Canada Innovation

Montreal, October 18, 2016

Re: PMPRB Guidelines Modernization

Teva Canada Innovation and Teva Canada Limited, Canadian subsidiaries of Teva Pharmaceutical Industries Ltd. (collectively "Teva") makes this submission in respect of the PMPRB's Guidelines Discussion Paper of June, 2016 (the "Guidelines").

Teva is a global leader in the pharmaceuticals market and has one of the broadest product portfolios in the industry, including both innovative and generic medicines. As a leading specialty pharmaceuticals company, Teva is developing and manufacturing innovative products in the following areas: Pain, CNS, oncology, respiratory, and women's health. At the heart of Teva's mission is a commitment to patients, through the development and manufacturing of high-quality, safe and efficacious products that promote global good health, value of product to patients, and well-being.

Teva Canada Limited, Teva's generic division is one of Canada's largest pharmaceutical companies based in Ontario and Quebec. It is the 5th largest pharmaceutical company in Canada by gross sales. More than 75 million Teva prescriptions are filled in Canada annually; one out of every seven prescriptions for Canadian patients is for a Teva product. It is important to note that Teva's portfolio saves Canada's publically funded healthcare system more than $3 billion annually.

Teva appreciates the initiative undertaken by the PMPRB in conducting a consultation on the modernization of its Guidelines. The questions raised are very important to ensure optimal access to medicines for Canadians in a sustainable and affordable way. These questions need to be delicately addressed as PMPRB is only one actor in a complex and interconnected pricing, access and reimbursement environment.

Teva encourages any measure that maintains or improves the sustainability of the pharmaceutical industry in Canada, along with improving patients' health. It is therefore open to engage with Canadian stakeholders to modify the reference pricing systems to make them more sustainable, to invest in R&D, to prioritize quality and supply stability, and to encourage greater competition.

Context

The PMPRB, during its pricing analysis, reviews the average price of each strength of an individual dosage form of each patented medicine, with reference to the following five factors, as outlined at section 85 of the *Patent Act*:

a) the prices at which the medicine has been sold in the relevant market;
b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;

c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada
d) changes in the Consumer Price Index; and
e) any other factors that may be set out in regulations.

External reference pricing, or ("ERP"), as a price regulation tool, has significant shortfalls in terms of how it is applied and what it is intended to do. The underlying assumption of including ERP as a factor in determining whether pricing of a patented medicine is excessive is that the prices in the reference countries are transparent and otherwise appropriate. Moreover, prices are generally heterogeneous and do not lend themselves to a straight and simple comparison.

Policy makers in the EU are very concerned with the unintended consequences of ERP systems because of the access issues they create. This is important evidence to use to disprove and invalidate any attempts to remove the US price as a comparator. As the PMPRB reviews its mandate, Teva draws attention to the global policy analysis of the use of international reference pricing in other jurisdictions. Policy makers and payers, particularly in Europe, are all critical of external/internal referencing for creating delays in access, shortages and affecting affordability.

- This policy tool has been condemned by all the major international public health agencies including the WHO, the Organization for Economic Development (OECD) and the Pan American Health Organization (PAHO), for undermining initiatives to improve affordability and access to medicines. These organizations conclude that ERP leads to higher per capita prices, on a relative basis, charged in low income countries.
- It is documented that ERP is affecting the launch cycles of some products, leading to delays, shortages and access issues. Prices obtained in ERP appear to be rather influenced by the rules of the system itself, without necessarily paying attention to factors intrinsic to the health care system in which it operates. Furthermore, ERP is exposed to exchange rate volatility when referenced prices are denominated in local currencies. *(European Commission study on enhanced cross-country coordination in the area of pharmaceutical product pricing-Final report December 2015).*

    - "ERP is likely to have a negative impact on access since it incentivizes the pharmaceutical industry to first launch in higher-priced countries and delay, or refrain from entering the market in lower-priced countries" *European Commission*
    - "ERP as a policy contributes to access and affordability problems." *Organization for Economic Coordination and Development*
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- In the 2015 annual report, the PMPRB reports that:
    - Prices of existing patented drug products were stable, while the Consumer Price Index rose by 1.1%. The PMPRB's Guidelines allow the price of a patented drug product to rise by no more than the CPI over any three-year period. (The Guidelines also impose a cap on year-over-year price increases equal to one and one-half times the current year rate of CPI inflation.) This effectively establishes CPI inflation as an upper bound on the amount by which individual prices may rise over any three-year period
    - In 2015, the United States prices rose at an average rate of 9.1% while prices in the United Kingdom were essentially flat, and prices in France, Italy, Switzerland, Sweden and Germany declined. These results are consistent with a long-term tendency for patented medicine prices to slowly fall over time in most comparable countries

- Generic drugs accounted for 70% of all prescription drugs in Canada in 2013 and it had the third-highest proportion of annual prescription generic drug use relative to the PMPRB7. Average generic drug prices in Canada declined from 63% to 36% of their brand-name counterparts between 2010 and 2014.
- The definition of R&D spending is nearly 30 years old and does not accurately capture the significant investments made by the pharmaceutical industry in Canada, which on the other hand continues to be negatively impacted by a challenging access, regulatory and intellectual property environment.

Feedback

Teva is of the opinion that the current PMPRB assessment methods used to establish drug price ceilings of patented medicines throughout their lifecycle do not take into consideration the value of the product to patients' health and to society, nor the increase in costs of goods over time and overall costs of doing business.

In an effort to fully assess the value of introduction of new drugs to the Canadian market additional metrics such as Real World Data (RWD) could be included. RWD outweighs direct drug costs by generation of savings for the healthcare system, workplace, society etc. allowing the PMPRB to fully understand the impact that a new drug could have on the overall system. RWD could also apply when the PMPRB evaluates the level of therapeutic improvement made by a new drug.

In Teva's view, it is also important to compare to countries with similar economic conditions and health care systems; exclude countries that suffer from extreme economic hardship; and limit the number of reference markets. Moreover, international pricing is only one of the metrics used to control prices and should not be assessed independently of the other measures such as the therapeutic class comparison, lower-than-CPI annual allowable price increases and the widespread comprehensive S.85 regulation factors which all contribute to further control prices.

We disagree with the need to revise the price ceiling again with the passage of time, given the numerous measures to control the price of patented drug products at introduction to the Canadian market and the strict way price increases are limited throughout their lifecycle, In addition, price variation between provinces/territories and payer types should also not be considered a form of excessive pricing since it is often different customers that demand lower costs.

All provinces & territories participate in the pan-Canadian Pharmaceutical Alliance (pCPA) and tiered pricing measures for generics have also been put in place ensuring price stability and cost containment to all payers across the country.

Finally, since the PMPRB definition of R&D spending is nearly 30 years old it does not accurately capture the significant investments made by the pharmaceutical industry in Canada. Teva strongly recommends that R&D investment not be the taken independently as a metric to evaluate the footprint of a company in Canada. Other important factors such as innovation investments, job creation, local manufacturing

footprint etc. should also be taken into consideration when evaluating a manufacturer's commitment to the Canadian healthcare system.

In conclusion, Teva recommends that the PMPRB does not implement any additional modifications to its guidelines until the consultation process is completed, and all fairness to the patentees, the changes made to the Guidelines as a result of this consultation process should apply exclusively to patented drug products introduced subsequent to the changes. The introduction of additional price limits will put significant pressures on pharmaceutical manufacturers and will limit their ability to operate in Canada, introduce new products to the market and improve the lives of Canadians. Teva urges the PMPRB to assess the impact on patients' access to new medication before making changes to the current guidelines.

It is important to note that in the case of generics, the Pan-Canadian Pharmaceutical Alliance (pCPA) has implemented since 2013 the 18% pricing rule on 18 products and instaured the tiered pricing framework, whereby generic prices are set and then reduced over time in a predictable fashion as additional suppliers enter the market. Massive savings have been achieved through steep price cuts of the 18% products. Based on data from IMS, over the course of the framework agreement, Canadian payers will save an additional $1.6 billion.

Teva Canada specific recommendations:

- Teva opposes international price referencing for both brand and generic products as it affects access to new medicines and leads to drug shortages.
- The US price as a comparator should not be removed, otherwise Canada could face the same access issues that they are experiencing in Europe.
- Teva requires clarity that PMPRB requirements will not apply to the sale of generic drugs, and not apply to Patented Generic Drugs.

Teva would be pleased to collaborate with PMPRB and all interested stakeholders to improve the sustainability of the pharmaceutical industry and patients' health in an affordable way.

Sincerely,

Ori Warshavsky
Senior Director Market Access