Teva Canada Limited Brief to the Standing Committee on Health
Study on the Patented Medicine Prices Review Board's Final Guidelines Issued on October 23, 2020
November 6, 2020

Teva Canada Limited (Teva) is pleased to submit this Brief to the House of Commons Standing Committee on Health to support its study of the Patented Medicine Prices Review Board's Final Guidelines issued on October 23, 2020.

Teva is concerned that the Final PMPRB Guidelines will have a negative impact on the continued competitiveness biopharmaceutical industry in Canada. The uncertainty created by the PMPRB Guidelines to drive down drug prices will impact the ability of the industry to make investment decisions, risking Canada's ability to compete globally in this vital sector. As we have seen during the current pandemic, Canadians need access to innovative medicines. As biopharmaceutical industry continues to bring new advances in treatments it is vital that Canada has sound public policies that ensures Canadians can access new innovations. The new PMPRB Guidelines potentially impact access to important treatments and therapies in Canada.

As a member of BIOTECanada, Teva strongly supports the position it has taken by highlighting the serious gaps relating to the implementation of the Guidelines. In its letter to this Committee, BIOTECanada has outlined its concerns regarding the impact that these Guidelines will have on the Canadian biotechnology ecosystem. Additionally, BIOTECanada has stated the new Guidelines are putting at risk Canada's standard of clinical practice and putting Canadian doctors and system of care behind in the knowledge required for the next generation of health innovation. Teva shares these concerns with BIOTECanada and urges the Committee to consider this as it studies this important issue.

Teva's specific comments on the PMPRB Guidelines are detailed below.

Introduction of Economic Factors

Teva is extremely concerned with the introduction of economic factors in the assessment of the price of Category 1 patented medicines. In particular, the use of pharmacoeconomic value assessments as part of the calculation to set price is problematic and introduces significant price uncertainty. The PMPRB's intended source for the pharmacoeconomic analysis used for its assessment will be primarily from the Canadian Agency for Drugs and Technologies in Health (CADTH) or the Institut national d'excellence en santé et services sociaux (INESSS). CADTH/INESSS conducts a reanalysis of the manufacturer's cost utility analysis (CUA) model and it is this reanalysis that will be used by the PMPRB to establish the Pharmacoeconomic Price (PEP) – the price where the Category 1 patented medicine's Incremental Cost-Utility Ratio (ICUR) would be equivalent to the Pharmacoeconomic Value Threshold (PVT).

Typically, this reanalysis differs significantly from the manufacturer's submitted CUA. The CADTH/INESSS reanalysis of submitted CUAs are not always transparent, are not peer reviewed, and are intended to address questions related to the reimbursement of medications. Under the Guidelines, patentees will not be provided an opportunity to refute the CADTH/INESSS reanalysis, nor is there an independent body that can be referred to when a patentee disagrees with this reanalysis. Patentees need to have a mechanism to challenge the CADTH/INESSS reanalysis when disagreements occur.

This uncertainty for patentees is compounded by the introduction of Therapeutic Criteria Levels (TCL) where the ICUR will be compared against the applicable Pharmacoeconomic Value Threshold (PVT). For new patented medications with a TCL III or TCL IV, the CADTH/INESSS reanalysis will likely result in ICERs (Incremental Cost-effectiveness Ratio) higher than the proposed thresholds resulting in reductions to the Maximum List Price (MLP) of approximately 40% and 50%. Teva is concerned that the PVT associated with the TCL appear arbitrary and make it very difficult for patentees to

predict prices, especially as the process of filing and reporting to the PMPRB may take several months or even years as patentees wait for a CADTH/INESSS reanalysis of submitted CUAs.

An additional concern is if a patentee decides to not to submit to CADTH/INESSS (such as a launch of a patented medication into the private payer market exclusively), the final Guidelines states that a Category I patented medication will have a 50% reduction from the MLP. Moreover, if a patentee conducts a cost minimization where a cost per course of treatment comparison is made when alternative therapies have demonstrably equivalent clinical effectiveness, the patented medication is automatically subjected to the median of domestic International Therapeutic Class Comparison (dTCC) and subject to a 50% reduction cap. These reductions from the MLP are arbitrary and also create concerns regarding confidentiality as these mandatory reductions in the Guidelines are transparent potentially allowing other countries to reference Canadian prices. Teva believes the application of automatic 50% reduction of the MLP needs to be reconsidered.

A further concern is the market size adjustment methodology that applies to Category I patented medications. In addition to the application of pharmacoeconomic value assessments, market size adjustments create additional price uncertainty to patentees through potential further reductions in price during the life cycle of their product. As annual revenue increases, incremental MLP adjustments can effectively decrease MLP by up to 35%. Not only is this problematic for long term product planning and revenue forecasting, it has the effect of placing an additional penalty on new innovative treatments.

Teva recommends that pricing uncertainty resulting from the introduction of economic factors needs to be addressed with changes to the Guidelines generally. Further, Teva believes that mandatory 50% price reductions from the MLP for patented medications without a CUA and subjecting products with a cost minimization to the median of the domestic dTCC subject to a 50% floor needs to be reconsidered.

<u>New Discretion of Board Staff</u>

Teva is concerned that Sections 95, 97 and 98 of the Guidelines provides Board staff with the ability to deviate from the Guidelines and modify tests and price thresholds that are deemed appropriate, in the event of an investigation. Section 95 states:

Staff may utilize any of the tests described in the Guidelines and modifications or variations of those tests (e.g., MIP [Median International Price] instead of HIP [Highest International Price] or median as opposed to the top of the dTCC, or comparing the net price to the MRP [Maximum Rebated Price]) depending on what it believes most appropriate to the factual circumstances surrounding the price of the medicine under investigation.

Additionally, Section 97 states that the tests and ceilings used during the investigation by Board staff may differ from the initial thresholds that led to the triggering of the investigation. *"In such cases, the investigation ceilings (as opposed to the triggering ceilings) will be used to calculate potential excess revenues."*

These new provisions in the Guidelines increase uncertainty to patentees by potentially applying tests and thresholds not considered prior to submission, nor considered during the PMPRB consultation process. Teva is very concerned about the broad discretion of Board staff to make, modify or vary price tests and thresholds in the event of an investigation and recommends that these sections be removed or revised to ensure the evaluation process of patented medicines is both fair and predictable.

The new Guidelines have also made significant changes in how the scientific review of patented medicines is conducted. Unlike the current Guidelines where the Human Drug Advisory Panel (HDAP) determines the level of Therapeutic Improvement, Board staff will now be tasked with determining the Therapeutic Criteria Level. Under the new Guidelines, Board staff will only consult with the HDAP on an *ad hoc* basis to provide clinical context to the scientific information being considered.

This new role of Board staff is problematic as the determination of the TCL is critical to determining the Pharmacoeconomic Value Threshold and setting the reduction cap off MLP. Moreover, unlike the HDAP whose current mandate is to provide credible, independent, and expert scientific advice to the PMPRB, Board staff may lack the necessary scientific expertise to determine the TCL of a patented medication.

In order to ensure that PMPRB continues to have access to expert, independent scientific advice when determining the TCL, Teva recommends that the HDAP should continue in its current role

Potential Impact of PMPRB Changes on the Price of Generic Medicines

Teva shares the concerns expressed by the Canadian Generic Pharmaceutical Associations (CGPA) in its August 4, 2020 feedback on the draft 2020 Guidelines regarding the potential impact on the reference-based pricing system for generic medicines in Canada. The price levels of generic drugs in Canada are internationally competitive and provide Canadians with significant value and savings. This is a result of the important work of the CGPA and the pan-Canadian Pharmaceutical Alliance (pPCA) to agree on five-year generic pricing agreement.

This agreement (which followed an earlier agreement) included a tiered pricing model which has different pricing level depending on the number of competitors on the market. Prices of generic medicines are calculated by the pCPA as a percentage of the price of the reference originator at the time of the first version of the generic product is listed on provincial formularies.

Since the development of generic medicines begins several years prior to their launch, changes in reference brand products as a result Guidelines would affect the pricing of the generic products under development. The Five-Year Agreement includes a clause that requires the pCPA and CGPA to review the changes to the PMPRB framework and address potential impacts on generic drug prices. Teva is concerned about the potential impact of the Guidelines on prices of the originator, creating uncertainty about the impact of the 5-Year Agreement.

Teva recommends that the Committee encourage the PMPRB consult closely with both the pCPA and the CGPA as it implements the new Guidelines to prevent potential negative impacts on the 5-Year Agreement as well as on the introduction and availability of generic medicines in Canada.

Complaint-Based Reporting for Patented Biosimilar Medicines

Teva supports the inclusion of patented biosimilars in a complaints-based system in the new PMPRB Guidelines. This approach is similar to the current treatment of patented generic medicines and patented medicines for veterinary use. As a Category II medicine, Teva believes that this approach reflects the low risk potential for excessive pricing as patents on biosimilars do not confer a market advantage, pricing power, or price premium in a similar manner as patents on

generic medicines. As well, prices for patented biosimilars are negotiated through the pan-Canadian Pharmaceutical Alliance (pCPA) which has visibility to prices in other jurisdictions.

Teva would like to recommend that patented biosimilar medications share the same criteria as patented generic medicines (as found in section 89 of the Guidelines) to trigger an investigation to ensure the merit of the complaint and that the process is not misused to prevent expanded access to biosimilar medications in Canada.

Teva proposes:

Board Staff will commence an investigation into the price of a patented biosimilar drug if all of the following three conditions are met:

- A complaint has been received in respect of the patented biosimilar drug;
- The patentee of the patented biosimilar drug is the only company in Canada which is selling a biosimilar of the patented medicine derived through the metabolic activity of living organisms that obtain market authorization in Canada with a demonstrated similarity to a reference biologic drug [1]in Canada; and
- The patented biosimilar is not the subject of a pricing agreement with the pan-Canadian Pharmaceutical Alliance (pCPA) to which it is compliant. The onus of proving to Staff that a patented biosimilar is subject to, and compliant with, a pricing agreement with pCPA will rest with the patentee for that patented biosimilar.

These criteria have worked well for patented generic drugs to date and are contained in the new Guidelines. Teva believes that incorporating the current criteria, revised to include patented biosimilars, into the Guidelines will help to ensure that limited PMPRB investigative resources are not diverted.

Teva suggests that the PMPRB assess the merit of any complaint it receives regarding a specific patented biosimilar by adopting similar criteria as patented generics, as found in section 89 of the PMPRB Guidelines.

Price Tests Required for Patented Biosimilar Medicines Investigations

Teva is concerned that the price test for patented originator medicines will also be applied to patented biosimilar medications in the event of an investigation is initiated by the PMPRB. The international biosimilar policy framework is evolving rapidly and there are multiple pricing regulations that have been implemented globally with some countries encouraging robust biosimilar competition where others do not. Additionally, many biosimilar medications are in-licensed at the national level. A patentee may hold a license for the Canadian market but not have visibility into the pricing decisions made by another licensee in another country. As a result, obtaining accurate international price comparison for biosimilar drugs may be difficult, potentially inaccurate and may not be reflective of the nature of the biosimilar market in Canada

[1] Definition of biosimilar drug on page 14 (footnote 13), *PMPRB Guidelines 2020*

Therefore, Teva recommends in situations where a patented biosimilar medication is under investigation, the PMPRB should establish a separate price test that utilizes the Canadian price of the reference biologic drug and in other countries, as adjusted by CPI. However, in the event the price of the reference biologic drug is reduced in a predatory manner, Teva recommends that such actions should not impact the price of the biosimilar medication in Canada.

Teva appreciates the opportunity to provide this written brief and its recommendations to the House of Commons Standing Committee on Health as it studies the final PMPRB Guidelines. We hope that the Committee will consider the above recommendations as it studies the impact that the final PMPRB Guidelines will have on access to important treatments and therapies in Canada.

About Teva Canada Limited

Teva is a global leader in the pharmaceuticals market and has one of the broadest product portfolios in the industry, including innovative, generic, biologic, as well as, biosimilar medicines and as such, holds a unique, balanced position in the industry.

Teva is one of Canada's largest pharmaceutical company, manufacturing more than 350 generic prescription and over-the-counter product employing close to 1000 employees in Canada. With one out of every six generic prescriptions filled with a Teva product, Teva's generic portfolio saved Canada's healthcare system close to $4 billion in 2018.

As a leading specialty pharmaceuticals company, Teva is developing and manufacturing innovative products in the following therapeutic areas: pain, CNS, oncology and respiratory. At the heart of Teva's mission is a commitment to patients, through the development and manufacture of high-quality, safe and efficacious therapies that promote global good health and well-being.

Teva is a member of BIOTECanada, Biosimilars Canada, the Canadian Biosimilars Forum and the Canadian Generic Pharmaceutical Association (CGPA).