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Patented Medicines Prices Review Board
Attention: PMPRB Guideline Consultations
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Submitted via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Sandoz Canada Inc

Sandoz Canada is pleased and welcomes the opportunity to provide its input regarding the proposed PMPRB Guidelines published November 21, 2019.

Sandoz Canada is part of Sandoz International GmbH, a global leader in generic pharmaceutical products and biosimilars and a subsidiary of Swiss multinational Novartis AG. A leader in its field, Sandoz Canada markets a broad line of generic and biosimilar products.

Context of the PMPRB Reform

Canadians spent $34 billion on prescription medicines in 2018[1]. Drugs represent the second largest health care expense, after hospitals and on par with physicians' wages. It is therefore normal for Canadians to be concerned about the cost of drugs. It is in this context that the PMPRB has undertaken a major reform to ensure that citizens can benefit from the best available drug price compared to other jurisdictions for patented medicines.

The premise behind the reform is that the price of drugs in Canada is higher than the average for OECD countries. Although the conclusions drawn by the PMPRB are factual, the fact remains that attention must be paid to the economic, demographic and regulatory context of a jurisdiction to make the right diagnoses beyond a cost comparison analysis. Any consumer goods sold in the world is intrinsically linked to its own market dynamic and this is why prices are different from one good to another. You will find different situations depending on the variables of the context of a given jurisdiction. When it comes to drugs, here in Canada or elsewhere, the price displayed is rarely the actual price paid by patients under their insurance plans, making price comparisons even less reliable.

To face the pressure of drug expenditures for Canadians, solutions already exist but they are not being used to their full potential.

[1] Canadian Institute for Health Information: https://www.cihi.ca/sites/default/files/document/pdex-report-2018-en-web.pdf .(Page consulted on February 6th, 2020)

1. Increase generic utilization, mostly with private payers: About 71.8% prescriptions are filled with generic medicines while the remainder 18.2% is still paid at the full price of brand products. According to the Canadian Generic Pharmaceutical Association, for every one percent increase in the use of generic medicine, Canadians would have saved an additional $**585 M** last year. Each 1% increase of generic utilization is worth $336M for private payers and $250M for public payers[2].
2. Implement biosimilars mandatory switch policies by jurisdictions: Biologic medicines are one of the fastest growing segments of drug spent in Canada. While the first biosimilar biologic drug was approved in Canada more than a decade ago, the uptake of biosimilar biologic drugs has been slow, particularly for use in treating chronic conditions. There has been increasing recognition on the part of public and private payers that interventionist policies are needed to support the adoption of biosimilar medicines. While there were some encouraging developments in 2019 such as the biosimilar transitioning initiatives announced by British Columbia, Alberta, Pacific Blue Cross and Green Shield Canada, the future of biosimilars in Canada remains somewhat uncertain.

While these two solutions are outside the PMPRB's scope of action, they constitute effective and concrete solutions to reduce expenditure of medicines for patients, and public and private insurers. Reducing the costs of drug spending in Canada requires concerted and consistent action. The approach advocated by the PMPRB is unfortunately a silo approach which has a domino effect on the other processes in place in the provinces and territories.

The PMPRB's initial jurisdiction mandate over "patented medicines" was intended to protect Canadian consumers from originator monopolies. It was not intended to cover products like biosimilar and generic drugs which contain the same active substance as an originator product under the PMPRB's jurisdiction.

At that time in 1987, it was obvious that a patented molecule was undoubtedly an innovative product and a generic product was not patented. The market has changed and today a number of generic products have patents. In addition, biosimilars were unknown at the time, and nowadays many submissions are made to Health Canada each year. The challenge is that biosimilars for the most part have a patent, although they are intended to compete directly with a brand name biological product. In both cases, the very strict definition of patentees included in the Act unfairly penalizes the introduction of generic and biosimilar medicines bearing a patent, while the fundamental reason for the existence of these products is precisely to compete with a brand name drug. The modernization of the PMPRB should have been revised to replace the current definition of "patentees". Having a definition that only applies to drugs for which there is only one version of a chemical entity, the PMPRB's mission to protect patients from excessive prices would be more relevant than monitoring products whose primary intention is to compete with innovative branded medicines. In short, generic or biosimilar drugs are at very low risk of excessive price as they have many competitors.

Impact Analysis

We have analyzed the different facets of the reform proposed by the PMPRB. If it is implemented as proposed, it will have effects on the following aspects:

A. Impact on drug pricing for generics and biosimilars medicines

[2] Canadian Generic Pharmaceutical Association : https://canadiangenerics.ca/sustainable-healthcare/1-increase-savings/ (page consulted on February 6, 2020)

Currently, the price of generic drugs is set according to a percentage discount taking into account the number of generic competitors in a given market. What will happen to the prices of generic drugs if the price of the reference molecule drops? Generic medicines are providing tremendous value and savings for Canadians, largely due to the work CGPA has done with the pan-Canadian Pharmaceutical Alliance (pCPA).

The pCPA and CGPA have a 5-year generic drug pricing agreement in place effective April 1, 2018 until March 2023. The 5-Year Agreement includes a review clause that requires the pCPA and CGPA to review the changes to the PMPRB framework and address potential impacts on generic drug prices. This clause was included to maintain the integrity of the agreement and to ensure generic drug prices remain at sustainable levels.

While PMPRB is not intervening on drug plan decision to list and pay for medicines with payers, the reform will, if it proceeds as is, force payers to substantially modify the pricing agreements in place with manufacturers. Inadvertently, the reform will engage payers and manufacturers to enter into a lengthy process to reset brand price level or percentage of brand price for generic molecules.

Regarding biosimilar medicines, although there is no tiered pricing framework like the generic drugs' one, the price positioning of these drugs is in relation to the price of the reference biologic medicine sold in Canada. In the proposed reform, it is unclear as to whether biosimilars will be subject to the comparison to the international benchmark basket. If so, the impact would be catastrophic since this type of product is the subject of several different pricing mechanisms between the applicable jurisdictions. This would result in a downward price spiral leading to a point of disinterest in launching biosimilars in the Canadian market. Biosimilars aim to compete with originator products once the patent has expired. Biologics represent sales of $ 7.88 billion[3] (MAT August 2019) in Canada and is the fastest growing market segment of all pharmaceuticals. It would therefore be counterintuitive to penalize products that aim to lower spending on biologic medicines.

B. On the decision whether to launch or not generics and biosimilars in Canada, and availability and supply of medicines

Manufacturers are making commercial decisions to launch generic and biosimilar medicines in Canada based on several criteria:

- Patent duration and IP regiment
- Potential market size
- Pricing conditions
- Number of competitors

In fact, manufacturers assess market and sales potential based on the prices of benchmark innovative medicines. By applying a potential drop in the price of reference drugs, it is certain that manufacturers will consider these new factors and certain molecules may never be the subject of competition by an alternative drug. In addition, a constant review of the prices of the innovative drugs compared to the international prices of the reference basket adds to the uncertainty of generics and biosimilars launches in Canada. In the end, this would potentially mean a perpetual monopoly of the innovative molecule, even if the patent has expired.

[3] IQVIA: *PharmaFocus 2023 Update*. Canadian Drugstore and Hospital Audit. MAT August 2019

It is generally recognized that if there are barriers in a given market, fewer active suppliers will be entering the market. The new guidelines raise several questions that could lead manufacturers to make decisions not to launch certain products in Canada. If there is less competition, there is therefore in some cases an increased risk of supply shortage. The FDA in the United States recently published a report on supply disruptions in which it stated:

> "*Root Cause 1: Lack of Incentives to Produce Less Profitable Drugs. When market conditions limit manufacturers' profitability, they reduce a firm's motivation to maintain a presence in, or enter the market for older prescription drugs, and to invest in manufacturing quality and redundant capacity. Manufacturers of older generic drugs, in particular, face intense price competition, uncertain revenue streams, and high investment requirements, all of which limit potential returns. Current contracting practices contribute to a "race to the bottom" in pricing"*[4]

C. Disclosure of confidential agreements with jurisdictions

Pharmaceutical manufacturers are concerned that the requirement to disclose confidential price agreements with various jurisdictions across the country may no longer be confidential in the long run. Since the reports published by the PMPRB are public, it might be fairly easy to calculate the price levels agreed with jurisdictions under confidential listing agreements. This would have the effect of granting a significant advantage to manufacturers of innovative products in the establishment of new price agreements to compete with biosimilar competitors and try to maintain market share in this segment of market.

D. On ecosystem (manufacturers/distributors/chains/pharmacists)

In our opinion, PMPRB has underestimated the impact across the entire Canadian drug supply chain. Any drop in the price of drugs will have collateral effects on distributors, wholesalers and pharmacies because their revenues are based on a percentage of the transaction value. This will force all players in the supply chain to have to renegotiate distribution costs with provincial jurisdictions while exerting additional pressure on local pharmacies which have to juggle with the domino effect of decisions made in isolation from partners in the pharmaceutical sector. Moreover, the budget impact forecast by the PMPRB was estimated at $ 1.6M for the entire supply chain. Several have raised the incongruity of this estimate for a reform aimed at reducing spending on drugs by a few billion dollars. For a market of more than $ 34B currently, a single percentage point is worth more than $ 340M, which is different from the $ 1.6M estimated in the Impact Regulatory Assessment.

This pressure of intermediaries' revenues will affect the frequency of distribution of pharmaceuticals, inventory levels and the number of distribution centers in the country. In addition, this could affect the number of local pharmacies open to serve Canadian patients. It would have been appropriate for the PMPRB to undertake a reform with the other jurisdictions and partners in the pharmaceutical sector to minimize the impacts of this reform.

E. Ambiguity whether patented generics and biosimilars medicines would be subject or not to submit to PMPRB

[4] Food and Drug Administration : *Drug Shortages: Root causes and potential solutions*; Oct 29th 2019; (https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions); (page consulted on January 16th, 2020)

The definition of "patentee" causes problems for generic and biosimilar molecules. In a market in which certain generic products and several biosimilars have patents, this will result in a double standard. Subjecting patented generics and biosimilars to PMPRB ruling would limit the ability of those products to compete against other manufacturers of the same medicine who do not have patents. This could disadvantage manufacturers of patented generics and biosimilars in relation to other non-patented generic and biosimilars medicines, especially since it is recognized even by the PMPRB that these molecules are at very low risk of presenting an excessive cost for the patients and the payers.

It would be pertinent to carve out all generic drugs and biosimilars from the scope of the PMPRB and maintain the ability to investigate on a complaints basis.

F. PMPRB will be challenged by CADTH's decision to bypass biosimilars

The process outlined in PMPRB's guidelines relies on pharmacoeconomic reviews from the Canadian Agency for Drugs and Technologies in Health (CADTH) as a key process input. However, as of June 1, 2019 CADTH no longer conducts biosimilars reviews, either through the Common Drug Review (CDR) or the pan-Canadian Oncology Drug Review (pCODR). This decision was made in consultation with public drug plans and the pan-Canadian Pharmaceutical Alliance, and reflects the Agency's view that the reimbursement process for biosimilars should be as simple and streamlined as possible given they are a source of much-needed system savings.

Recommendations

We recommend the following suggestions to the PMPRB:

1. Patented biosimilars must be carved out from PMPRB: There are already exemptions reporting requirements for patented generic drugs, veterinary drugs and over-the-counter drugs. Biosimilars must be included in those exceptions as well.

2. Maintain the complaint-based mechanism for generic medicines and extend this provision to biosimilars. The PMPRB price control function remains in effect in this situation, but it has many advantages. On one hand, manufacturers would not have to submit reports to the Board, on the other hand, the Board would not need to process these reports unless a complaint is triggered. This is especially true since these products have a very low risk of being in a situation of excessive price because their price is normally linked to the price of a reference drug and prices are regulated by provincial governments. We don't foresee any situation where a biosimilar could end up in a monopoly situation, therefore posing a very low risk of excessive price.

3. Harmonize price regulation decisions with other government organizations: Prices of generic and biosimilar drugs are negotiated through the pan-Canadian Pharmaceutical Alliance (pCPA). The current reform of the PMPRB is out of alignment with the objectives of pCPA and the participating jurisdictions because the main challenge does not result only in controlling prices but rather in the use of less expensive drugs than original brand medicines. Currently, the proposed reform imposes more barriers and uncertainties on manufacturers of generic and biosimilar medicines and will result in the number of competitors decreasing in the long term when a reference medicine expires.

   In addition, this reform may result in changing several parameters of a pivotal agreement on the prices of generic drugs. If implemented as proposed, this will force all provincial jurisdictions to have to review terms and conditions of the negotiated agreement with the generic industry. It would have been beneficial for the PMPRB to

propose a reform that is aligned with the provincial jurisdictions' pharmaceutical spending reduction objectives.

Thank you for reading this submission. Our company provides pharmaceutical products that help lower pharmaceutical costs for patients and healthcare facilities. If you would like, we are available to discuss with you concrete solutions that will contribute to achieving the objective of the PMPRB reform in the patients' interest.

Best Regards,

Michel Robidoux

President and General Manager
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