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
K1P 1C1

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

Telephone 905-631-4515

Telefax 905-639-9359

E-Mail carole.bradley@boehringer-ingelheim.com

5180 South Service Road
Burlington, Ontario, Canada
L7L 5H4
Telephone 905-639-0333
Telefax 905-639-3769
www.boehringer-ingelheim.com

June 21, 2021

Re: Consultation on the Guideline Monitoring Evaluation Plan (GMEP)

Dear recipients:

Boehringer Ingelheim (Canada) Ltd/ltée (BICL) would like to thank the Patented Medicine Prices Review Board (PMPRB) for the opportunity to provide feedback on the Guideline Monitoring and Evaluation Plan (GMEP). However, given the ongoing legal challenges with the new *Patented Medicines Regulations* and the COVID-19 crisis, we believe that moving forward with the GMEP would not be constructive.

BICL maintains that 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 have been under appeal.

ELEMENT 1. It is too early to move forward with the GMEP.

Given the outcome of the June 2020 Federal Court decision that confidential third-party payments are *ultra vires* the *Patent Act* and the ruling in the Constitutional Challenge, there remains significant uncertainty as to how the PMPRB will implement the pharmacoeconomic factors and Maximum Reimbursed Price (MRP). It is incumbent on the PMPRB to amend the Guidelines to address this uncertainty, and subsequently proceed with consultations. Development and implementation of the GMEP should be placed on hold, as stakeholders cannot provide feedback on its content when the Guidelines are ambiguous.

ELEMENT 2. The scope of the GMEP is too broad.

The PMPRB has a dual mandate to protect consumers from excessive pricing patented medicines and reporting trends in pharmaceutical sales and pricing and research and development (R&D) expenditures by patentees. Many of the metrics proposed in the GMEP fall well outside of the PMPRB's mandate. Proposed assessments relating to system coordination and Access (i.e., Health Technology Assessments, pCPA price negotiations and reimbursement by federal, provincial and territorial drug plans) are out of scope and should be removed from the GMEP.

ELEMENT 3. Harmonize the reporting on Research and Development with other agencies.

Patentees have been repeatedly criticized throughout the *Patented Medicines Regulations* and Guideline amendment processes with respect to R&D investments in Canada. This criticism belies the reality that the PMPRB uses a definition of R&D that is outdated and inconsistent with the definitions used by comparator countries. Investments by patentees in Canada that fall outside of the strict tax definition of R&D are not factored by the PMPRB. For example, BICL's extensive investments in health care system projects that improve patient care (e.g., ABILD, INSPIRED, etc.) are not considered to be R&D. Nor are our significant investments to create knowledge, such as the first-of-its-kind collaboration between BICL and IBM on using blockchain in clinical trials or our multimillion-dollar endowments to create university research chairs.

Statistics Canada reports annually on R&D using a definition that is consistent with the Organisation for Economic Cooperation and Development (OECD)[1] that is more inclusive than the PMPRB's definition. The PMPRB should adopt Statistic Canada's definition of R&D in its reporting.

Conclusion

We thank the PMPRB for the opportunity to provide feedback on the GMEP. While we are encouraged that the PMPRB continues to reach out to stakeholders, we believe that the GMEP would benefit by being put on hold until the scope can be adjusted to reflect the outcome of ongoing legal challenges to the *Patent Act* and *Patented Medicines Regulations*. We look forward to continuing constructive dialogue.

Sincerely,

Carole Bradley-Kennedy
Director, Health Economics, Pricing and Outcomes Research
Boehringer Ingelheim (Canada) Ltd./ltée

[1] Statistics Canada. Annual Survey of Research and Development in Canadian Industry (RDCI). Last update: 2021-05-04. Available at: Surveys and statistical programs - Annual Survey of Research and Development in Canadian Industry (RDCI) (statcan.gc.ca)