INNOVATIVE MEDICINES CANADA | MÉDICAMENTS NOVATEURS CANADA

January 29, 2016

Mr. Guillaume Couillard
Director, Board Secretariat
Communications and Strategic Planning
Patented Medicine Prices Review Board (PMPRB)
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Re: Innovative Medicines Canada Response to PMPRB Guidelines Notice & Comment

Dear Mr. Couillard:

We are writing to provide you with input on the Notice and Comment issued on December 4th, 2015 regarding the proposed and recently implemented amendments to the Reasonable Relationship Test for line extensions of the same patentee and on a newly introduced requirement that applies to Canadian list prices (i.e. six public list price sources as identified in the Guidelines).

Innovative Medicines Canada is the national voice of Canada's innovative pharmaceutical industry. We advocate for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of all Canadians. We support our members' commitment to being valued partners in the Canadian healthcare system.

We have serious concerns regarding the lack of consultation and accelerated implementation of these amendments, given the significant negative impact that these Guideline changes may have for our industry members as well as for Canadians. We are requesting that a meaningful consultation take place before implementing these changes, and that the implementation of these changes should be deferred by one year, or at least until our association members have had a reasonable opportunity for a true consultation with PMPRB staff.

Consultation Process and Timeline

As an initial comment, we have serious concerns about the consultation process associated with the proposed changes. Although patentees were advised during the PMPRB outreach sessions on November 5 and 6, 2015 that the PMPRB would be seeking comments to the proposed changes to the Guidelines, the timeline provided to respond to the Notice and Comment – notwithstanding the extension until January 29th – is not proportional to the significant nature of the proposed changes.

We also take issue with the procedural fairness of the proposed implementation of these changes on January 1, 2016, four weeks before the deadline for stakeholder comments. This timeline suggests that the consultation is merely pro forma in nature, and calls into question PMPRB's willingness to listen to and consider stakeholder perspectives. Indeed, the combination of the abbreviated consultation process and retroactive implementation date suggests a lack of understanding with respect to the impact of the proposed changes on patentees and other stakeholders, making a full and fair consultation process and subsequent analysis before any implementation all the more important.

Additionally, we take issue with the characterization of these Guideline changes as "Incremental Reforms". This implies that the changes are not significant. On the contrary, and as explained below, we believe these modifications are significant and could have consequences beyond their stated intent.

In light the above, we would request that the implementation of these changes should be deferred by one year, or at least until our association members have had ample opportunity for a reasonable consultation with your staff. In that regard, we propose the establishment of a working group to include PMPRB and patentees to study the Guidelines changes in detail as has been the accepted PMPRB practice for prior policy and Guidelines changes.

Finally, with respect to the process, we note that the Notice and Comment document states that "further consultation may be undertaken on the proposed text in the Guidelines, as well as on operational and transitional details, prior to final adoption and implementation." We respectfully disagree with this approach, and question the legitimacy of any consultations with stakeholders that take place after the proposed effective date of the changes.

Reasonable Relationship Test for Same Patentee Line Extensions

We understand that this particular change is offered as a potential solution to an ongoing issue on pricing for line extensions. We appreciate that the PMPRB recognizes the need for change and we support the underlying intent of this proposed Guidelines change. However, we are concerned that, although this particular solution may appear to resolve issues that have arisen in a number of specific cases, it may also have unintended consequences for other products in other situations. We would welcome the opportunity to explain in greater detail the implications of this proposal in the context of a robust consultation. Until then, we provide the following initial comments and concerns.

Under the proposed policy, the MAPP for line extensions introduced by the same patentee would be set by the National Average Transaction Price (N-ATP) (i.e. the average of all sales net of rebates and benefits reported to PMPRB divided by units sold) instead of the lowest of the six publicly available sources used by the PMPRB. This change is similar to the policy that was in place prior to the implementation of the PMPRB 2010 Guidelines, with the exception that this policy would apply only to line extensions by the same patentee. We note that the original policy was replaced in 2010 based on an extensive five-year consultation with patentees. To revert to this older policy without proper consultation represents an unfortunate departure from the extensive previous consultative work that was undertaken with respect to the 2010 revisions to the Guidelines.

We have concerns that although the proposed Guideline change may appear to resolve some isolated cases, it will not solve all situations, and there will still be cases where prices for new line extensions will be deemed

excessive because of pricing the same as the existing product in each market (see examples in Table 1 below). Moreover, line extensions for which a Therapeutic Class Comparison (TCC) test applies rather than the RRT, which may be deemed excessive due to pricing equally in each market under the current Guideline, would not be resolved by this Guideline change, and would continue to be deemed excessive. A true, meaningful consultation is crucial in order to find a solution that will work in almost all of the cases, with sufficient discretion and flexibility to resolve the remaining cases with common sense.

We also have concerns regarding the level of analysis conducted to assess the impact of this Guideline change. According to the analysis that accompanied the Notice and Comment, PMPRB suggests this new policy would impact only a small subset of products (7 of 46 in 2014), for which the N-ATP was higher than the lowest of the six public sources. We note that one year of analysis is quite limited. The intent appears to be to allow these seven DINs to price at the higher N-ATP instead of at the lowest of six public sources. It is not, however, clear whether and how the other 39 DINs would be impacted. According to our analysis below, we have highlighted specific examples of cases where the new rule could have the desired outcome (1 & 2), and where the new rule would unfortunately continue to incorrectly deem the price of the new line extension as excessive (3 & 4).

Another concern is the potential negative impact on offering benefits by patentees. In cases where benefits are offered for an existing product such that the N-ATP is lower than the list price(s), according to the new rule, a new line extension would be forced down to the *lower* N-ATP rather than the lowest of the six public prices of the existing product (see 3 & 4 in Table 1 below). In that case, in order to be compliant, the new line extension would either be forced to offer the same benefits as the existing product (which may be commercially impossible at launch), or to lower its list prices to the N-ATP that includes benefits from the other product. This would create a situation where although the existing product could use the DIP methodology and its ATP could go back to list price later, the new line extension would not be allowed to match its price to the existing product's list price down the road. This would in turn exacerbate the problem that the new policy is trying to resolve and would create disincentives to offer benefits for products where line extensions are planned.

Table 1 – Examples of Potential Calculation and Impact of New RRT Rule

	List				Benefits in RoC	N-ATP	Lowest of 6 sources	N-ATP higher?
	QC	% share	RoC	% share				
1	$0.90	30%	$1.00	70%	0%	$0.97	$0.90	yes
2	$0.90	70%	$1.00	30%	0%	$0.93	$0.90	yes
3	$0.90	30%	$1.00	70%	20%	$0.83	$0.90	no
4	$1.00		$1.00		20%	$0.80	$1.00	no

QC = Quebec; RoC = Rest of Canada

These and other potential impacts deserve to be fully analyzed in the context of a full and fair consultation to ensure that the proposed policy intent is achieved without inadvertent negative consequences. Once again, we request the opportunity for further dialogue on this particular Guideline change and the policy issues that it is intended to resolve.

List Prices Below Maximum Average Potential Price (MAPP)

We also have a number of significant concerns with the proposed requirement that list prices cannot be higher than the MAPP.

First, the PMPRB has not explained adequately the rationale underlying this proposed change, what this proposed change is intended to achieve, or how this change would achieve the intended goal.

As described by the PMPRB, the issue is that the gap between the national average transaction price and the list price included in the Block 5 as filed by patentees appears, on average, to be growing. It is presumed, although not explicitly stated, that the PMPRB is seeking to "protect consumers" by ensuring that there is no or limited gap between the list price, which is a price that a particular customer might pay in a particular market, and the average transaction price, which is the culmination of many different prices that many different customers pay, some of which are equal to the list price, and others which are lower than the list price *due to benefits being offered to those customers*.

The fact that a gap exists between the list price and the average price is completely fully in keeping with the policy intent under the *Patent Act* and the *Patented Medicines Regulations*, and implemented in the PMPRB Guidelines through the DIP Methodology to encourage benefits being offered to customers. Although forcing list prices to be lower than the MAPP *may* at first glance narrow the gap between N-ATP and list prices at launch (although not necessarily later), this would likely come at the expense of offering benefits to customers, which was specifically the policy that the government sought to encourage. Therefore, it is unclear how removing the opportunity to have differential pricing to different customers would further protect consumers in practice.

Secondly, it is unclear whether regulating list prices as proposed falls under the jurisdiction of the PMPRB under *the Patent Act* and *the Patented Medicines Regulations*. Trying to set list prices equal across different customers and markets is clearly outside the scope of the *Patent Act*, under which PMPRB is intended to compare prices in the relevant market in order to ensure that prices are not excessive in that market. A proposal to regulate list prices in the current context constitutes an attempt to eliminate price differentiation which goes against the intent of the *Regulations* to incent patentees to offer benefits to customers. Moreover, limiting *list prices* of new medicines – which represent the maximum price paid by any one customer in the relevant market – based on the *lowest* existing list price in a *different* and therefore *irrelevant* market, is also inconsistent with PMPRB's jurisdiction, which is to review prices against the *maximum* non-excessive price in the *relevant* market. The PMPRB itself has acknowledged this inconsistency between its existing Guidelines and its mandate, and has attempted to propose a change to resolve this inconsistency (RRT for line extensions of same patentees), although unfortunately this change does not properly resolve the aforementioned issue.

Thirdly, we are concerned that the PMPRB has not adequately conducted its own analysis to understand the reasons for the apparent gap between the N-ATP and the list prices filed in the Block 5. The gap is based on an average of all the products reported to the PMPRB. Indeed, the PMPRB has acknowledged that "Board Staff have not systematically evaluated whether domestic list prices exceed the MAPP". We respectfully submit that trying to remedy a "problem" without understanding its root cause is premature and could be counterproductive. Indeed, it is unclear whether the widening gap is a product of a growing number of products with an increasing gap in their own list prices and N-ATPs, which might indicate more benefits being offered to more customers for more products – in which case, as explained above, we respectfully submit that this is not problem, and therefore, this change to the Guidelines is not required; or, whether this is an artificially widening gap due to certain outliers – in which case, it it not clear whether there is a problem, nor whether the proposed solution will address it.

We are also concerned that the PMPRB may not fully understand the impact of this change. As noted in Table 2, this new Guideline would actually work against the proposed change to the RRT for line extensions by the same patentee, by making the N-ATP unachievable by patentees that have a higher N-ATP than the lowest of six public price sources. In addition, there are other potential unintended consequences that we are still evaluating and would be pleased to elaborate upon at a later date.

Table 2 – Examples of Potential Calculation and Impact of New RRT Rule in Combination with List Prices vs MAPP Rule

List				Discount	N-ATP	Lowest of 6 sources	N-ATP higher?	MAPP, if proposal 1 adopted	List prices limited to:	N-ATP of new product with same sales mix
QC	% share	RoC	% share							
$0.90	30%	$1.00	70%	0%	$0.97	$0.90	yes	$0.97	$0.97	$0.95
$0.90	70%	$1.00	30%	0%	$0.93	$0.90	yes	$0.93	$0.93	$0.91

QC = Quebec; RoC = Rest of Canada

Finally, it is questionable whether it would even be possible to control patentees' list prices, as patentees have little control over the six public list price sources. In the specific case of IMS Health, this is not even an actual price since it is based on actual utilization and sales mix in the market, includes mark-ups, and may include errors due to projections. Patentees cannot be held responsible for a "price" that is not the real price and that they cannot control. There may also be unintended consequences associated with imposing such a requirement, such as patentees no longer providing their pricing information in publicly available sources.

Conclusion

Thank you for the opportunity to provide input. However, we also reiterate our serious concerns that these changes are significant rather than "incremental", and therefore warrant both further consultation and a deferral of their implementation until full and meaningful consultations can be completed.

Please do not hesitate to contact me directly should you have any questions or comments.

Sincerely,

Declan Hamill
Chief of Staff and Vice-President, Legal Affairs

cc: Ms. Mary Catherine Lindberg, Chair
cc: Mr. Doug Clark, Executive Director