Via Online Submission

July 31, 2020

The Patented Medicine Prices Review Board
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Dear Sir or Madam:

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We at Bayer Inc. ("Bayer") appreciate the opportunity to provide a written submission[1] in response to the Patented Medicine Prices Review Board ("PMPRB")'s 2020 draft guidelines, published on June 19, 2020 for consultation ("Draft Guidelines"). As you will see below, we continue to have concerns. Notably, while we have seen some progress made on 'Grandfathered' and 'Gap' medicines, 'New' medicines are still being regulated using the flawed Maximum Rebated Price ("MRP") model. The MRP concept is now untenable given Justice Manson of the Federal Court of Canada ruling that "the Governor in Council cannot exceed the scope of her regulation-making authority…and is therefore *ultra vires* the *Patent Act*."[2] thereby making it unlawful to require that patentees report confidential third-party payments. As **compliance to the MRP is highly dependent upon the reporting of these rebates**, the PMPRB must pause the roll-out of the new PMPRB Framework and work with stakeholders to develop new Draft Guidelines that are reasonable and achievable.

Bayer aligned with Innovative Medicines Canada ("IMC")

Bayer's position is aligned with the written submission presented by IMC in respect to the Draft Guidelines. Despite the close alignment in our positions, we would like to reinforce some of the key issues that remain outstanding. Much of the discussion is consistent with Bayer's previous submissions, but we feel that they should be reiterated as many concerns have not been addressed in these Draft Guidelines.

Key issues identified by Bayer on the Draft Guidelines

Issues related to the MRP concept

The exclusion of third-party rebates in the patentee's sales reporting to the PMPRB will make it difficult, if not impossible, to be compliant with the MRP. As such, the Draft Guidelines will require significant revisions or outright elimination of the MRP concept. Although we recommend regulation of Maximum List Price ("MLP") only, our discussion below continues to highlight the follies of the MRP concept.

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[1] This written submission reflects Bayer Inc.'s position in respect to select elements of the 2020 Draft Guidelines and should not be taken as Bayer's acceptance of the PMPRB's mandate and operations, including the New PMPRB Framework. Bayer Inc. is a named applicant in *Merck Canada Inc. et al v Canada (Attorney General)*, Quebec Superior Court file 500-17-109270-192.

[2] Innovative Medicines Canada v. Canada (Attorney General) 2020 FC 725 https://decisions.fct-f.gc.ca/fc-cf/decisions/en/item/481803/index.do

Patentee confidential information not sufficiently protected - With publicly available information, it is feasible to reverse engineer the MRP which will introduce a myriad of issues for the patentee. While the PMPRB has indicated that the Therapeutic Criteria Level ("TCL") will remain confidential, in many of the cases it will be possible to ascertain the TCL based on CADTH and INESSS' reviews and clinical trial publications. The ability to reverse engineer MRP would have dramatic consequences as foreign countries, competitors and pCPA negotiators would be able to ascertain the manufacturer's maximum net price. Foreign countries would likely leverage the MRP to confer lower prices in their domestic country. This could deprioritize Canadian launches in order to reduce the impact of international price referencing. In addition, in a patentee's submission to CADTH a waiver is signed which allows information sharing amongst CADTH, pCPA and the PMPRB[3]. The sharing of the TCL or the MRP would confer a significant negotiation disadvantage to the patentee which could cause manufacturers to not launch certain medicines in Canada.

The use of the dTCC is problematic – while we are in favour of using the highest of the domestic Therapeutic Class Comparison ("dTCC") as described in the MLP for new products when international pricing is unavailable, we are opposed to the median of the dTCC that was proposed in the MRP. The use of the median dTCC will result in multiple investigations as each molecule that is included or excluded from the therapeutic class can have a considerable impact on the price. This decision is complicated by the fact that the comparator decision will be driven by Board Staff rather than relying on the expertise of the Human Drug Advisory Panel ("HDAP"). We are also opposed to the use of the lowest, often a generic, price when there are multiple manufacturers of a molecule. The use of the median of the lowest priced molecules will create a regulatory environment that deters new innovative patented medicines to launch in a therapeutic area that has not seen innovation for many years. Fairness is severely compromised when novel medicines are evaluated against generic medicines. Any use of a median dTCC is inconsistent with an excessive price standard and should not be utilized.

Pharmacoeconomics and Market Size – consistent with our responses to previous consultations, we reiterate that the use of pharmacoeconomics and market size are incongruous with PMPRB's mandate to prevent patent abuse by ensuring that patented drug prices are not excessive. Distilling a range of ICUR's down to a single point that is applicable for both the public and private market is highly subjective, and its use for price control is incongruent with its intended use. The outsourcing of pharmacoeconomics to Health Technology Assessment bodies is also problematic in that publication of a cost minimization or inability to calculate the Pharmacoeconomic Price ("PEP") could reduce the MRP to 50% of the MLP. Indeed, any patented medicine that is meant solely for the private market, such as PDE-V inhibitors, could automatically be subject to an MRP that is half of the MLP. When only a handful of private payers can enter into third-party rebate agreements, we question the viability of launching a private payer exclusive drug in the future. Alternatively, the patentee could be forced to submit a private payer only drug to CADTH in order to obtain a more favourable MRP with no intention of securing public coverage. Significant resources would be wasted by both the patentee and CADTH and would be one of the unintended consequences of establishing such an arbitrary pricing test based on a pharmacoeconomic measure.

[3] https://cadth.ca/sites/default/files/cdr/process/Procedure_and_Guidelines_for_CADTH_CDR.pdf

The use of the market size adjustment acts to regulate revenues rather than the PMPRB's mandate. The proposed market size factor would move the PMPRB away from determining excessive prices to actively controlling expenditures, which is the responsibility of federal, provincial and territorial governments. It is our recommendation that these two price tests be utilized only upon investigation of a patented medicine.

Despite the TCL, on average, the MRP will gravitate to higher discounts – While the Draft Guidelines attempted to show a TCL-dependent range of 20-50% reduction of the MRP with respect the MLP, we believe that the table is illusory. Based on the historical distribution of therapeutic improvement ratings, the average discount of MRP to MLP could be as low as 46%[4,5]. Consequently, the MRP floor should be set substantially higher given that an incremental MRP adjustment factor (MRP[A]) could compound the reduction of the MRP ceiling. We would argue that Justice Manson's ruling suggests that the regulation of MRP is no longer practical and that the PMPRB should strictly adhere to the regulation of MLP. While we agree with utilizing TCL's to recognize innovative medicines, we believe that TCL's should be used to solely regulate MLP. One such construct could see a TCL Level IV to have the MLP set at the MIP of the PMPRB11, TCL Level III MLP to be priced at the MIP + 1 country above, TCL Level II MLP to be priced MIP + 2 countries above and TCL Level I MLP to be priced at the Highest of the PMPRB11.

Other Issues in the Draft Guidelines

"Grandfathered" patented medications not really "grandfathered" - Patented medicines that received a Drug Identification Number ("DIN") prior to August 21, 2019 are inaptly labelled as Grandfathered because they still may be affected by the Draft Guidelines. The prices of these drugs have already been subjected to assessment and negotiation by multiple Canadian bodies and funding decisions based on value for money and affordability. Embroiling existing medications in the new pricing regime is unfair to patentees and patients because significant investments have already been made based on an existing price control framework. For Grandfathered medicines to be truly grandfathered, any patented DIN that are 'Within PMPRB Guidelines' that have not undergone any list price increase in the year should continue to be deemed compliant under the new Guidelines. No other price tests should be conducted on Grandfathered products. The price tests outlined in the Draft Guidelines should be applied only if the patented drug's list price has been increased during the year.

Using the NEAP creates unfairness for Grandfathered, Line Extension, and Gap medicines - The MLP for Grandfathered, Line Extension and Gap products are also contingent upon how patentees report their sales. While some manufacturers include all benefits, others may not which could result in a disparity of how NEAP is reported between patentees. This could penalize those patentees who choose to report all compassionate units in their semi-annual reporting to the PMPRB.

[4] Based on Overall 2010-2017 Revenue Share breakdown of Therapeutic Benefit from the 2017 Annual Report, Figure 1, Page 11. The weighted-average estimate assumes that the breakdown of TCL will remain consistent with historical HDAP evaluations and that each DIN reaches the floor regardless of the TCL.

[5] The evaluation does not consider MRP[A]

Although the PMPRB has built in a provision that would allow the patentee to negotiate a NEAP adjustment, it adds significant uncertainty and unpredictability as the factors which would allow for a NEAP adjustment will be determined on a case-by-case basis[6]. NEAP is a measure of the Average Transaction Price (ATP), not a list price, and it should not be used to determine the MLP. The NEAP is a figure that is derived from the information patentees provide in their Form 2 Block 4 submissions, the confidentiality of which is protected by the Patent Act. As such, the NEAP should not be used to determine the MLP as this would undermine the confidentiality of sales reporting by the patentee. Although the PMPRB indicated that the MLP would remain confidential[7], the price reduction of a patented product below the Highest or Median[8] of the PMPRB11 will signal that the patentee has provided benefits that were not accepted in the NEAP adjustment. This could have the unintended consequence of patentees no longer offering benefits to patients if they are penalized for doing so. In the place of NEAP, the highest publicly available list price should be utilized so that the MLP would be the lower of: 1) the Highest of the PMPRB11; and 2) the highest list price in Canada.

Significant discretion at the hands of PMPRB **Staff** – PMPRB Staff has substantial leeway to determine whether the patentee is compliant with the Draft Guidelines as many of the tests and parameters are based on subjective measures. For instance, PMPRB Staff: 1) can utilize any test, including modified and variants of tests upon the investigation of a drug; 2) can determine the Relevant Indication; and 3) can determine the TCL and the drugs within the therapeutic class. To remain objective and predictable, the PMPRB should adhere to the price tests outlined in the Draft Guidelines as they are laid out and allow the expert HDAP to determine the TCL, the dTCC and Relevant Indication. Regardless, given the discretion provided to PMPRB Staff, an arms-length arbitration panel is recommended to avoid lengthy and costly Hearings for the PMPRB and the patentee.

Significant uncertainties remain surrounding the Draft Guidelines - despite the webinar conducted by the PMPRB on June 29th, questions posed by participants were not visible and therefore many were not addressed. In the spirit of transparency, we request that the questions posed in the webinar be posted and addressed by the PMPRB. Many of the answers to these questions are critical to foster a greater understanding of these Draft Guidelines. In addition, the critical Online Help Tool which replaces the PMPRB Guide to Reporting will only be available following this consultation which makes our commentary incomplete.

With regards to the Judicial Review, the PMPRB indicated that it does not believe any substantive changes to the June 2020 Draft Guidelines are required[9]. While it is not clear what would constitute substantive changes, maintaining the MRP price tests and thresholds unchanged will render the MRP so low that it would not be possible for patentees to achieve these targets. For the patentee to remain compliant with the MRP, they would need to provide <u>additional</u> PMPRB reportable benefits on top of the confidential third-party rebates already provided which would reduce the number of commercially viable innovative drug launches. Another significant drawback of the current Draft Guidelines is that it does not confer

[6] July 21, 2020 meeting between PMPRB and IMC and BTC members
[7] July 21, 2020 meeting between PMPRB and IMC and BTC members
[8] Highest for Grandfathered and Line Extension products and Median for Gap products
[9] July 8 PMPRB communication posted on https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines.html

operational certainty in that the MRP will not be known until well after the launch of the medicine. Patentees need to know with fair certainty the ceiling prices prior to launch so that they can make the appropriate launch and investment decisions. Without this certainty, many innovative patented medicines will not launch until the MRP can be evaluated which will result in the Canadian launch occurring much later than other countries.

Conclusion

The PMPRB would be better served if its Guidelines provided the 'bright lines' that were originally promised. The regulation of only the MLP will provide pricing certainty and bright lines to patentees and yet yield significant savings to payers and patients. The flawed MRP concept adds significant uncertainty to the ceiling prices in Canada and could result in delayed or aborted launches. Confidentiality of business information, predictability and fairness are critical for any business to function. It is critical that ceiling prices are predictable to the patentee before the drug is commercialized in Canada. The lack of these basic elements will cause pharmaceutical companies to bypass Canada or to relegate Canadian launches behind those countries that reference it.

Justice Manson's ruling makes the MRP concept untenable. Hence, we urge the PMPRB to pause the roll-out of the new PMPRB Framework and amend the Draft Guidelines with the assistance of a working group consisting of government, patient groups and industry. Changes to the Draft Guidelines are required and this requires proper and fulsome consultation in order to ensure that the most innovative medicines continue to be available in Canada.

Yours sincerely,

Dale Toki
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Bayer Inc.