



CANADIAN FEDERATION
OF NURSES UNIONS
LA FÉDÉRATION CANADIENNE
DES SYNDICATS D'INFIRMIÈRES
ET INFIRMIERS

Submission to PMPRB Draft Guidelines 2020 Consultation

July 28, 2020

About the Canadian Federation of Nurses Unions (CFNU)

The CFNU is the voice of nearly 200,000 unionized nurses and nursing students across the country. We are proud to advocate for our members and promote the nursing profession on the national level, and we work tirelessly to protect the quality of health care for our patients and our universal public health care system. As nurses have been arguing for decades, we strongly believe that this system must include universal access to prescription drugs.

Recommendations

Canada's nurses make the following recommendations to the PMPRB.

- The PMPRB should base each of its decisions with regards to the Guidelines on its mandate to protect consumers from excessive drug prices. Making concessions to industry based on a perceived threat to profit margins should not take precedent over the PMPRB's consumer protection mandate.
- The PMPRB should revert to the provision in the 2019 Draft Guidelines regarding the gross price ceiling of grandfathered patented medicines. The gross price ceiling should be set as the lower of the Median International Price (MIP) for the PMPRB11 comparator countries and the domestic Therapeutic Class Comparison (dTCC) to set the Maximum List Price (MLP).
- The PMPRB should revert to the provision in the 2019 Draft Guidelines regarding the threshold for being classified as a Category 1 drug. In order to save money for Canadians and protect against excessive prices, Category 1 drugs should have an annual treatment cost greater than 50% of GDP per capita.
- The PMPRB should revert to the provision in the 2019 Draft Guidelines regarding the Pharmacoeconomic Value (PV) threshold. The PV threshold should be \$60,000 per Quality-Adjusted Life Year (QALY), rather than between \$150,000 and \$200,000.
- The PMPRB should make publicly available the therapeutic criteria levels used in calculating the Maximum Rebated Price (MRP) in Category 1 medicines.
- The PMPRB should treat the price of a patented biosimilar or patented generic in the same way it treats the prices of other patented medicines if the patented biosimilar or patented generic is the only available version of a particular drug.

Context of the CFNU's submission

We would like to reiterate our strong support for the *Patented Medicines Regulations*. The regulatory changes that will come into force on January 1, 2021, will result in significant savings for Canadians on

patented medicines. We were disappointed, however, that this date has been postponed from the previous coming into force date of July 1, 2020, thereby delaying these savings for Canadian consumers by six months. We recognize the enormous pressures that the PMPRB has been subjected to by the pharmaceutical industry and certain industry-funded patient groups, but we hope that the PMPRB has the fortitude to refrain from bowing to such pressures going forward.

Canada's nurses embrace these regulatory changes as well within the broader context of the changing regulatory environment for pharmaceuticals in Canada. With the federal government's commitment to implement a national universal pharmacare program, as recommended by the Advisory Council on the Implementation of National Pharmacare, the *Patented Medicines Regulations* set the stage for further regulatory changes that will lead us to a public single-payer pharmacare program. The savings that will result from the PMPRB's efforts will be incomplete without ensuring that all those living in Canada have equal and universal access to the medicines they need.

Regarding the revised draft Guidelines for the *Patented Medicines Regulations*, this current round of consultations is taking place within a different context as compared to the previous round. In the last several months, millions of Canadians have lost their jobs because of COVID-19, meaning that there has been a large increase in the number of Canadians living without access to prescription medicines. Before the current pandemic, approximately 1 in 5 Canadians had either no drug coverage at all, or inadequate coverage.¹ We can expect that number to have gone up with the large number of job losses, and hence the loss of employer-sponsored plans for many.

Another development that has changed the landscape since the previous round of consultations is the federal court challenge from Innovative Medicines Canada (IMC). We were pleased by the portions of the Federal Court's decision pertaining to the use of pharmacoeconomic factors in price assessments and the PMPRB11 basket of countries, but we were displeased that the provision in the new regulations pertaining to the reporting of rebates was deemed to fall outside of the PMPRB's authority.

Being able to require patentees to report the rebated drug prices to third parties would have given the PMPRB a helpful tool in determining if the maximum price for a drug that it allows is too high for Canadian consumers or not. When rebated prices are kept confidential, it enables pharmaceutical companies to continue using the inflated public list prices in negotiations, thereby hampering the ability of buyers to obtain a lower price that is more closely in line with the actual market price. Through a national universal single-payer pharmacare program, there should only be one Canadian rebate price per drug. We look forward to that system being implemented in Canada in the years ahead.

In this time of heightened social and economic vulnerability for Canadians, it is more important than ever that these regulations and their accompanying guidelines come into force, and that they be followed by a broader implementation of a public universal single-payer pharmacare program. It is with this vision in mind that the CFNU provides observations on the Draft Guidelines 2020.

The CFNU's observations on the Draft Guidelines 2020

Maximum List Price (MLP) Test – International Price Comparison

¹ <https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare/final-report.html>

In the 2020 Draft Guidelines, the PMPRB believes the gross (list) price ceiling of grandfathered patented medicines should be set as the lower of the Highest International Price (HIP) of the PMPRB11 countries, and the applicable ceiling under the previous Guidelines. The HIP will also be used to set the Maximum List Price (MLP) of Line Extensions of Grandfathered medicines (i.e. new strengths and dosage forms).

This is a marked shift from the 2019 Draft Guidelines, which uses the lower of the Median International Price (MIP) for the PMPRB11 comparator countries and the domestic Therapeutic Class Comparison (dTCC) to set the MLP. This was regarded by the CFNU and numerous other stakeholders as fair, given that Canadians have been paying excessive prices on these drugs for years, many out of pocket or as hefty co-payments and deductibles.

Nonetheless, the PMPRB appears to be yielding to pressure from the pharmaceutical industry, admitting that the change in the 2020 Draft Guidelines is motivated by “a concession to patentees.” While industry claims the proposed changes from the 2019 Draft Guidelines would result in drug shortages and a decline in support services available to patients, there is no evidence this would be the case.

According to the PMPRB’s website, the PMRPB “protects the interests of Canadian consumers by ensuring that the prices of patented medicines sold in Canada are not excessive.”² This is the basis of the PMPRB’s mandate. Canada’s nurses are concerned by the fact that the PMRPB is prioritizing the interests of the highly profitable pharmaceutical industry over the consumers it is mandated to protect.

Classifying a Patented Medicine as Category 1

The CFNU does not support the new threshold for classifying patented medicines. The PMPRB has set an approximate target of 25% of new patented medicines to be classified as Category 1. To achieve this seemingly arbitrary target, the 2020 Draft Guidelines has limited the number of Category 1 medicines. Whereas the threshold for being classified as a Category 1 drug in the 2019 Draft Regulations was an annual treatment cost greater than 50% of GDP per capita (or roughly \$30,000 per capita), the new threshold is an annual treatment cost greater than 150% of GDP per capita (or roughly \$90,000). With a much higher threshold, the PMPRB is limiting the number of drugs that would be heavily scrutinized under their purview.

The rationale for the approximate target of 25% of new patented medicines being classified as Category 1 is that it would fit within the PMPRB’s administrative capacity. It is surprising that this target was not referenced in the 2019 Draft Regulations, and that it is now used as the basis for limiting the number of drugs that would be classified as Category 1. As was explained by the PMPRB in the July 8, 2020, consultation, there was no magic behind the number – it is merely the number they notionally had in mind. We do not believe this to be an adequate rationale for significantly altering the number of patented medicine prices being regulated under the PMPRB’s purview as Category 1.

Given that the PMPRB has received additional resources as of 2018-2019 – aimed at increasing the organization’s capacity to accommodate the regulatory changes ahead – we believe that the PMPRB ought to prioritize the fulfilment of its mandate over any perceived capacity limitations. The mandate of the organization is to protect the interests of Canadian consumers by ensuring the prices of patented medicines sold in Canada are not excessive. If the PMPRB is unable to demonstrate that the specific

² <http://www.pmprb-cepmb.gc.ca/about-us>

25% target was arrived at after exhausting all potential resources available, it should not set this target as a means of limiting its responsibilities vis-à-vis its mandate.

Pharmacoeconomic Value (PV) Threshold & Accounting for Therapeutic Comparators – High Cost Medicines

The PV threshold of \$60,000 per Quality-Adjusted Life Year (QALY) was used in the 2019 Draft Guidelines, which the CFNU supports. However, in the 2020 Draft Guidelines the PV threshold has been increased significantly to between \$150,00 and \$200,000/QALY. This rise in PV threshold seems excessive, especially considering the lack of evidence that this is what PMPRB11 countries are using as their threshold.

While the 2020 Draft Guidelines Backgrounder does mention a few other countries, it fails to demonstrate that this high threshold and range is justifiable across the board for patented drugs. The PMPRB appears to be succumbing to pressure from the pharmaceutical industry on this issue at the expense of Canadians.

Confidentiality of Therapeutic Criteria Level for Maximum Rebated Price (MRP) Calculation

Under the 2020 Draft Guidelines, the therapeutic criteria levels used in calculating the MRP in Category 1 medicines will not be known beyond the PMPRB and the patentee. Canada's nurses are opposed to the confidentiality of this information, as we believe that the public has the right to know the information underlying the calculation of the MRP. Researchers rely on this information to assess industry research, and physicians use this information to prescribe medications. Furthermore, it is the confidentiality behind the pricing of pharmaceutical drugs which has exacerbated the problem of excessive drug prices around the world.

Regulatory Review of Patented Biosimilars and Generics

As is recommended in the Advisory Council's report on national pharmacare, generic medicines and biosimilars are an affordable substitute that ought to be mandated to make up a national formulary as part of a universal pharmacare program. As such, the CFNU is supportive of these affordable medicines replacing the original patents as part of a bulk purchasing strategy to further lessen the cost of prescription medications for Canadians.

With regards to patented biosimilars and patented generic medicines, we note from the 2020 Draft Guidelines that the PMPRB will only investigate their price in the event of a complaint. The CFNU takes issue with this approach, since a patented biosimilar or generic may be the only drug of its kind on the market, and hence control the entire market for that drug. This would be the case if the original patentee sees a falloff in sales and hence it removes that drug from the market. Therefore, we believe that if the patented biosimilar or patented generic medicine is the only one of its kind on the market, it should automatically be subjected to the PMPRB's scrutiny.

Concluding thoughts

As previously mentioned, Canada's nurses are very supportive of the *Patented Medicine Regulations* that will come into force on January 1, 2021. We are appreciative of the diligent work put into the Guidelines by the PMPRB staff. However, the CFNU believes that several of the changes made to the

2019 Draft Guidelines amount to generous concessions to the pharmaceutical industry, which appear to run contrary to the PMRPB's mandate.

Canada's nurses recommend the PMPRB take the following actions:

- Revert to the provision in the 2019 Draft Guidelines regarding the gross price ceiling of grandfathered patented medicines.
- Revert to the provision in the 2019 Draft Guidelines regarding the threshold for being classified as a Category 1 drug.
- Revert to the provision in the 2019 Draft Guidelines regarding the Pharmacoeconomic Value (PV) threshold.
- Make publicly available the therapeutic criteria levels used in calculating the Maximum Rebated Price (MRP) in Category 1 medicines.
- Treat the price of a patented biosimilar or patented generic in the same way it treats the prices of other patented medicines if the patented biosimilar or patented generic is the only available version of a drug on the market.

We sincerely hope that the PMPRB reconsiders the noted changes to the 2019 Draft Guidelines from this submission and makes the appropriate adjustments to the finalized Guidelines.

Thank you for your consideration of our feedback on the 2020 Draft Guidelines.