

Boehringer Ingelheim (Canada) Ltd/Ltée - Burlington, Ontario

**Boehringer Ingelheim
(Canada) Ltd/Ltée**

Human Pharmaceuticals
Patient Access & Healthcare Affairs

Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
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February 14, 2020

**Re: Patented Medicine Prices Review Board (PMPRB) Draft Guidelines
Consultation**

Submitted via email

Dear recipients:

Boehringer Ingelheim (Canada) Ltd/Ltée (BICL) is committed to improving the health of Canadians. We have been operating in Canada for almost 50 years, with some 550 employees residing across the country and reflective of the diversity of Canada. We therefore provide the following comments as part of the consultation process relating to PMPRB draft guidelines published November 21, 2019. This submission follows a bilateral meeting with the PMPRB in Ottawa on January 8, 2020 to discuss the draft guidelines, the nature of investments made by BICL in healthcare innovation in Canada, and to describe the impact that the draft guidelines and amendments to the *Patented Medicines Regulations* had on BICL operations and investment in Canada to that point in time. We understood that PMPRB is willing to revisit aspects of the draft guidelines and the PMPRB encouraged us to use this submission to identify those elements we view as most harmful to our industry and to provide specific recommendations for consideration. In that spirit, we are focusing our comments on four elements of the draft guidelines.

While BICL has engaged constructively with the PMPRB throughout the guideline consultation process, our participation in the consultation process should not be construed as acceptance of the constitutionality of Sections 79-103 of the *Patent Act* and the *Patented Medicines Regulations*, which are currently under review by the Superior Court of Québec.

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ELEMENT 1. Confidential Rebates: The draft guidelines do not provide adequate protection for sensitive confidential business information.

The confidentiality of product listing agreements (PLAs) rebates is a well-established expectation in the global pharmaceutical industry. Contractual clauses are systematically included in BICL's PLAs and Letters of Intent (LOIs) which prohibit the disclosure of the rebate and other benefits. Provincial laws also prohibit disclosure of the contents of PLAs. Even within BICL, access to LOIs and PLAs is restricted to a strict need-to-know basis.

Based on the RIAS and draft guidelines, the PMPRB may use PLA rebate information of BICL's new and existing medicines to set the price of new medicines that enter the Canadian market. This would involve comparing the price of a new medicine to prices of existing medicines after adjusting those prices using their PLA rebates. Since patentees will be told what their price ceiling is and the products they were compared against to establish this price ceiling, the PMPRB will inevitably disclose enough information for BICL or its competitors to work out the confidential PLA rebates of the products used for the comparison.

Furthermore, the RIAS and draft guidelines state that the PMPRB will determine pharmacoeconomic (PE) value of medicines using target cost-per-QALY ratios for certain medicines. As a result, a PMPRB ruling that requires a price reduction in order to meet those ratios will allow anyone to calculate the size of the rebates applicable to that medicine. This is because the cost-effectiveness information is contained in public HTA documents, and this information can be combined with a PMPRB ruling to recover pricing information. As a result of the above, BICL, its competitors and other foreign jurisdictions will be able to get very close to the PLA rebate using the information and methods outlined above. While these estimates will not be perfect, they will be within a commercially-manageable margin of the ultimate value, making it worthwhile to carry out the exercise.

The pharmaceutical industry is global in scope. By way of example Boehringer Ingelheim has products marketed in 145 countries. Canada represents approximately 2% of the world market and many countries that represent substantially larger markets than Canada either directly or indirectly reference prices in Canada. If the price reduction in Canada is mirrored into other countries, the Canadian market will generate a net loss globally for the company. BICL will not be allowed to offer large rebates in Canada where those rebates will also affect prices in other markets around the world.

Indeed, the Patent Act imposes a statutory duty on the PMPRB to maintain the confidentiality of patentee's sensitive commercial information. In order to comply with its own statutory mandate, the PMPRB cannot adopt procedures which will make that confidential business information available to the public, directly or indirectly. The draft guidelines will indirectly make patentees' confidential information available to the public via pricing tests that allow rebated prices to be worked out using publicly available information. Such a scenario is inconsistent with the letter and spirit of section 87 and 88(4) of the Act.

Recommendation:

Sensitive confidential commercial information of a Patentee must be protected in a manner consistent with the guarantees of section 87(1) and 88(4) of the Patent Act, and not be disclosed directly or indirectly by allowing competitors to back calculate with a high-degree of accuracy confidential rebates through various sources of publicly available data.

ELEMENT 2. Transition time to compliance with new MLP for existing products should be extended and clearly articulated in the guidelines.

It is currently unclear when patentees will be impacted by the new list of countries (“the Schedule”) that will be used for setting the Maximum List Price (MLP). Our understanding is that the PMPRB intends to communicate new MLPs “shortly” after the July 30, 2020 reporting deadline and provide a grace period of July 1 – December 31, 2020. We further understand that the PMPRB proposes to begin assessing excess revenues as of January 1, 2021 and afford patentees a full year to bring list prices into compliance with the new MLP. It was also communicated that at some time after the January 2022 reporting deadline, PMPRB may begin enforcing non-compliance. Irrespective of when compliance will be enforced, patentees have no time to smoothly transition; instead, the full financial impact must be absorbed in one fiscal year.

The impact of the new MLP on existing products may be, in some cases, as high as 70%. This impact is not a matter of simply changing the price of a drug. Contracts will need to be renegotiated and because list prices are determined by provincial regulation, there is an entire process to be followed on a province-by-province basis. Changing the price list is not merely a matter of updating catalogues. Enterprise Resource Planning (ERP) systems will be impacted; ERP systems allow businesses to manage transactional, financial, reporting, planning and data aspects of their operations without manual intervention at the time of ordering. Resourcing and personnel are impacted. Based on our assessment of the impact of MLP on one of our products, BICL has had to make the extremely difficult decision to reduce the field force for that product by approximately 50 employees. Contracts, ERP and personnel changes take time to implement, and we still need to assess the full effect of the final guidelines on our business.

Recommendation:

The guidelines should clearly articulate the transition plan for existing products. In this transition plan, no excess fees should be assessed or payable for sales in January 1 – 31, 2022 and thereafter a staggered transition period of no less than five years to achieve the new basket pricing should be in effect. Furthermore, no excess fees should be assessed or payable until a product has transitioned to the new MLP under the transition period wherein price reductions are capped to no more than 5% per 12-month period.

ELEMENT 3. The new pharmacoeconomic factors should be reserved for extraordinarily high-priced medicines rather than the full scope of products Category I currently contemplated.

The implementation of the PE factors as written in the draft guidelines is problematic. They are unique from reimbursement systems in other jurisdictions in that they are a sequence of price tests that are layered upon one another. The net result is that they capture 75%¹ of medicines, which is far more than the PMPRB cited as their rationale for implementing these factors. In BICL's experience, virtually **every** medicine launched in the last two decades would have been categorized as Category I through some combination of the PE factors.

This cumulative approach to price tests will penalize medicines that may provide significant benefit to Canadians. For example, Drug A is launched into the Canadian Market. Drug A is considered "dominant" from a cost-effectiveness perspective [i.e., is more effective and less costly than its comparator(s)]. Due to its superior efficacy, Drug A displaces existing medicine(s) with sales of \$40 million, but because it has sales of \$50 million, it is classified as Category I, and would be considered "excessively" priced. This is counterintuitive as Drug A would not only be less costly and more effective than the medicine(s) it displaced, but the marginal (incremental) cost to the system of \$10 million implies more patients are getting access to the medicine.

Under the Draft Guidelines, Drug A would be treated as having a full \$50 million impact as opposed to the actual marginal cost of \$10 million. Ultimately, the manufacturer would be penalized from bringing a medicine that provides more value to the healthcare system and provides greater access to medicine for patients.

These new factors may also have an impact on future access to new medicines. Historically, Canada has been among the first wave of countries to launch new therapies, including products such as Jardiance®. BICL has also run more than 215 clinical trials in Canada since year 2000, with 40 clinical trials currently ongoing. Canadian investigators have also led the way in major clinical trial programs, including for Jardiance® and Pradaxa®. New programs and launches may be at risk of delay if every new medicine launched is subject to the new PE factors.

Further, with reduced revenue for every product launched in the Canadian market, ancillary programs, services and investment may be impacted. For instance, BICL has invested tens of millions of dollars since 2012 to provide real-world solutions to reduce health care spending. One such project is INSPIRED™, a collaborative effort between BICL and the Canadian Foundation for Healthcare Improvement, which reduced emergency department visits, hospital admissions and days in hospital for COPD patients. Last year, BICL collaborated with IBM and Health Canada to integrate blockchain technology into a clinical trial, and thus improve safety and efficiency. This was a first of kind collaboration in the world. Canada is also only one of two countries offering Head Start™, a world-class Patient Assistance Program for Ofev®. These and other innovative initiatives may be more difficult to implement if the price of every new drug launched is further reduced by 40% or more.

¹ Innovative Medicines Canada. An assessment of Canada's current and potential future attractiveness as a launch destination for innovative medicines. January 2019.

Recommendation:

The pharmaco-economic factor thresholds (cost per QALY, market size and GDP per capita) should be increased so that they only apply in extraordinary circumstances, such as once clearly abusive pricing is determined from an economic or competition law perspective. The PE factor thresholds should be better aligned with the stated PMPRB policy intent of policing the outliers where extreme market power exists. .

ELEMENT 4. Continuous re-assessment of the maximum rebated price (MRP) based on retrospective sales data is too complex and does not provide reasonable certainty for business.

The draft guidelines state that medicines subject to the PE factors would have their MRP reassessed every year based on actual sales from this previous year. This undermines a patentee's ability to forecast and plan investments, as they would constantly have to look backwards to the prior calendar year before planning for the future. In BICL's experience, provinces often take far, far longer than 12-months to report rebate information under PLAs and the numbers may not even exist to assess compliance.

In addition, the draft guidelines state that a number of factors can either move a medicine from Category II to Category I or trigger a re-assessment of the MRP:

- Actual sales exceeding the market size threshold in the previous calendar year;
- New economic evidence is introduced by any public third-party; and,
- GDP per capita changing and thus the thresholds changing.

The launch of a product may depend on a number of factors that are impossible to predict. In our experience, it can take several years before the market dynamics may be properly understood. The goal of Boehringer Ingelheim's clinical development program is to develop first-in-class innovative therapies. For example, in 2008 BICL launched Pradaxa[®], the first new oral anticoagulant (NOAC) available in Canada. Before that time, the standard of care was warfarin (a vitamin K antagonist). Today, Canadian guidelines consider NOACs the standard of care². However, at the time of launch of Pradaxa[®], BICL had to educate physicians of the mechanism of action of a new class of drugs and our predicted market share was reached only once market experience in Canada with Pradaxa[®] was sufficient for prescribing physicians.

Due to the retrospective nature of the way the MRP will be calculated and the factors that can trigger reassessment, it is neither possible to determine what the price ceiling will be, nor possible to assess compliance in a timely manner even if the MRP is known due to data problems. This is not a reasonable framework to evaluate business decisions.

² Andrade JG et al. Management of atrial fibrillation : complete CCS guidelines listing. Canadian Cardiovascular Society. 2018.

Recommendation:

The MRP should be calculated and established for a fixed period of no less than three years. The PMPRB should provide clear guidance on the timelines for how long a patentee is expected to wait after a health technology assessment (HTA) and when the MRP will be established.

Conclusion

We thank you for the opportunity to provide feedback on these proposed guidelines and we would be pleased to discuss the elements outlined in this submission in a face to face meeting. We look forward to constructive dialogue.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Carole Bradley-Kennedy'.

Carole Bradley-Kennedy
Director, Health Economics, Pricing and Outcomes Research