



GE Healthcare
100-1919 Minnesota Court,
Mississauga, Ontario
L5N 0C9

Patented Medicines Price Review Board

Delivered via email to PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

August 4, 2020

Subject: Written Feedback re: PMPRB June 2020 Draft Guidelines Consultation

On behalf of GE Healthcare Canada Inc., I'd like to thank you for the opportunity to present additional feedback on the Patented Medicines Price Review Board's revised proposed guidelines. We have attached our initial feedback as an appendix to this letter, as we believe that still contains relevant and important background information on our place in Canada's life sciences sector.

While we do appreciate the significant thought and effort that went into these revised guidelines, we still believe that there are gaps that should be addressed as part of the significant changes that have been proposed – specifically, the continued absence of a specific pathway for diagnostic radiopharmaceuticals.

Our ongoing concerns with the proposed revised guidelines

As a company, GE Healthcare Canada Inc. remains very concerned that the changes proposed in the revised guidelines continue to further limit access to novel diagnostic agents that Canadians both deserve and need. With a high cost of market entry and a 'one dose-one patient' model, the costs associated with bringing a patented diagnostic radiopharmaceutical to market may translate to unsustainable business models. In some cases, companies can manage this – however, as new agents are discovered, there may be situations where this is not financially feasible, and companies simply may not bring novel diagnostic agents to Canada.

Diagnostic radiopharmaceuticals also pose complex logistical challenges resulting in significant costs – most of which are covered by manufacturers. The efficacy of a radiopharmaceutical depends on its half-life – meaning the patient must receive it in an extremely short window after it is manufactured. In most cases, these products are manufactured in other countries and require on-demand transportation to the patient. This process involves incredibly complex logistics, which are managed and covered by the manufacturer, often resulting in significant costs - yet these costs are not factored into any kind of pricing decisions made by PMPRB or others.

Our proposed approach

We remain concerned that these revised guidelines fail to adequately address this class of drugs, and that the lack of recognition could be harmful to the Canadian market in the future. We believe that this class requires an exemption from the current guidelines, with a revised approach that accounts for the significantly different market conditions faced by manufacturers. To that end, **we are seeking a meeting with you** to further discuss this approach, and how this could be operationalized in a way that satisfies the PMPRB's mandate while ensuring access for patients that require diagnostic radiopharmaceuticals.

We are seeking a discussion with your team

Given the continuing COVID-19 situation, we would be happy to meet via teleconference or videoconference – whichever you prefer. Should you have any questions, please contact me using the information below.

Best Regards,

Luke Chrusciel
Commercial Manager, Pharmaceuticals Diagnostics
GE Healthcare Canada Inc.
905-399-1854
luke.chrusciel@ge.com

Attachment: GE Healthcare Canada PMPRB Guidelines Submission (March 18, 2020)

APPENDIX



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Mississauga, Ontario
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Patented Medicines Price Review Board

Delivered via email to PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

March 18, 2020

Subject: Written Feedback re: PMPRB Draft Guidelines Consultation

To whom it may concern,

In light of the recent COVID-19 concerns and cancellation of public consultations, I am writing to provide the view of GE Healthcare Canada Inc. on the Patented Medicines Price Review Board's (PMPRB) proposed Guidelines and the potential impact on diagnostic pharmaceuticals.

As an organization, we feel that we bring a different perspective to the table with respect to the proposed Guidelines changes. We specialize in diagnostic pharmaceuticals – an area that may be overlooked and be negatively affected by the changes as an unintended consequence to the government's stated policy direction. As a result, we are writing to ensure that this important medical area isn't overlooked by the Board as changes to the Guidelines are refined and finalized.

What are radiopharmaceuticals, and how do they work?

GE Healthcare Canada Inc. supplies diagnostic pharmaceuticals such as contrast media used in X-Ray or MRI applications, in addition to nuclear medicine diagnostic agents made up of a cold kit or radiolabeled agents. The latter are ligands labelled with a short-lived isotope enabled to perform nuclear medicine diagnostic tests. A very small amount of radiolabeled agent is injected into a patient's blood stream and imaging can be performed following appropriate biodistribution timeline.

Family physicians and specialists such as neurologists, gastroenterologists, oncologists, cardiologists etc. rely on such specific tests to obtain clinical information to guide their patient management decisions. Nuclear medicine physicians have access to a variety of radiopharmaceuticals and cold kits, which are specific to a clinical presentation or suspicion.

Why radiopharmaceuticals are different

Radiopharmaceuticals and many other diagnostic pharmaceuticals are one-time, niche products for a specific subset of patients. Unlike conventional pharmaceutical products (as an example, those used for chronic disease management) that generate a continuous revenue stream, diagnostic agents are seldom used multiple times with the same patient. This is because there simply isn't a need: the first diagnostic test often provides the answers a clinician is looking for.

Most of the radiopharmaceuticals are shipped in from overseas or the US, which requires complex & costly logistics to ensure that a specific patient dose arrives on time for the planned injection due to the short window of dose calibration and expiry. These products are not kept nor cannot be in warehouses or inventory; instead, these radiopharmaceuticals are made on demand across various locations for specific patients that require such tests.

Different market conditions than conventional pharmaceuticals

The pharmaceutical diagnostic imaging market is significantly smaller than the conventional pharmaceutical market. However, under the current system, our products fall into the same categories with both Health Canada

and PMPRB. Just as conventional pharmaceuticals, radiopharmaceuticals are also manufactured under the same cGMP requirements and meet the exact same standard that is expected from any pharmaceutical manufacturer. Our costs for regulatory submissions and documentation remain the same. Under a 'one dose, one patient' model, these are expensive requirements coupled with the changing regulatory landscape.

Effects of regulatory burden already evident for diagnostic agents - even without proposed changes

In fact, some diagnostic agents have already been removed from the Canadian market. These agents were removed largely as a result of the high cost and access to raw materials supplied under the same conditions that are needed in small amounts to produce the final active agents, which include DMSA, stannous agent, mebrofenin and others. *We understand that, as unpatented medicines, these products did not fall under the purview of the PMPRB Guidelines, but these are products that were impacted by the rising costs of regulatory and manufacturing oversight.*

Our concerns with the proposed guidelines

As a company, GE Healthcare Canada Inc. is very concerned that the changes proposed in the upcoming guidelines will further limit access to novel diagnostic agents that Canadians both deserve and need. With a high cost of market entry and complex and expensive logistics for a 'one dose-one patient' model, the costs associated with bringing a diagnostic pharmaceutical to the market would be further compounded by the new Guidelines.

Specifically, we believe that the proposed changes to reference countries will put the diagnostics industry at risk of delaying or preventing new agent submissions, thereby preventing Canadians from accessing tests that can result in life saving or QOLY improvements - in addition to potentially increasing the downstream costs of patient mismanagement.

With the already significant costs and low margin associated with diagnostic pharmaceuticals, changing the PMPRB7 to PMPRB11, along with the MLP based on the lowest MIP, it is our concern that new, novel patented diagnostic agents may not be able to enter the Canadian market. We believe this would be a significant and unintended consequence of making these changes, and not indicative of the Board's overall policy direction.

Seeking an opportunity for further discussion

Given the points above, we would like to propose a meeting with PMPRB staff to discuss our concerns. Given the unfortunate events surrounding the COVID-19 pandemic, we would propose conducting a meeting via videoconference or teleconference at your convenience.

Should you have any questions, please contact me using the information below.

Best Regards,



Luke Chrusciel
Commercial Manager, Pharmaceuticals Diagnostics
GE Healthcare Canada Inc.
905-399-1854
luke.chrusciel@ge.com