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November 6, 2020

Mr. Ron McKinnon
Chair, Standing Committee on Health
House of Commons
Ottawa ON K1A 0A6

Submitted online via portal.

RE: Pfizer brief in response to Standing Committee on Health's study on the Patented Medicine Prices Review Board's Final Guidelines

Dear Mr. McKinnon,

As the House of Commons Standing Committee on Health (HESA) takes on the vital task of studying the Patented Medicine Prices Review Board (PMPRB)'s Final Guidelines set to take effect in January 2021, Pfizer Canada ULC ("Pfizer") would like to bring to the attention of the Committee a number of key considerations consistent with our feedback on this matter throughout the policy development process.

Pfizer is the Canadian operation of Pfizer Inc., one of the world's leading biopharmaceutical companies. Our diversified health care portfolio includes some of the world's best known and most prescribed medicines and vaccines. We apply science and our global resources to improve the health and well-being of Canadians at every stage of life. Our commitment is reflected in everything we do, from our disease awareness initiatives to our community partnerships.

We would first like to thank you and all members of the Committee for engaging in this work. We believe it to be of critical importance for HESA to carefully examine the Final Guidelines and, specifically, their impact on Canadian patients and on Canada's international position. While we have highlighted a number of key concerns in this submission, we are also pleased to provide HESA with our most recent submission (June 2020) on the last version of the PMPRB Guidelines, as well as that of the Vaccine Industry Committee (VIC). These provide greater detail on a range of concerns, which remain largely unaddressed in the final Guidelines currently before the Committee.

Consistent with our prior correspondence with the PMPRB, Pfizer's present submission is being made without prejudice to any ongoing litigation with respect to the PMPRB's regulatory framework.

We acknowledge as a positive step the PMPRB's decision to treat vaccines on a complaints-based process in the same manner as patented biosimilars and generics. However, this change does not remove the ongoing burdensome reporting obligations on vaccine manufacturers, irrespective of any potential or actual complaint being submitted. Full exclusion from reporting for vaccines, given how they are managed and reimbursed in Canada, remains the most appropriate solution; it would still allow for complete PMPRB oversight on a complaints-basis in

a more efficient process for vaccine manufacturers. During the existence of the PMPRB, vaccines have not emerged as an area of consumer complaints or in Board hearings. This points to an effective system that is already prepared to negotiate the price of vaccines effectively, thus managing costs, without the addition of a separate federal process and/or body.

Overall, any incremental gains from this adjustment for vaccines are more than offset by the continued flawed approach to medicines for rare diseases. Pfizer joins with a diverse range of stakeholders in expressing grave concern that the new Guidelines will negatively impact Canadians' access to innovative medicines, particularly those living with rare diseases.

The PMPRB has overstepped its mandate with overcomplicated new Guidelines that cross over into provincial jurisdictions.

The regulatory reform that was undertaken by the PMPRB has resulted in a mandate overreach into provincial jurisdictions and has deviated from the intent originally set for the reform. While provinces continue to explore policy alternatives to strike a policy balance between patient access to innovative therapies and vaccines with sustainable reimbursement frameworks, the PMPRB has missed an opportunity to modernize its method and adopt a risk-based approach. It should also be noted that, in the context of its submission to the U.S. Food and Drug Administration's proposed rule on the importation of prescription drugs, Canada's Federal Government itself indicated that along with the combined "collective buying power of federal, provincial, and territorial governments to negotiate lower prices on brand name drugs" that offers the pan-Canadian Pharmaceutical Alliance (pCPA), provincial and territorial governments "can also control the prices of medicines reimbursed in their jurisdictions through other statutory, legal, or policy tools, such as restricting price increases." This view directly conflicts with the PMPRB's considerations for the reform.[1]

Regulatory reform is a legitimate process and should be conducted in an open manner, with clear objectives and a strong commitment to not only consult but also to address feedback and conduct real conversations with impacted stakeholders, and justifying why their input may or may not be reflected in any changes. Instead of streamlining and simplifying its process, the PMPRB has elected to pursue a highly complex approach that will result in a significant increase in compliance uncertainty and overall burden on patentees. This result directly conflicts with the ongoing Government-wide efforts, principally directed by the Treasury Board Secretariat, to modernize and streamline regulations to achieve policy goals in a predictable and efficient manner, not to mention the explicit conflict with the Government's stated ambitions for fostering a stronger health and bio-science sector in Canada.

Without a stated policy goal, the PMPRB has moved forward with an extraordinary expansion of its own mandate. A preferable approach for quasi-judicial bodies is to pursue reforms in a much more judicious and measured way, making incremental changes, studying their impact, and adjusting rules and expectations along the way. Such a deliberate and considered approach is of the utmost importance, especially where the health and wellness of Canadians are concerned.

[1] See https://beta.regulations.gov/comment/FDA-2019-N-5711-1208.

Of note, the Regulatory Impact Assessment (RIAS) was completed without considering the impacts of the Guidelines, hence misleading decision-makers on the real consequences of the reform. Taken alone, the proposed changes to the international basket of comparator countries (PMPRB11) would have significant impact on savings of close to $20B over 10 years. This would exceed previous Government estimates.

The PMPRB's new Guidelines are discriminatory towards Canadians living with rare diseases.

Far too many Canadians living with rare diseases have limited or no treatment options. With approximately one in 12 Canadians living with a rare disorder, this is a serious health policy issue for Canada. While their individual conditions and needs wildly differ, rare disease patients share a common goal: to increase their choice and access to safe and effective therapies to help ensure they live full, productive and fulfilling lives. Time is of the essence. All Canadian jurisdictions should set out clear objectives and plans, like that expressed by the Government of Quebec and other international health systems, to enable patient access to treatments as quickly as possible once approved by Health Canada as safe and effective.

Canada continues to lag other international jurisdictions in offering a clear regulatory and reimbursement framework for rare disease medicines, including a science-based definition and associated incentives for clinical research, product development, and commercialization. Regrettably, the new PMPRB Guidelines will compound this policy gap and pose a serious risk for Canadians living with rare diseases as they will undermine their ability to access new therapies.

For drugs for rare diseases, the new Guidelines introduce a complex, multi-step series of assessments which will lower the pricing threshold for some of these drugs, in some cases by very drastic levels. By raising new barriers and placing Canada far outside of the international realities for the commercialization of these medicines, there is serious concern that many products will no longer be viable for the Canadian market. Moreover, we are concerned about the implications for clinical research given the need for Canada to offer the standard of care in addition to a reasonable pathway to market approval and reimbursement. Absent an appropriate framework that properly recognizes biomedical innovation along with the need for timely patient access to treatment, the availability of clinical trials for Canadian patients would be expected to decline relative to other jurisdictions.

Under the new Guidelines, most if not all treatments for rare diseases will, by default, fall under the new Category I classification. In that Category, the new economic factors and other price tests will be applied in a generalized manner, disadvantaging small patient populations while increasing uncertainty. This is a heightened concern given that many rare disease medicines already face significant challenges in finding a pathway to regulatory approval and reimbursement in Canada. Generalized approaches to assessments, designed for larger general medicine patient populations, are inappropriate in the rare disease context. There have been efforts in Canada to address the unique aspects of oncology medicines within our assessment frameworks, and rare disease medicines warrant comparably distinct consideration.

An extensive list of stakeholders, including independent Provincial governments and agencies, healthcare professionals, researchers, and patient organizations have already expressed strong

concerns on this point. It is an unfortunate policy misalignment that these measures run counter to the federal government's commitment to pursue a rare disease strategy and set aside significant funding for rare diseases, a welcome approach which depends upon the availability of and access to new medicines to treat these conditions in Canada.

Solutions and levers to manage sustainable access to patented medicines exist and are effective without negatively impacting access to innovative medicines for citizens.

Multiple mechanisms are already in place and functioning – both domestically in Canada and around the world – that work well to support drug plan decision-making and budget management. These include negotiations, health technology assessments, and risk-sharing arrangements to ensure a fair evaluation of the value of innovative medicines and how best to meet patient healthcare needs. As a developed nation, Canada has a responsibility to prepare its policies and systems for future healthcare innovations against the needs of its population.

Quebec's Exceptional Patient Program (*patients d'exception*)[2] is a great example of adapting policy to the realities of health care delivery within a provincial jurisdiction. Through the introduction of new price tests and a significant increase in compliance uncertainty impacting the ability of new medicines to be launched in Canada, the new PMPRB regime will disrupt current well-functioning provincial tools to address reimbursement and sustainability considerations.

Recommendation.

We encourage HESA to call on the Government of Canada to rethink its approach to the PMPRB reform. The new Guidelines are overly complicated and flawed for many key areas of patient care. They intrude on provincial jurisdictions and lack any clearly defined policy objective. We also recommend that HESA examine this issue within the context of the PMPRB's Annual Report for 2018, which noted that sales of patented medicines decreased by 0.6%[3] from the previous year. The PMPRB's 2019 Annual Report remains outstanding.

Pfizer continues to be focused on solutions to the important challenges of enhancing patient care in a sustainable and timely way, and we remain open to further discussions with the Government and the PMPRB on other approaches.

Sincerely,

Cole Pinnow
President, Pfizer Canada
Enclosure

[2] See: https://www.ramq.gouv.qc.ca/fr/professionnels/medecins-omnipraticiens/medicaments/medicaments-patient-exception/pages/patient-exception.aspx
[3] See: https://www.canada.ca/en/patented-medicine-prices-review/services/reports-studies/annual-report-2018.html

August 3, 2020

Dr. Mitchell Levine
Chairperson of the Board
Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
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Submitted electronically: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: Feedback on PMPRB Draft Guidelines

Dear Dr. Levine:

Pfizer Canada ULC ("Pfizer") would like to offer our perspective with respect to the PMPRB Draft Guidelines released in June 2020. This current submission builds on our prior representations to the Board on this subject, the most recent one submitted in February 2020.

At the outset, we have taken careful note of the PMPRB's 2018 Annual Report (the latest edition currently available) as our point of reference for our assessment of the Guidelines. The 2018 report found that patented medicine sales declined in 2018 by 0.6% to below 60% of all medicine sales. Moreover, the PMPRB notes that, "In 2018, the increase in patented medicine prices was, on average, less than the rate of inflation, as measured by the Consumer Price Index (CPI), and therefore, did not contribute to sales growth."[1] The policy rationale often referenced to justify the changes to the PMPRB Guidelines is not well supported by recent Canadian market evidence as outlined in the 2018 Report.

Consistent with our prior correspondence to you, Pfizer's present submission is being made without prejudice to any ongoing litigation with respect to the PMPRB's regulatory framework. This is a highly relevant issue given the decision of Justice Manson at the Federal Court in June 2020 that certain aspects of the PMPRB's regulatory framework are *ultra vires* the *Patent Act.* Pfizer endorses the submissions from Innovative Medicines Canada, BIOTECanada, Biosimilars Forum and the Vaccine Industry Committee, especially as they relate to the implications of this specific issue for the future of the Guidelines. It is our view that not only does the Justice Manson decision undermine a key foundation of the PMPRB's proposed approach, namely the Maximum Rebated Price (MRP) concept, it reinforces the argument that a more fundamental reformulation of the Guidelines is urgently required. Policy impact should not be conflated with complexity. It is our view that a major reconstruction of the Guidelines is warranted in order to ensure consistency with the statute and to reflect customary

[1] PMPRB 2018 Annual Report, p. 38.

standards of regulatory efficiency, predictability, and overall compliance feasibility for all stakeholders, including Board staff.

Prior to offering our specific comments on certain aspects of the Guidelines, it is also important to take note of the broader policy and public health context in which we are all working. Canada's ongoing experience with the COVID-19 pandemic has underlined the challenges and vital importance of advancing innovative treatment options for human health, including novel vaccines and other therapeutics. All stakeholders – governments, citizens, healthcare providers – have rightly approached this problem with a primary focus on availability and access to treatment. At Pfizer, we are proud to have mobilized the full scale of our global resources to respond to this societal challenge, but we recognize that we cannot succeed in isolation. Collaboration and timely access to innovation will be critical to advancing and deploying treatments for COVID-19, in addition to ensuring that Canada is in the best possible state of preparedness for any future public health threats.

Despite the current public health challenge, it remains our sincere hope that Canada will continue to stand as a leading jurisdiction for private sector research and development, clinical trials and new product launches. Pfizer is concerned of the negative consequences the regulatory changes may have on Canada's life sciences and research investment ecosystem. Rewarding advancement in medicines is not just an urgent health imperative but also a key component of any eventual economy recovery and normalization of daily life.

Pfizer would like to highlight the following specific aspects of the current draft Guidelines, consistent with our previous submissions and recommendations to the PMPRB.

The Guidelines Do Not Reflect A Risk-Based Approach

Despite the overwhelming feedback and recommendations provided during the previous consultation period, we are disappointed that on balance the current iteration of the Guidelines do not align with the prior public comments made by the PMPRB with respect to a risk-based approach. Pfizer acknowledges and welcomes the proposals in the current draft to handle biosimilars and patented generics in a differential manner (complaints-basis only). This is a welcome and important recognition of risk-levels and market mechanisms already in place and functioning in Canada for those products. There is remaining opportunity to extend this approach to other, comparably differentiated product categories, in order to focus Board and patentee resources on compliance in the areas of greatest potential concern.

The separate acknowledgement by PMPRB elsewhere in the proposed Guidelines that both vaccines and blood plasma products face a structurally separate market context, notably the mandatory application of tendering for procurement and reimbursement purposes, is a very modest but warranted step. However, the application of the unique elements of these products falls well short of what would be appropriate given the characteristics already acknowledged by the PMPRB. It provides no meaningful purpose to limit the recognition of the circumstances for those products to only that Board staff "may" consider the existence of tendering in the context of an investigation. We submit that the discretionary nature of this recognition (which we address in more detail below) provides minimal comfort and predictability for vaccine and blood plasma product patentees, already challenged to navigate monopsonist purchasing structures for their products in Canada.

We are unclear on the source of hesitation and the disconnection of separately acknowledging the different circumstances for some product categories without providing details in the draft Guidelines to account for those differences. At an absolute minimum, both vaccines and blood plasma products should be limited to Category 2. Pfizer would recommend that the PMPRB consider going much further, as has already been established for biosimilars and patented generics, by explicitly directing those product categories to be addressed on a similar complaints-only basis.

Proposed Price Tests Inconsistent With "Grandfathering"

Contrary to feedback submitted during the prior round of consultations, the use of "lower of" price tests have been retained to impact all patented medicines including those that received Notice of Compliance (NOC) prior to August 2019. This basic element of the PMPRB's approach undermines any claim that "grandfathering" is being applied to any category of medicines in the draft Guidelines.

This shift away from "excessive price" to something different, including the application of multiple price tests in Category 1, lacks any explanation or adequate foundation and is a major contributor to the overall complexity and impracticality of the proposed approach to the Guidelines offered to date.

Guidelines Will Disproportionately Impact Innovative Therapies

The disproportionate impact on the products addressing the most urgent health needs, for example rare diseases with limited or no treatment options, remains a serious shortcoming in the Board's proposed approach. This has been consistently identified by stakeholder as a concern from the outset of this process and was a specific focus of the last round of consultation feedback from Pfizer and many others. While we note that PMPRB has made certain minor adjustments in the current draft Guidelines (e.g. to the specified thresholds for new price tests and other similar elements), the larger concern remains valid.

The PMPRB's recognition of the differential clinical and market context for different types of products is welcomed, but the relatively small changes in the current draft do not go far enough in properly recognizing and accounting for these differences. Pfizer would recommend that additional work is urgently required in this area, which would benefit from a collaborative approach to policy development with patentees and other stakeholders to ensure the unique elements of those products are adequately reflected in the Guidelines.

The PMPRB has acknowledged that the prior draft would have resulted in a very large percentage of all new products falling under Category 1, and that some adjustments have been made to decrease this share in the current draft. This recognition is important in that it supports our ongoing contention that the use of these tools, in the manner contemplated by the PMPRB, is extraordinary for a quasi-judicial body and is fraught with operational challenges. Moreover, the consequence of the application of these tools will be of significant concern for all stakeholders as increased complexity and uncertainty for new product launch calculations negatively impact Canada's designation as a tier one country for access to innovation.

The current draft Guidelines contain some adjustments to the proposed application of pharmacoeconomic tools (e.g. the increase in certain thresholds). Pfizer reiterates that the rigid application of these calculations is not appropriate in a regulatory context independent of budget-holders and other broader public policy and societal perspectives (and accountabilities). These tools are

not used in the manner proposed by the PMPRB in any jurisdiction in the world, with good reason: these tools and methods were never designed for regulatory, price-setting activities, but rather to inform and provide helpful context for policy decision-making by budget-holders.

Guidelines Remain Highly Complex with Questionable Operational Feasibility

Rather than streamline and simplify its proposed approach, we are concerned about the movement to introduce increasing layers of complex calculations at different time frames. The PMPRB has not established the necessity of pursuing such a complex approach, and Pfizer (and others in our industry) have been challenged to assess the full impact of the PMPRB proposals on our current portfolios and product pipelines. This is a challenge given the limited time frame before the new regulations take effect.

We are also concerned at the notable increase in Board staff discretion being inserted into the Guidelines and the overall compliance process. Increased discretion for Board staff – especially in subject areas beyond their mandate or competence (such as scientific and clinical determinations of levels of therapeutic improvement) - requires further consultation with all stakeholders. This increase in staff discretion is inconsistent with a regulatory approach to commercial decision-making for patentees and will not contribute to predictability and greater compliance. It also confuses and calls into question the future role and relevance of the existing expert Human Drug Advisory Panel (HDAP).

Combined with a substantially higher burden on compliance being placed upon patentees, and the continuing absence of key information such as filing requirements, submission portals and related specifications, we question the benefit and necessity of designing a process which increases complexity and uncertainty with unresolved questions about implementation and expectations for patentees.

As an agency of the Government of Canada, we would encourage PMPRB to take greater note of the ongoing Government-wide efforts, principally directed by the Treasury Board Secretariat, to modernize and streamline regulations.[2] Indeed, the approach being proposed by PMPRB not only increases compliance complexity and burden on patentees by many orders of magnitude, it fails to offset these changes with any commensurate and appropriate reductions elsewhere within the compliance framework. An updated cost-benefit analysis outlining the burden of implementation for patentees has not been provided in the context of the draft Guidelines.

[2] See for example, "*Canada revamps its Directive on Regulations - more agile, transparent, and responsive so businesses can thrive*" (News Release, September 7, 2018). https://www.canada.ca/en/treasury-board-secretariat/news/2018/09/canada-revamps-its-directive-on-regulations---more-agile-transparent-and-responsive-so-businesses-can-thrive.html

Finalization of Guidelines Must Be Deferred

Apart from specific content, we would encourage the PMPRB to approach the modernization of its Guidelines from the perspective of prioritizing predictability, simplicity, and operational feasibility. There has been limited recognition of the viability and utility of adjusting the application of Guidelines to different product categories and market conditions, but far more movement is required in this regard.

Against the backdrop of questions raised regarding the legal foundation for the PMPRB's proposed approach to its Guidelines, Pfizer respectfully submits that a more fundamental redesign is warranted. For all products, the PMRPB should seek to anchor to principles that establish a predictable and reasonable pricing floor.

Accordingly, Pfizer reiterates our previous request that the PMPRB defer the adoption of the Draft Guidelines until appropriately inclusive working groups are established to quantify impacts of possible changes to the Guidelines while ensuring operational clarity and compliance predictability. The Board would retain its powers under the existing regime to fulfill its mandate and address any specific product situations of concern.

Thank you for your consideration of our feedback. Please do not hesitate to contact me directly should you have any additional questions for Pfizer Canada regarding this submission and the future evolution of the Guidelines.

Sincerely,

DocuSigned by:
Cole C. Pinnow
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Cole Pinnow
President, Pfizer Canada

cc: Douglas Clark, Executive Director, Patented Medicine Prices Review Board

Vaccine Industry Committee
Le comité de l'industrie du vaccin

August 4, 2020

Dr. Mitchell Levine,
Chairperson Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
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Submitted electronically: PMPRB.Consultations.CEPMB@PMPRB-CEPMB.gc.ca

Dear Dr. Levine,

Following the release of PMPRB updated draft guidelines in June 2020, the Vaccine Industry Committee (VIC) wishes to submit the below response as part of the consultation process.

The VIC is an industry led group focused on improving vaccine awareness and understanding and supporting the development of vaccine related regulatory policy in Canada. It is a unique mix of large multinationals and pre-commercial Canadian vaccine innovators.

The committee works to ensure secured supply of vaccines for Canada, advocates for equitable access to vaccines for all Canadians, promotes the value of immunization as one of the most cost-effective health interventions available[1], and expands Canadian vaccine innovation and manufacturing capacity.

We would like to reiterate that vaccines are unique and possess features that are very different from other medicines and health interventions. Canadians have been reminded in recent months about the complexity and rapid development of public health risks faced by Canada in a global context. Vaccines can and do play a critical role in addressing many public health challenges. Where novel infectious diseases emerge, our industry works to mobilize the full scope of our scientific and manufacturing resources to respond. Our focus is on doing everything in our power to safeguard public health, and we continue to work urgently to remove any needless barriers, regulatory or otherwise, which may negatively impact achieving that critical objective.

As we have conveyed to PMPRB previously, there is minimal level of consumer risk related to the negotiated prices of vaccines in the Canadian system. Indeed, we see no evidence from the last round of consultations that vaccine prices are a policy concern for Canadians or Canadian health agencies. There is an established and well-functioning vaccine recommendation and reimbursement mechanism through the National Advisory Committee on Immunization (NACI) and centralized procurement via the federal government on behalf of the Provinces and Territories. The value of vaccines is being realized through the use of these entities combining not only competitive tenders and negotiated prices but efficacy, effectiveness, safety, security and predictability of supply. Unfortunately, the proposed guidelines continue to disregard the unique nature of vaccines (tendering process, manufacturing complexity, global allocation, population health objectives, etc.).

In addition, several components of the guidelines could significantly hinder immunization goals across the country.

Vaccine Industry Committee requests all vaccines to be treated in the same fashion as biosimilars and generic products in a complaint-based manner and, at minimum, be classified only as Category II.

The proposed guidelines will result in high levels of pricing uncertainty for vaccines. There is great concern that this destabilizing uncertainty will complicate vaccine patentee decision making and encourage delays or deferred vaccine product launches. Global manufacturers may deprioritize Canada and choose other jurisdictions to launch vaccines where threshold economic factors and market size does not impede pricing. This would impact the reputation that Canada has withheld as being a leading country to launch vaccines, as well as hinder its access to vaccine clinical trials. For applicability to the Canadian public health context, if a new vaccine emerged for a global health threat, the uniquely Canadian requirements linking vaccine prices to market size, would result in issues of access and supply in Canada, thereby restricting availability for public health officials to manage potential future endemic and pandemic outbreaks. Therefore, PMPRB needs to ensure that this process does not impede Canadians access to new/existing vaccines due to complicated pricing control measures.

We would like to take this opportunity to thank PMPRB for meeting with us to discuss our concerns and as suggested, look forward to the offer of more direct discussions with PMPRB and key stakeholders (Ministries, Public Health Agencies, Health Canada, etc..), in order to ensure the vaccination rate goals and the needs of Canadians are fully considered through the appropriate application of complaint-based mechanisms with Category II designation.

Sincerely,

Catherine Paquette, R.N., B.ScN
Chair, Vaccine Industry Committee

Rational for vaccines to be only Category II, similar to biosimilars and patented generics :

1. Canadian tendering process already ensure competitive pricing and security of supply

Considering the unique Canadian tendering process for vaccines and its proven impact on price reduction, such amendment would be completely aligned with PMPRB's risk-based approach to regulating ceiling prices. Furthermore, it would create the proper conditions to ensure that Canadians have optimal access to vaccines, hence, contributing to improved population health. We believe this ultimate objective is shared by both the VIC and the Government of Canada. By changing the rules to allow vaccines to always be in Category II, will still mean that prices will be competitive in Canada, since vaccines cannot be priced higher than the median price of the PMPRB11 comparator countries.

In addition, the Canadian public tender process is already designed to encourage discounts off the list price. These tenders are usually competitive bids and companies usually give a significant discount off list price to win higher share of doses. For sole source contracts, companies must certify prices are "not in excess of lowest price for similar quality & quantity" charged to any other customers.

2. Market size thresholds for Category I bring no benefit to public health objectives for Canadian patients, as it hinders the ability of manufacturers to provide competitive prices for tenders and to supply additional vaccines during outbreaks

PMPRB's market size threshold conflicts with the Public Health Agency of Canada vaccination rate targets, as the rule penalizes manufacturers when revenues hit a certain threshold. This disincentives companies from providing higher volumes of vaccines, which conflicts with the public health mandate to achieve herd immunity, which requires large volumes of vaccine to protect the population

- As part of the Federal Governments' National Immunization Strategy objectives, vaccination coverage goals and vaccine preventable disease reduction targets were set with the expectation of achieving vaccination goals for various diseases of ~95% in children and upwards of 80% in adults. Which goal is the Federal government looking to achieve – a public health or pricing goal?
- The award criteria in publicly-funded contracts favours the bidder with the lowest price. The current tendering process may be jeopardized, as manufacturers would not be able to bid at the lowest price possible and/or may only be able/willing to secure a limited supply of vaccines for a given price point. This results in provincial governments not obtaining the best possible price for publicly funded vaccines and creates potential challenges in cases of market shortages or higher market demand.

- The changes proposed add uncertainties to manufacturers especially in outbreak situations, which cause significant fluctuations in market size from one year to another and demand rapid decisions from manufacturers regarding supply prioritization on a global scale. Because Canada may be competing with other countries for vaccine supply, delays in making these decisions (i.e., caused by the additional time required to obtain approval for exceptions

from PMPRB, local authorities, or company's global pricing teams) can hold up supply allocations to Canada and negatively impact Canadian public health.

See Appendix 1 for example.

3. **Pharmacoeconomic (PE) review process is not applicable to Vaccines: Vaccines do not exceed PMPRBs' planned ICER thresholds and public PE analysis will not be available at product launch**

- NACI and CIQ lack a robust Pharmacoeconomic (PE) review process, and PMPRB Guidelines lack clarity on the use of PE for vaccines, making PE price test redundant for vaccines
- The relatively low cost and high effectiveness of vaccine results in most being cost-effective, or even cost-saving[1]
- The revised guidelines state that Guidance Reports from NACI will be considered for the PE assessment for vaccines; it is, however, not clear where in the process and for what purpose PE assessments will take place, given the low price per patient of vaccines.
- Further, NACI's mandate to conduct pharmacoeconomic assessments is in its infancy: a framework is currently under development and there is no clear deadline for implementation within their economic recommendations – NACI currently can take up to 650 days[2] to publish its scientific recommendations.
- The undefined PE review process as well as the uncertain place of PE evaluation, in the context of vaccines, creates predictability issues and feeds into the perception of increased board discretionary powers.

4. **Non-Excessive Average Price (NEAP) for Grandfather products will create anti-competitive market dynamics for tenders**

Grandfathered vaccines would not be subject to any market size adjustment whereas new-to-market vaccines with forecasted annual sales of over $50M would be subject to a price adjustment, creating unfair and anti-competitive market dynamics in a tender situation.

Simply put, a vaccine manufacturer with a new vaccine would be competing head-to-head to win a given tender in an uneven playing field - against one or more manufacturers with older vaccines that would be playing under different rules. The case study below illustrates how this could play out in practice, with Company A having a clear advantage over Company B in the tendering process due to favorable treatment for the former under the new rules.

The clear solution to both the NEAP problem and the head-to-head tendering problem described in the case study below would be to follow the example set in the June 2020 Draft Guidelines with respect to biosimilar medicines and simply classify **all** vaccines as Category II medicines

See Appendix 2 for example.

5. **Using NEAP will cause confidentiality concerns and create undue administrative burden, while compromising manufacturers' ability to offer volume-based discounts**

In addition to the NEAP issue above, the revised PMPRB guidelines state that the lower of the Highest International Price (HIP) or NEAP will be uses to set the MLP for Grandfathered products. This is of concern to the VIC as the NEAP for a vaccine can be significantly lower than list price simply due to the competitive bid process and discounts given on public tenders. The NEAP for vaccines

can significantly fluctuate year over year due to win or loss of a public tender adding further complexity to MLP calculations.

If NEAP is used to set the MLP for Grandfathered medicines, there is a risk that:

- Manufacturers may not be able to offer the same discounts on the public contracts, since the NEAP would set a maximum list price based on average transaction prices,
- In the global context, where Canadian list prices are referenced by other countries, this may compromise manufacturers' leeway to offer these rebates.
- It would give a very clear indication of confidential contract tender prices to competitors, since most vaccines sales are at the discount price for public contract and would be in contradiction to the confidential procurement and tender process implemented by Public Services and Procurement Canada (PSPC) for the acquisition of Vaccines under the standard procurement policies issued by the Canadian government.

The PMPRB has offered a solution to this issue in Paragraph 76, where patentees can request a higher MLP if the NEAP is "uncharacteristically low". However, even with the addition of this section, there remains considerable price uncertainty as Section 76 can only be invoked after MLP has been re-set using the NEAP and not before.

Given all of this, implementation of the NEAP as the reference for the new MLP for Grandfathered vaccines moving forward is likely to result in a significant increase in submissions by industry (under Section 76) and workload for PMPRB as it will necessitate reviews for almost all vaccines currently supplied in Canada.

In order to safeguard confidentiality, efficiency and to support the public health mandate associated with access to vaccines for preventable diseases, the VIC asks non-excessive MLPs remain at the level set under the previous regulations and guidelines

6. Inability to consider level of therapeutic improvement in absence of international prices to establish list price creates a clear disincentive to prioritize the Canadian market in the vaccine launch sequence

If a vaccine has not been launched in any PMPRB 11 countries, the list price will be set using highest price of the domestic therapeutic class comparators, which tend to be vaccines using older technologies and are generally less effective. Without any price adjustment for therapeutic improvements, or other offsetting adjustments, companies may decide to delay the launch of vaccines in Canada, and launch in other countries first, in order to get a fair price for them.

References

1. 2019, the World Health Organization (WHO)
2. Vaccine Industry Canada (VIC) internal review and analysis

APPENDIX 1 – CASE STUDY: TWO PLAYER TENDERS IN POTENTIAL CATEGORY 1 SIZE MARKET

Consider two competing products launched within a year to prevent the same condition. The first product to enter the market triggers a NACI review for potential inclusion into routine immunization schedules. By the time NACI has completed its review with a positive recommendation and provinces have moved forward with implementation and procurement, both manufacturers are able to participate in a competitive tender.

TABLE 1. PRODUCT INFORMATION AND PMPRB ASSESSMENT RESULTS FOR 2 COMPETING VACCINES

Vaccine A		Vaccine B	
1st sale	Jan-2021	**1st sale**	Jan-2022
MIP	$100	**MIP**	$100
MLP	$100	**MLP**	$100
List Price	$100	**List Price**	$100
median dTCC	$60	**median dTCC**	$80
PMPRB Level	III	**PMPRB Level**	IV
Reduction Floor	40%	**Reduction Floor**	50%
MRP	$60	**MRP**	$80

We first notice from Table 1 that the introduction of a new entrant in Jan 2021 has the effect of increasing the median dTCC for Vaccine B; however, the level of therapeutic improvement for Vaccine B is lower as it is considered equivalent to Vaccine A, which lowers the potential MRP.

TABLE 2. VACCINE A AND B SALES INFORMATION

	2021	2022	2023	2024	2025
Vaccine A					
Actual Units	100,000	450,000	650,000	50,000	250,000
Revenue at MLP	$10,000,000	$45,000,000	$65,000,000	$5,000,000	$25,000,000
Vaccine B					
Actual Units		250,000	50,000	650,000	450,000
Revenue at MLP		$25,000,000	$5,000,000	$65,000,000	$45,000,000
Situation description	Vaccine A introduction, some level of private sales occurs while NACI is reviewing the new vaccine.	Vaccine B introduction & competitive tender completed (2 years firm + 1 option year); Vaccine A wins majority.	Vaccine B suffers a major supply issue and Vaccine A provides additional units; triggers Category 1 designation.	The situation is inverted in the 3rd option year, Vaccine B is subject to a higher MRP[a] due to the improved median dTCC after introduction of Vaccine A	Vaccine B wins the new tender. Both vaccines have triggered the Category 1 designation at one point but, neither currently sell above $50 m

From Table 2, both vaccines have had similar stories and volumes, yet different MRP. Both vaccines were penalized on peak volumes in one year, while vaccine A was further penalized on lower dTCC median.

APPENDIX 2 – CASE STUDY: Vaccines sold only in Public Market

- **2 Companies to tender on a 3-year national Contract (see table for details)**
  - Company A with Product A with NOC before August 2019
  - Company B with Product B with NOC on January 2021
  - Global supply constraint for both products
  - Canadian prices are amongst the lowest in the world, even less than China and Brazil, for example

Company	List Price	Tender price	Units Awarded	Revenues	Comments
A	$10.00	$8.00	6.0M	$48.0M	Not subject to PMPRB factors
B	$10.00	$9.00	4.0M	$36.0M	Subject to market size factor – putting Company B in a disadvantage

Company A goes on backorder in Year 2

Company B cannot provide the additional supply of Company A in Year 2 due to PMPRB market size factor:

- The maximum price in Year 3 would become ~$8.08 (dTCC = $7.00) but the supply would go back down to $36.0M (distortion to price volume market dynamics recognized by Canadian Vaccine Procurement Agencies)
- Due to global constraints – supply would not come to Canada but go to Countries with more favorable environments
- Fairness: Both companies are not treated equally under the PMPRB Guidelines

Vaccines should be Category II PMPRB

New PMPRB Guidelines will negatively impact vaccine market dynamics and become a barrier to Manufacturer' ability to guarantee supply in the Canadian market