BIOQuébec's Comments on the Patented Medicine Prices Review Board (PMPRB) Guidance Document for Consultations

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BIOQUÉBEC

BIOQuébec is a non-profit association funded entirely by its members. It represents over 140 organizations in Quebec's life sciences industry, particularly in the biopharmaceutical and biotechnology fields. Our members are involved in every stage of the healthcare innovation chain, including drug discovery, development, manufacturing, and marketing. BIOQuébec is the voice of the industry, promotes networking and economic development, and serves as a link between the private sector and stakeholders.

BACKGROUND

BIOQuébec has spoken out several times in recent years in favour of effective changes to the regulatory framework governing drug pricing in Canada. This is an extremely important issue for the development of the life sciences sector, in a context where medical advances are accelerating and taking on a global scope. Canadians cannot afford to see their economy left behind in this technological revolution as a result of misguided public policies that undermine the significant investments made by both the private and public sectors.

BIOQuébec is committed to a stable, predictable business environment that benefits patients, the public sector, and innovative companies. This is why BIOQuébec strives for coherence between the numerous public policies that affect our sector.

To this end, BIOQuébec promotes ongoing dialogue between the community, including academic research, the clinical field, patient groups and industry, and regulatory bodies. The Patented Medicine Prices Review Board (hereinafter referred to as the "Board" in the document) must be equipped with more frequent and ongoing consultation mechanisms, prior to the publication of interim guidelines. It needs to adopt the most holistic approach possible, to foster the greatest possible coherence.

We are very pleased that the Board has chosen to engage in a broader dialogue on its guidelines with civil society. BIOQuébec is grateful for this opportunity to make its views known.

BIOQUÉBEC'S COMMENTS ON THE GUIDELINES

PRINCIPLES

At the outset, BIOQuébec wishes to emphasize that the substance of this consultation is directed at stakeholders on subjects and issues that are generally very specific and precise, not to mention technical. BIOQuébec is not in a position to comment at this level of detail, and we hope that the other participating parties will be able to brief the Board according to its expectations.

On the other hand, BIOQuébec feels very comfortable commenting on the principles it would like to see reflected in the directions and guidelines laid out by the Board.

The principles advocated by BIOQuébec are:

INTEGRITY OF THE BOARD'S MANDATE

PREVENTING EXCESSIVE PRICES OR REGULATING PRICES?

The essence of BIOQuébec's arguments, and of a significant proportion of the opinions expressed over the years, concerning the execution of the Board's mandate, is the need to focus on preventing excessive prices and to uphold its constitutional powers, as reiterated by the Federal Court of Appeal and Quebec Court of Appeal rulings in 2021 and 2022.

Indeed, if the Board were to interfere in greater detail and beyond its mandate, it would, for all practical purposes, become a price-fixing body. In fact, there are already several price-control mechanisms in Canada that fall under the jurisdiction of the provinces alone. A complex, multi-faceted mechanism, involving a number of private and public players, comes into play between the price submitted to the Board and the price actually reimbursed by insurers (private and public).

The Board's role in this economic system must remain as circumscribed as possible, to avoid creating pernicious and undesirable effects that impact the public interest. The Board should not interfere, even indirectly, in matters that essentially concern the management of private or public insurance schemes.

The mechanism based on a comparison between the initial Canadian reference price and the median price of the PMPRB11 group of countries is far from adequate, as it often fails to take all the factors and circumstances that can influence international prices into account.

BIOQuébec believes that the *Highest International Price* (HIP), not the *Median International Price* (MIP), should be the reference standard. This would ensure that it avoids going down the road of price control as opposed to the prevention of excessive prices.

Furthermore, it is important to remember that neither the Board nor the federal government, with some exceptions, are drug payers in this country. While it is absolutely necessary for the Board to uphold the principles of the Patent Act, engaging in the practice of making value judgements about the therapies available on the market clearly encroaches on the responsibilities of public and private payers, which are in a much better position than the Board to reconcile the needs of the population with the supply of biopharmaceutical products, based on the insurance plans they have set up and for which they are responsible.

Ultimately, although the Board's action has a very real impact on the subsequent steps, if a public insurer chooses to make a drug available, the decision is made independently of the administrative processes proposed by the Board, since these issues are resolved downstream in the chain between the other parties involved.

For this reason, BIOQuébec recommends that the Board preserve the original integrity of its mandate and limit its intervention, directly and indirectly, to preventing excessive prices within the meaning of the Patent Act.

PREDICTABILITY, FLEXIBILITY WITHOUT RE-EVALUATION OR RETROACTIVITY

BIOQuébec is a grouping of businesses. Its members face the constant challenges that entrepreneurs and business leaders must overcome to ensure the long-term survival of their organizations. This is why we believe that any effective regulatory framework must provide predictability and flexibility.

The mechanisms proposed by the Board must absolutely allow predictability, flexibility to take account of inflation, no revaluation once the price ceiling has been set, and no retroactive impact. They must also be limited to verifying whether the initial price level when new compounds are launched on the Canadian market is excessive in relation to the reference price. New indications should not trigger a price revision.

It should be remembered that once a price has been accepted by the Board, it is very difficult, if not impossible, to adjust it upwards for the remaining period of its availability on the market. On the contrary, multiple pressures are exerted over time to lower the net price.

For these reasons, BIOQuébec recommends not re-evaluating the price after a compound has been launched, except to allow for an inflation adjustment as provided for in the Patent

Act, and instead to review the price of new compounds launched on the Canadian market only.

CONSISTENCY WITH GOVERNMENT AND SOCIETAL PRIORITIES

Finally, our third principle concerns the need to harmonize the Board's action with other Canadian public policies relating to innovation, support for the biopharmaceutical sector, and the sustainability of the healthcare system. It is counterproductive to address the issues facing Canada's healthcare system in isolation, without taking its interdependence into account. It is essential to understand that the regulation of drug prices, even in cases where it is perceived as minor, can have a significant impact on patients.

BIOQuébec points out the inconsistency of investing in research and development while giving the impression of minimizing the importance of innovation by focusing exclusively on price. The Board must stay within its legislative mandate and avoid sending negative signals to innovators. Clear, consistent guidelines that uphold these principles will be perceived as aligned with overall public policy, to the benefit of the ecosystem we represent, as well as the Canadian public and patients.

We thus encourage the Board to act as a constructive player, mindful of its essential role in our business environment, and to develop its future guidelines taking the Federal Government's focus on a modern regulatory framework into account.

IMPACTS OF OVERSTEPPING THE BOUNDARIES OF THE BOARD'S MANDATE

This section highlights the potential consequences of guidelines that do not reflect the principles defended by our association.

INNOVATION

It must be stressed that the life sciences industry is intrinsically linked to innovation. BIOQuébec regularly stresses the need to emphasize that while public research is crucial, concrete advances for society depend heavily on our ability to translate research results into concrete applications that can be produced on an industrial scale. At a time when governments are encouraging innovation in various sectors, innovation is not an option in the life sciences – it is a vital imperative.

This is why BIOQuébec insists on the need for extreme caution in shaping public policies that could undermine the capacity for innovation in a sector that is so vital to the country's future. It is also crucial to recognize that the Board's practices affect all patented innovations, regardless of their origin, including those from Canadian academic and public research. BIOQuébec attaches particular importance to this aspect.

NEW ACTIVE SUBSTANCES LAUNCHED IN CANADA

BIOQuébec and Life Sciences Ontario have carried out a rigorous analysis[1] of data on the availability of new active substances (new drugs or NAS) in 2022, using IQVIA data, with a disquieting conclusion. Canada has lost its traditional position as a priority country for launches, as the time to launch an NAS has increased and the number of launches has decreased in recent years.

Undoubtedly, while this situation can be explained by a combination of various factors, the issue of Canada's "price regulation" system cannot be ruled out. Market conditions cannot be dealt with in silos without properly measuring their impact, not only in relation to domestic issues, but also on an international scale.

ACCESS

Even once the initial pricing hurdles have been overcome and the decision has been made to launch a new drug in Canada, patient access to these medicines is not guaranteed. Innovators are then required to meet criteria set by health technology assessment agencies such as CADTH and INESSS, and to undergo the negotiation process of the Pan-Canadian Pharmaceutical Alliance (pCPA). These different stages can lead to delays and create additional obstacles to patients' access to medicines.

Although the Board's action is separate and independent from these downstream processes, it nevertheless represents a first stage of control that can influence the overall medication process. This underscores the importance of limiting its scope of action to the framework of its legislative mandate.

INVESTMENTS

A sector as innovative as life sciences depends on an investment-friendly business environment. If prospects for profitability diminish and Canada, including Quebec, is no longer seen as an attractive market compared to other global innovation centers, we will miss out on the opportunity to build a world-leading life sciences sector. This is clearly unsustainable and inconsistent with the economic development objectives of the federal and provincial governments.

Ill-advised price regulation policies have the potential not only to diminish Canada's attractiveness to foreign direct investment, but also to hamper the ability of our start-ups

[1] The webinar can be viewed here https://youtu.be/V3YtajDBqrs?si=e84VICNQVQOPQixg

to attract private capital and development partners. We cannot rely solely on public funds to support the sector.

For one thing, the costs associated with obtaining Health Canada approval are not negligible. According to our estimates, the investment required to obtain Canadian registration is comparable to that required by European authorities, for the same new active substance. However, at comparable prices, and taking into account the population of both markets, it is almost 6 times more expensive per capita to enter the Canadian market.

BIOQuébec believes it would be disastrous to add the problem of inadequate price regulation to the many existing challenges our companies already face in financing their development and operating in the Canadian market.

EFFECT ON THE SUPPLY CHAIN

Finally, like other groups with an interest in the pharmaceutical sector, we want to emphasize that the negative consequences of inappropriate price regulation can also affect the physical availability of medicines. It is important to reiterate that, while the Board's intervention is an initial step towards patient access to medicines, it has a significant influence on subsequent steps. A reference price that is defined as "non-excessive" but that falls short of the economic realities of the Canadian market may jeopardize the viability of commercialization, including for generic products with prices linked to those of breakthrough products.

In a context where international pressures affect the availability of certain compounds, and where geographic allocation decisions are necessary, it is crucial to recognize the influence of local market conditions on these decisions. It is essential for the manufacturer, along with the wholesalers, pharmacies, carriers and other logistical players involved, to be adequately remunerated for distributing a product in Canada. Weakening any one of these links can lead to shortages.

To BIOQuébec, these considerations underscore the importance of limiting the Board's actions to avoid unforeseen consequences that could be detrimental to the public interest within this complex chain.

CONCLUSION

The Board's mandate derives from the Patent Act. This mandate is not a negotiating tool, nor is it intended as a tool for managers of the Canadian healthcare system. Its legislative objective is to prevent potential abuses by patent holders.

The Board's interventions appear to be more likely to harm rather than improve the health of Canadians. Although its role is to prevent abuse, its actions do not tend to foster innovation. In keeping with the Hippocratic principle of "first, do no harm" *(Primum non nocere)*, the Board must ensure that its actions do no unnecessary harm.

In this document, BIOQuébec stresses the need for the Board to remain true to its original mandate, and thus promote a viable business environment for the industry and maintain consistency with government policies.

We emphasize that deviation from these principles can seriously undermine national innovation, the health of Canadians, the prosperity of the life sciences sector, and the drug supply chain.

We hope that our perspective will contribute to the Board's reflection in the public interest.

Thank you again for the opportunity to express our views.

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