CANADIAN PHARMACISTS ASSOCIATION | ASSOCIATION DES PHARMACIENS DU CANADA

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Patented Medicines Prices Review Board
(Rethinking the Guidelines)
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In 1907, fifteen pharmacists created the Canadian Pharmacists Association (CPhA) when they came together to act on issues affecting their profession. Since then, CPhA has been the national voice for pharmacists, dedicated to advancing the health and well-being of Canadians through excellence in pharmacist care.

CPhA actively develops policies and positions outlining the role of the pharmacist as the medication management expert and partner in provision of high-quality drug therapy. These policies and positions are intended to advance the interests of the pharmacy profession to help Canadians live healthier lives and to define the role of the pharmacist within the health care system. CPhA welcomes the opportunity to comment on the *PMPRB Guidelines Modernization: Discussion Paper* (Discussion Paper) and looks forward to participating in the Phase 2 Public Policy Hearing.

Pharmacists, like all health care professionals, are concerned by the cost of prescription drugs and the stress that that drug costs place on the financing of our health care system. Pharmacists also see first-hand the value in terms of health benefits that prescription medicines offer to patients. This value is realized only when drugs are appropriately prescribed, dispensed and adhered to by the patient, and when pharmacists play a key role in achieving optimal drug therapy. CPhA is pleased to make seven recommendations in response to the Discussion Paper which contemplate the role of the PMPRB to better contribute to the changing health care and pharmaceutical landscape.

Pharmacists believe that no Canadian should be denied access to the drugs they need to be healthy. The right prescription, taken appropriately, is a low-cost, high-value intervention that improves health outcomes, especially when compared with alternatives like surgery or visits to the emergency room. CPhA is encouraged by the renewed momentum around national pharmacare and commitments to improve drug access; however, much of the conversation to date has focused on cost-containment. As pharmacists, our members understand that regulating the price of medicines is only one piece of the puzzle. Appropriate access, safety and quality of care are the most important considerations for the sustainability of the Canadian health care system, of which pharmaceutical care is a single component.

CPhA Recommendations in Response to the PMPRB Guidelines Modernization Discussion Paper

Recommendation 1

The PMPRB should be clear in its reporting that ex-factory prices used to conduct international price comparisons are not representative of Canadian consumer prices, or of the relative position of prices paid by Canadian public and private payers.

In an environment where policymakers face difficult choices to ensure that Canadians receive the best possible care, clear and reliable data is critical to inform these decisions and educate the public. As governments set policy to manage limited resources, they rely on the PMPRB to define the scope of the problem. While the PMPRB continually refers to the "prices paid by Canadians", suggesting that consumer prices are high relative to other countries, this is a mischaracterization of the ex-factory prices that the Board uses to make international comparisons.

The Discussion Paper acknowledges "the worldwide practice of confidential discounts and rebates and the concomitant unreliability of public list prices". As long as the PMPRB relies on this metric when conducting reviews, the Board must be clear that ex-factory prices – and therefore, Canada's ranking among the PMPRB7 – are likely misrepresentative of, and an unreliable proxy for, relative prices paid by public and private payers. If the Board is to provide stakeholders with price information to help them make timely and knowledgeable medicine pricing, purchasing and reimbursement decisions, it must be careful not to mischaracterize the relative position of the consumer price of Canadian pharmaceuticals.

Recommendation 2

The PMPRB should adopt an evidence-based approach that considers the value added to the health care system when reviewing markups and dispensing fees in its reporting.

Related to the PMPRB's mission to provide payers with the information they need to make smart reimbursement choices is the Board's portrayal of public drug plan reimbursement to pharmacies in its reporting. While the PMPRB tracks public drug plan expenditures on dispensing fees and markups, the Board does not account for the value these services provide. Dispensing fees cover professional services associated with a prescription, including preparing the medication, checks for safety, allergies, drug interactions and side effects, as well as patient education to ensure the prescription is taken appropriately. Mischaracterizing these fees solely as a cost driver, without acknowledging the value they provide to the health care system, the moderate nature of these fees relative to international comparators, or the fact these fees are regulated by public payers themselves, does not provide a complete picture of the pricing and reimbursement landscape in Canada.

In addition to core dispensing services, CPhA notes that cognitive pharmacy services can help patients and payers realize the full value of pharmaceutical investment and support health care system sustainability. Across the country, expanded scope of practice means that pharmacists are doing more than ever before to help patients manage their medications and achieve optimal drug therapy, often while reducing expenditures on drugs and other health services. For example, pharmacist-led medication management (including medication reviews, adapting prescriptions, and therapeutic substitution) can reduce adverse events; with the associated benefit of reducing health system utilization and costs (e.g. deprescribing, emergency room visits).

Recommendation 3

Any changes to the PMPRB Guidelines, the Patented Medicine Regulations, or the Patent Act must take into account the current HTA and pCPA environment. The PMPRB should ensure its Guidelines are not inconsistent or overlapping with the policies of the HTA agencies and the pCPA.

Brand (sole source) drugs should be considered in terms of their clinical value, whereas generic multi-source drugs are commodities in the sense that there are generally several manufacturers offering the same product. The clinical and cost effectiveness of brand drugs are reviewed by health technology assessment (HTA) agencies such as the Canadian Agency for Drugs and Technology in Health (CADTH) and the l'Institut national d'excellence en santé et en services sociaux (INESSS) in Quebec. Recommendations from these agencies are considered collectively by government payers through the pan-Canadian Pharmaceutical Alliance (pCPA) that negotiates confidential product listing agreements (PLAs) that usually involve confidential, non-transparent rebates to the participating jurisdictions. The terms of these agreements are rarely (if ever) disclosed to the PMPRB and a Federal Court decision precludes PMPRB from requiring manufacturers to report the rebates. The PMPRB price review process is conducted apart from the HTA reviews and the pCPA process. The Discussion Paper acknowledges the changing pricing and reimbursement environment; any legislative or regulatory changes must complement existing processes that support value-based assessments of patented medicines.

Recommendation 4

The PMPRB should maintain an evidence-based approach that considers clinical effectiveness when reviewing the introductory prices of new patented medicines.

Regulation of drug prices should reflect the clinical value offered by drug therapy. Furthermore, the value of a drug at a given price can only be assessed in the context of the clinical outcomes the drug delivers. Poorly defined economic metrics are not a viable substitute for clinical effectiveness. The PMPRB7 reference countries (and other developed countries) rely on clinical evidence in assessing whether a price premium is warranted for a particular therapy. Some countries (e.g. France, Germany) employ a similar

system to the Canadian categories of therapeutic improvement. The Discussion Paper offers no rationale why the evidence based approach should be abandoned and replaced with unspecified economic metrics.

Furthermore, the Discussion Paper suggests that pharmaceutical companies are charging higher prices due to market concentration and price discrimination, and that economic metrics should form the basis of price reviews. However, this market concentration theory is dependent on buyers with no purchasing power, when the opposite is the case. Provinces and territories dictate prices through the pCPA. Private payers insist increasingly on PLAs, and hospital buying groups (MedBuy, Health Pro, Sigma Santé) exert significant buying power on behalf of hospitals. Hospital and pharmacy are fundamentally different markets with different supply and demand drivers for patented medicines.

Recommendation 5

The PMPRB should avoid adding further complexity and uncertainty to the PMPRB Guidelines by relying on (as yet unspecified) economic metrics as proposed in the Discussion Paper.

The PMPRB Guidelines are highly complex, often employing complicated algorithms that calculate non-excessive prices. Complex guidelines, combined with a preoccupation with precision, create an illusion of legitimacy at the expense of transparency. Moreover, the regulatory burden on the PMPRB (and tax payers) is such that it appears that PMPRB requires staffing and resources far greater than comparable agencies in other countries with similar responsibilities. The PMPRB does not need to introduce new, more complicated economic metrics. Instead, the PMPRB should streamline its price review procedures with those of the pCPA and private payers, such that there is not duplication or inconsistency in the price regulation process.

Recommendation 6

The PMPRB should limit its price review activities to sole source, patented medicines.

For generic drugs, the pCPA has established a generic framework that establishes clear transparent pricing rules. CPhA notes that in recent years, the PMPRB has expended considerable effort and resources through hearings and protracted court proceedings attempting to regulate generic drug prices in cases where there may be some connection between the generic manufacturer and the original patent holding, brand manufacturer even in cases where there are several competing generic products. This activity distracts from the PMPRB's core mandate (ensuring that the price of patented medicines are not excessive) and is not in the interest of Canadians who are already well served by the generic pricing framework established by the pCPA. Defining patented medicine in legislation (instead of through litigation) would provide greater certainty and allow the PMPRB to focus on its mandate.

Recommendation 7

The PMPRB should limit international price comparisons to developed countries with advanced health care systems. Any changes to the current basket of countries should be based on thorough analysis to ensure an appropriate comparison, not simply a desire to achieve lower prices.

Although the Discussion Paper suggests that the PMPRB has no preconceptions with respect to changes to its *Guidelines* that should result from the consultation process, the background analysis suggests that the PMPRB has concluded that Canadian prices are too high relative to other countries. This conclusion is reinforced by the misperception that the PMPRB is required to benchmark Canadian prices to high price jurisdictions, including the United States. In fact, Canadian domestic prices of comparator drugs establish the large majority of Canadian prices for patented medicines. It is only in cases of innovative drugs with proven therapeutic improvement that the median international price may become the benchmark. Furthermore, the international price comparison is to a range of low and higher price countries with the median, effectively eliminating outlier prices such as in cases where US prices are significantly higher than corresponding European prices.

The Discussion Paper cites international price comparisons with OECD countries which suggest that significant savings are possible if Canadian prices were tied to a basket of countries including nations with emerging economies and health care systems that lag well behind Canada. Only a subset of patented drugs available in Canada would be available in these emerging markets, and the value these countries place on drugs is with reference to their domestic health care system. Moreover, the Discussion Paper provides limited information on the reliability of neither the underlying pricing data nor any discussion regarding the limitations of Canada to OECD price comparisons. International price comparisons and their interpretation are challenging enough with the existing PMPRB seven reference countries. Comparisons to the full OECD basket of countries would be impractical and of questionable value.

Conclusion

Drug prices are a single component of drug expenditures. The Canadian Institute for Health Information has identified utilization, not price, as the most significant driver of total drug spending increases. Nevertheless, the Discussion Paper suggests that a reduction in prices by a given percentage would result in a corresponding reduction in drug expenditures. These analyses do not consider supply factors (manufacturers may not be prepared to sell some products at reduced prices), follow-on effects (greater reliance on lower priced but less effective therapies), or the likelihood that lower prices will result in limited volume increases. Pharmacists are deeply concerned about compromises to patient care resulting from simplistic recommendations which may not even be successful in reducing overall drug expenditures.

The pharmaceutical environment has transformed since the PMPRB was created. Ensuring safe and appropriate access to medicines as part of a sustainable health care system will require a coordinated approach among patients, policymakers, industry, and health care professionals. Improving access to necessary prescription medications and pharmacy services is CPhA's top priority. While the PMPRB acts as an important safeguard to ensure that Canadian drug prices are not excessive, Guidelines modernization is not an effective or appropriate means to achieve this objective directly. Instead, changes to the Guidelines are an opportunity to improve the PMPRB's capacity to provide payers with the information they need to make smart reimbursement choices, and policymakers with the intelligence to improve access to prescription medication in Canada.

On behalf of Canada's 40,000 pharmacists, CPhA looks forward to the next steps in this process, and would welcome the opportunity to participate in the Phase 2 Public Policy Hearing when it is scheduled.

Sincerely,

Perry Eisenschmid, CEO
Canadian Pharmacists Association