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September 11, 2024

Patented Medicine Prices Review Board (PMPRB)
Standard Life Centre, Suite 1400
333 Laurier Ave.
Ottawa, ON
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RE: Response to July 2024 Discussion Guide re PMPRB Guidelines – Second Phase of consultation.
Dear Mr. Digby,

On behalf of Viatris, please find enclosed information to be considered by the PMPRB in this second phase of consultations on its new Guidelines. We appreciate the opportunity to share our perspective on the new Guidelines, informed by Viatris' unique position, delivering both brand and generic products.

Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review:

Option 1: *MIP*
Option 2: *HIP, or*
Option 3: *midpoint between the MIP and HIP*

Viatris Canada supports Option 2: Highest International Price for initial and post-initial price reviews within PMPRB11 countries. This approach aligns with our mission to provide patients with access to high-quality medications and supports the sustainability of the healthcare system.

1. **Encouragement of Innovation:**
    - **Launching Innovative Products:** Setting prices at the highest international level ensures necessary revenue to support the introduction of groundbreaking therapies in Canada.
    - **Financial Incentives:** Higher potential revenues encourage continued innovation and development of new treatments.
2. **Global Competitiveness:**
    - **Market Alignment:** Aligning with the highest international prices keeps Canada competitive, preventing launch delays and benefiting Canadian patients.
    - **Investment Attraction:** Higher prices make Canada more attractive to global pharmaceutical companies, potentially increasing local investments.
3. **Prioritization of Supply**: in markets where prices reflect fair value, there is often greater priority for timely and sustained supply, ensuring patients have continuous access to innovative treatments.
4. **Timely Access to Medications:**

- **Quick Access:** Countries with higher prices often enjoy faster access to new treatments. Adopting the HIP ensures timely access to cutting-edge therapies in Canada.
- **Global Best Practices:** Leveraging global best practices in pricing and market access helps ensure that Canadian patients receive advanced treatments without delay. By aligning with global standards, Canada can maintain its position as a priority market for new and innovative therapies, thereby ensuring that patients benefit from the latest medical advancements.

5. **Economic Benefits:**
   - **Industry Growth:** Higher prices can drive economic growth through increased revenue and investment in local operations.
   - **Enhanced Operations:** Increased revenues enable operational efficiencies and better service to healthcare providers and patients.
6. **Simplification and Transparency:**
   - **Clear Benchmark:** The HIP provides a straightforward pricing benchmark, reducing complexity and making pricing negotiations more predictable.
   - **Administrative Efficiency:** Simplifies the administrative burden, facilitating smoother regulatory processes and faster decision-making.
7. **Actual Selling Price Considerations:**
   - **List Price vs. Actual Price:** The list price is not the actual selling price due to confidential rebates and discounts. Setting the list price at the highest international level allows room for negotiation, ensuring the net price remains competitive.

Countering Affordability Concerns:

- **Patient Assistance Programs:** Viatris Canada implemented programs to mitigate the impact of higher prices on vulnerable populations, ensuring access to necessary medications for all. It's important to note that decreasing prices might impact the quality and availability of these programs, as these are expensive initiatives. Maintaining sustainable pricing is crucial to continue offering these comprehensive support services, which play a vital role in patient care.

Topic 2: The Length of Time Staff Should Wait to Determine Whether the IPC Identification Criteria for an Existing Medicine is Met

The Board is considering the following options:

- ***Option 1:** One year*
- ***Option 2:** Two years*
- ***Option 3:** Three years*

Viatris Canada support of option 3, which allows a three-year period for companies to adjust their prices to meet the International Price Comparison (IPC) identification criteria, is a strategic choice for several reasons:

1. **Sufficient Adjustment Period:**
    - The pharmaceutical industry operates in a complex and highly regulated environment. Adjusting prices to comply with new regulations is not a straightforward task. It involves thorough market analysis, internal reviews, and potential restructuring of pricing strategies. A three-year adjustment period provides adequate time for companies to meticulously plan and implement these changes without causing disruption to their operations or supply chains.
2. **Financial Stability:**
    - A longer adjustment period helps ensure financial stability for companies. Sudden and significant changes in pricing could impact revenue streams, especially for existing medicines that are already established in the market. Gradually aligning prices over three years helps mitigate the risk of financial shocks and allows for more predictable financial planning.
3. **Regulatory Compliance:**
    - Ensuring compliance with the PMPRB 11 pricing framework is crucial for maintaining market access and avoiding potential penalties. A three-year period allows for comprehensive compliance checks and necessary adjustments, ensuring that all requirements are met in a systematic and controlled manner. This period also provides an opportunity to address any unforeseen challenges that might arise during the transition.
4. **Market Dynamics:**
    - The pharmaceutical market is influenced by various factors, including international pricing trends, competitive landscape, and healthcare policies. A longer adjustment period enables companies to better respond to these dynamic market conditions. It allows for more flexibility in pricing decisions and helps in maintaining a competitive edge while aligning with the PMPRB 11 benchmarks.
5. **Stakeholder Collaboration:**
    - Adjusting prices in accordance with new guidelines often requires collaboration with various stakeholders, including payers A three-year period facilitates better communication and negotiation with these stakeholders, ensuring that the transition is understood and accepted by all parties involved. This collaborative approach helps in maintaining trust and transparency in the pricing process.
6. **Global Pricing Considerations:**
    - Many pharmaceutical companies operate on a global scale, and pricing decisions in one market can have implications in another. A three-year adjustment period allows for better synchronization of pricing strategies across different markets, taking into account the international pricing policies and the specific requirements of the PMPRB 11.

In conclusion, selecting Option 3 for a three-year adjustment period is a prudent and strategic decision. It provides ample time for thorough planning, financial stability, regulatory compliance, and effective stakeholder collaboration, ensuring a smooth transition to the new pricing guidelines set forth by the PMPRB.

Topic 3: In-Depth Review Based on CPI Increase Criteria

The Board is considering the following options:

- ***Option 1:** If the list price increase is above one-year CPI.*
- ***Option 2:** If the cumulative increase in list price over the last two years is above the combined CPI for the past two years and the increase only took place within the last year (i.e., no increase in price in the first of the two years, followed by an increase in the second year).*

Viatris Canada's Support for Option 2: Cumulative Two-Year CPI Increase Criteria

1. **Balanced Approach to Pricing:**
    - **Consideration of Market Dynamics:** Option 2 provides a balanced approach that takes into account market dynamics over a longer period. This allows for flexibility in pricing strategies, accommodating periods where price stability is necessary followed by adjustments to reflect cumulative inflation.
    - **Avoiding Overly Frequent Reviews:** Focusing on a two-year cumulative increase reduces the frequency of in-depth reviews, allowing companies to plan and implement pricing strategies with greater confidence and stability.
2. **Mitigating Short-Term Volatility:**
    - **Smoothing Out Price Adjustments:** A two-year cumulative approach helps smooth out short-term price volatility. It allows companies to adjust prices in a manner that reflects economic conditions over a longer period, avoiding abrupt changes that could disrupt market stability.
    - **Reflecting Realistic Cost Increases:** Inflationary pressures and cost increases may not always be evenly distributed year-to-year. Option 2 ensures that price adjustments reflect realistic and cumulative cost increases over two years, providing a more accurate representation of economic conditions.
3. **Encouraging Strategic Planning:**
    - **Long-Term Planning:** By focusing on a two-year cumulative CPI, pharmaceutical companies are encouraged to adopt long-term strategic planning for pricing. This approach supports more thoughtful and measured price adjustments that align with broader business and economic trends.
    - **Predictable Pricing Environment:** A two-year evaluation period contributes to a more predictable pricing environment, fostering stability and confidence among stakeholders, including healthcare providers, patients, and payers.
4. **Administrative Efficiency:**

- **Reduced Administrative Burden:** Option 2 reduces the need for annual in-depth reviews, alleviating the administrative burden on both the PMPRB staff and pharmaceutical companies. This allows resources to be allocated more efficiently, focusing on more strategic oversight and long-term planning.
- **Streamlined Processes:** By evaluating cumulative price increases over two years, the review process becomes more streamlined and less prone to annual fluctuations, ensuring a more consistent and manageable regulatory environment.

5. **Alignment with Economic Conditions:**
   - **Reflecting Economic Trends:** Economic conditions, including inflation rates, often fluctuate over multi-year periods. Option 2 ensures that price increases align with broader economic trends, providing a fairer and more accurate reflection of economic realities.
   - **Support for Sustainable Pricing:** This approach supports sustainable pricing practices that take into account long-term economic indicators, promoting a fair balance between affordability and the financial viability of pharmaceutical companies.

By supporting Option 2, Viatris Canada advocates for a rational and balanced approach to price reviews based on cumulative CPI increases over two years. This approach mitigates short-term volatility, encourages long-term strategic planning, enhances administrative efficiency, and aligns with broader economic conditions, ultimately contributing to a stable and sustainable pricing environment.

Topic 4: The Individuals/Groups Permitted to Submit a Complaint

The Board is considering the following options:

- ***Option 1:** Limit complaints to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts.*
- ***Option 2A:** Limit complaints to Option 1 above plus public payors only.*
- ***Option 2B:** Limit complaints to Option 1 above plus private and public payors.*
- ***Option 3:** Limit complaints to everyone except for Rights Holders.*
- ***Option 4:** No limits/restrictions.*

Viatris Canada's Support for Option 1: Limiting Complaints to the Federal Minister of Health or Provincial/Territorial Counterparts

1. **Minimizing the Number of Complaints:**
   - **Controlled Complaint Volume:** Limiting complaints to key government officials reduces the administrative burden on the PMPRB and pharmaceutical companies, ensuring a more efficient resolution process.
   - **Focusing on Pertinent Issues:** With fewer eligible entities, the PMPRB can address the most significant cases of potential price excessiveness.
2. **Ensuring Legitimate Complaints:**

- **Relevant Stakeholders:** Restricting complaints to the Federal Minister of Health and their Provincial/Territorial counterparts ensures that only those with a vested interest in public health can bring forward complaints, minimizing frivolous ones.
- **Expert Oversight:** Government officials, with their understanding of the healthcare system, ensure complaints are well-informed and based on substantial evidence.

3. **Consistency with Legislative Framework:**
   - **Alignment with the Patent Act:** Limiting complaints to key officials is consistent with Section 86(2) of the Patent Act, maintaining regulatory consistency.
   - **Legislative Intent:** This focus reflects the legislative intent to have informed and authoritative oversight on drug pricing issues.
4. **Encouraging Public Engagement through Elected Officials:**
   - **Indirect Public Involvement:** The public can voice concerns through their elected officials, ensuring grievances are considered while maintaining a controlled complaint process.
   - **Accountability through Representation:** Engaging representatives ensures public concerns are brought forward by accountable individuals.
5. **Streamlined Regulatory Oversight:**
   - **Efficient Resource Allocation:** With fewer eligible complainants, the PMPRB can allocate resources efficiently, focusing on significant complaints.
   - **Reducing Administrative Burden:** A streamlined process reduces the PMPRB's administrative workload, enhancing regulatory effectiveness.

By supporting Option 1, Viatris Canada advocates for a controlled and efficient complaint process that minimizes complaints, ensures legitimacy, aligns with legislative frameworks, encourages public engagement through elected officials, and streamlines regulatory oversight, balancing public health interests and industry sustainability.

Topic 5: Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines

Option 1: *The PMPRB will treat patented biosimilars and/or vaccines the same as other medicines. This means that these products will be subject to routine reviews and potential investigations without the need for a complaint.*

Option 2: *The PMPRB will only open an in-depth review for biosimilars and/or vaccines when a complaint is received. This option indicates that biosimilars and vaccines will not be routinely scrutinized unless a specific concern is raised through a formal complaint.*

Viatris Canada endorses Option 2 for the following reasons:

1. **Resource Optimization:** Limiting in-depth reviews to cases where a complaint has been filed allows the PMPRB to allocate its resources more effectively. By focusing on products with specific concerns, the Board can ensure a more targeted and efficient use of its review capabilities.

2. **Encouraging Innovation and Accessibility:** Biosimilars and vaccines play a crucial role in improving patient access to essential medicines. By reducing unnecessary regulatory burdens on these products, Option 2 can help foster innovation and expedite the availability of cost-effective alternatives in the market.
3. **Maintaining Oversight:** Even with the implementation of Option 2, all patented biosimilars and vaccines will remain under the jurisdiction of the PMPRB. This ensures that any legitimate concerns about excessive pricing can still be addressed through the complaint-driven in-depth review process.
4. **Stakeholder Confidence:** Option 2 strikes a balance between regulatory oversight and market flexibility. It reassures stakeholders that the PMPRB will intervene when necessary while avoiding undue interference in the market dynamics of biosimilars and vaccines.
5. **Precedent and Consistency:** This approach aligns with how other product categories may be treated, ensuring consistency in the regulatory framework. It sets a clear and predictable standard for when an in-depth review is warranted, based on actual market complaints.
6. **Nature of Product Listing Agreements (PLAs):** The pricing landscape for biosimilars and vaccines often involves confidential agreements, such as Product Listing Agreements (PLAs), where the list price may not reflect the actual transaction price. In many cases, the net price or the confidential price is more significant in determining the economic impact and value of these products. Therefore, focusing regulatory efforts based on complaints allows for a more accurate assessment of potential pricing issues, considering the true cost rather than the list price.

In conclusion option 2 provides a practical and balanced approach to regulating biosimilars and vaccines, ensuring that resources are efficiently used, innovation is encouraged, and legitimate pricing concerns are addressed when they arise through formal complaints. This method ensures that all patented products remain under PMPRB's oversight, with in-depth reviews triggered by specific concerns rather than routine scrutiny. Moreover, by considering the nature of PLAs and the importance of net prices, Option 2 allows for a more accurate and fair evaluation of pricing practices.

Topic 6: Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC

Option 1: *One level of similarity is identified for the comparators as a whole. This approach treats all comparators equally, without distinguishing between different degrees of clinical similarity.*

Option 2: *Each comparator will be assigned a level of similarity. This approach allows for a nuanced assessment, where comparators are evaluated and categorized based on varying levels of clinical evidence and similarity.*

Viatris Canada endorses Option 2 for the following reasons:

1. **Enhanced Precision:** Assigning each comparator a level of similarity allows for a more precise and tailored comparison. This method acknowledges the varying degrees of clinical evidence and similarity between different products, leading to more accurate evaluations.
2. **Better Informed Decision-Making:** By categorizing comparators based on their specific levels of similarity, the PMPRB can make better-informed decisions regarding pricing and regulation. This approach ensures that products with closer clinical equivalence are compared more rigorously, while those with lesser similarity are assessed appropriately.

3. **Reflecting Clinical Realities:** The clinical landscape is complex, with products exhibiting different degrees of therapeutic similarity. Option 2 reflects these clinical realities more accurately than a one-size-fits-all approach, providing a more realistic framework for comparator assessment.
4. **Supporting Innovation:** A nuanced approach to comparator similarity can encourage innovation by recognizing and rewarding the unique clinical benefits of new products. This can drive the development of novel therapies that offer distinct advantages over existing treatments.
5. **Stakeholder Trust:** Option 2 builds trust among stakeholders by demonstrating a commitment to thorough and evidence-based evaluations. This transparency can enhance confidence in the PMPRB's regulatory processes and decisions.
6. **Improved Fairness:** Treating each comparator according to its level of similarity ensures a fairer and more equitable assessment. Products are evaluated on their own merits, leading to a more balanced and just regulatory environment.

Option 2 provides a more sophisticated and accurate method for contextualizing the degree of similarity of comparators identified for the TCC. This approach enhances precision, supports better-informed decision-making, reflects clinical realities, encourages innovation, builds stakeholder trust, and improves fairness in the evaluation process. By assigning each comparator a level of similarity based on clinical evidence, the PMPRB can ensure a more nuanced and effective regulatory framework.

Topic 7: Future role of HDAP

The Board is considering two options:
***Option 1:** HDAP will be used only on an ad hoc basis when deemed necessary by Staff.18*
***Option 2:** No HDAP – the scientific process will be conducted by Staff.*
Should the Board opt to utilize HDAP recommendations on an ad hoc basis, it will do so only when PMPRB's scientific review team identifies specific issues or questions necessitating additional advice. Aiming for increased efficiency, this marks a change from the previous process where HDAP reviewed every medicine subject to PMPRB's jurisdiction.

Viatris Canada supports Option 1, where the Human Drug Advisory Panel (HDAP) is used only on an ad hoc basis when deemed necessary by Staff. This approach ensures that HDAP's specialized expertise and independent oversight are available for complex or contentious cases that require additional scrutiny, while streamlining the overall review process for routine evaluations.

By employing HDAP selectively, the PMPRB can maintain a balance between efficiency and thoroughness. This targeted involvement allows the PMPRB to allocate resources more effectively, ensuring that critical cases benefit from HDAP's input without unnecessarily burdening the review process. Furthermore, this method aligns with the goal of reducing administrative overhead and focusing on the most significant issues, thereby enhancing the overall effectiveness of the PMPRB's regulatory framework.

From Viatris Canada's perspective, this approach provides the assurance that the most challenging and high-stakes evaluations receive the appropriate level of expert review, while routine cases can be processed more swiftly and efficiently. It also helps foster stakeholder confidence by demonstrating a commitment to thorough and balanced evaluations when needed, without compromising the efficiency of the regulatory process.

Conclusion:

In conclusion, Viatris Canada appreciates the opportunity to contribute to the ongoing consultation on the PMPRB's new Guidelines. We continue to advocate for policies that support innovation, maintain global competitiveness, and ensure timely access to high-quality medications for Canadian patients. Our position remains that the PMPRB should not have jurisdiction over patented products that already face generic competition in the market, as these market forces sufficiently regulate prices. By focusing on areas where its oversight is most needed, the PMPRB can more effectively fulfill its mandate while supporting a sustainable and innovative pharmaceutical industry in Canada.

We look forward to further discussions and collaboration to ensure that the final Guidelines reflect the needs of all stakeholders.

Sincerely,

Jeffrey Long

Jeffrey Long

Country Manager

VIATRIS™ Canada