should be based on published evidence from clinical trials.

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?**

As the PMPRB's discussion paper notes, the PMPRB's Act and Guidelines restrict price increases of patented drug prices to the Consumer Price Index (CPI) in any given year. We would suggest that this approach is not appropriate from a consumer protection perspective. In many other markets, prices for a particular good will be expected to remain flat or potentially decline due to new competition in the market. As such, we would strongly urge the PMPRB to revisit this requirement and require prices of patented medications to be automatically reduced at regular intervals of time rather than to contemplate them increasing at a rate of CPI.

As noted in Question3, the current PMPRB's current approach allows all new drugs, even those that have no incremental therapeutic value, to price up to the top of their respective Therapeutic Class Comparison (TCC) price. There is currently no process for the PMPRB to reset the TCC over time if market conditions change.

The CLHIA believes that it is essential that a mechanism be implemented to review therapeutic price levels on a periodic basis in order to ensure that the price ceilings reflect the current market reality.

There are three situations, in particular, where we believe that it would be appropriate to revise the therapeutic class ceiling over time. The first situation is where the indications, or off-label use, for a particular drug have expanded to the point where the market they serve is significantly greater than that to which the drug's price was calibrated to originally. The second situation is where there have been many new "me-too" type competitors in a therapeutic class. The third situation is where a number of generics may have come to market in that particular class. For example, the ACE and, ARB class medications have many generic options, yet the sole brand name can continue to price at the top of the TCC.

Therefore, the CLHIA recommends that therapeutic class price levels be reviewed periodically (e.g., every 5 years), or sooner, if increased indications result in a material change in volume (e.g., a 100 per cent increase) or if a number of generics have come to market in that class, to ensure that the therapeutic class price reflects any material changes in the market since the prior review.

9. 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?

The CLHIA believes that more granularity and transparency on the information the PMPRB provides publicly would be helpful. The following are some examples:

- The PMPRB webpage displays what appears to be an actively maintained "List of Patented Medicines" however, this list is only searchable by the manufacturer name currently. Ideally, this list would be searchable by a variety of factors including a) the drug's *Brand Name*, b) the drug's Chemical Name, or c) the drug's sub-type for Status of price review.
- The "List of Patented Medicines" has a column for *Comments*, but it is unfortunately mostly blank or not very informative. It would be much more helpful if this *Comments* column contained more details for those sub-types for Status of price review which are impactful (e.g. Under Investigation, Voluntary Compliance Undertakings, Price Hearings, etc).
- In addition, in Table 5 of the PRPMB Annual Report 2014, it lists Voluntary Compliance Undertakings (VCU). However, the *Price Reduction* column is consistently blank – could this info be shared? And could the data in these VCU tables be shared more frequently, than annually via the annual report?
- The industry would also benefit from a regular public listing of the ratio of the list prices submitted by patentees to the Board (the domestic "Block 5" price) to the National Average Transaction Price (N-ATP). As payers, we would be interested to learn which specific drugs had ratio increases, and what those ratios are.

The CLHIA also believes that the PMPRB needs to re-evaluate its approach to how the funds are returned by patentees through voluntary compliance undertakings (VCUs). Currently the excess amount is payed to the Minister of Health based on volume/units sold, which includes products which have been solely reimbursed by private payers. We would encourage the PMPRB to develop a mechanism to ensure that any financial penalties assessed to manufacturers be allocated in an equitable way to all payers who have borne the burden of the overpricing.

We believe that the most sustainable approach to the management of the overall prescription drug system in Canada is to incorporate the expertise and knowledge of the PMPRB into the clinical and pHTA that are done by other areas of the system. This would ensure that there is alignment between the prices that are being assumed during the clinical and HTA and what is being reviewed during the PMPRB's pricing review. As such, we would strongly support both informal and formal approaches to having the PMPRB work more closely with both the CADTH/INESSS, the pan-Canadian Pharmaceutical Alliance and private insurers. A robust and integrated regulatory environment for new drugs, informed by rigorous analysis, will ensure that Canadians are paying a fair price for new breakthrough drugs and that pricing and costs are well integrated into listing decisions.

Finally, we would note that many newer drugs have significant indirect costs to the consumer over and above the ingredient costs alone. For example, the costs associated with distributing (e.g. pharmacy and other wholesalers), storing, infusing and conducting pharmaco-genetic testing all add up to the true financial burden on consumers, governments and private payers. Given the PMPRB's consumer protection mandate, we would support any move by the PMPRB to broaden its scope of regulation to include

consideration of these indirect costs when determining the maximum non-excessive price of a drug.

10. 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?

The CLHIA believes that any changes made as a result of this consultation should apply to all patented drugs. For clarity any new interpretation of the PMPRB guidelines should apply to drugs already on the market and not just those introduced subsequent to the changes.

11. 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?

The CLHIA believes that, following quickly upon the completion of this phase of the review, the PMPRB should conduct a review of its overall mandate and regulatory structure so as to allow it to reduce or eliminate its use of international reference pricing and transition to a market-based approach to establishing the lowest possible price for Canadians.

Also, as outlined in Question 5, we believe that the PMPRB should have an exclusively consumer protection mandate and that any industrial policy intent should be pursued through other mechanisms.

Conclusion

The industry appreciates the opportunity to provide input the PMPRB Guidelines Modernization Discussion Paper and would be pleased to assist in any way we can, including providing further detail on our comments above, if it would be helpful.

Sincerely,

Stephen Frank