



Pharmaceuticals

Montreal, June 28, 2017

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Re: Teva Canada Innovation and Teva Canada Limited Response to Health Canada Proposed Amendments to the Patented Medicines Regulations

Teva Canada Innovation and Teva Canada Limited, the Canadian subsidiaries of Teva Pharmaceutical Industries Ltd. (collectively "Teva") make this submission in respect of the Health Canada consultation on Proposed Amendments to the Patented Medicines Price Review Board (PMPRB) Regulations of June 2017 (the "Modernization of 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. Teva is Canada's largest pharmaceutical company by volume and is the 3rd largest pharmaceutical company in Canada by gross sales. More than 120 million Teva prescriptions are filled in Canada annually; one out of every five prescriptions for Canadian patients is for a Teva product. It is important to note that Teva's generic portfolio saves Canada's publically funded healthcare system more than \$3 billion annually.

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 appreciates the initiative undertaken by Health Canada in conducting a consultation to provide the PMPRB with more relevant and effective regulatory measures to better meet health care system needs and protect Canadians from excessive prices for patented drugs.

As previously stated in its position paper on *Rethinking the Guidelines* dated October 31, 2016, Teva encourages any measure that maintains or improves the sustainability of the pharmaceutical industry in Canada, along with improving patients' health.

The questions raised by Health Canada are 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.

As a member of BIOTECanada, Biosimilars Canada and the Canadian Generic Pharmaceutical Association, Teva is in agreement with, and fully supports, the responses provided by these industry associations.

As such Teva encourages Health Canada to continue to collaborate closely with Canadian stakeholders to modify the reference pricing systems to make them more sustainable, to optimize investments in R&D, to ensure quality and supply stability, to encourage greater competition and to ensure that Canadians will continue to have access to innovative therapies.

Context and feedback

Teva wishes hereby to respond to the consultation initiated by Health Canada that proposes five important changes to the PMPRB regulations that would involve the:

1. Introducing new, economics-based price regulation factors;
2. Updating the list of countries used for price comparison;
3. Formalization of a move to a complaints-based system of oversight for patented generic drug products;
4. setting out the pricing information required of patentees to enable the PMPRB to operationalize the new pricing factors; and
5. requiring of patentees to provide the PMPRB with third party information related to rebates and discounts on domestic prices.

1. Introducing new, economics -based price regulation factors

Canada is the only country with two parallel and distinct processes designed to arrive at a price recommendation– PMPRB (national) and the Canadian Agency for Drugs and Technologies in Health (CADTH), the Institut national d'excellence en santé et services sociaux (INESSS) and the pan-Canadian Pharmaceutical Alliance (pCPA) (provincially).

It is Teva's position that the proposal to require the PMPRB to specifically consider pharmacoeconomic evaluation in a price review and to introduce fixed cost-per-QALY thresholds would create redundancy with CADTH and INESSS who already have state of the art processes and measures to assess these thresholds. Additionally, the redundancy with CADTH and INESSS may mislead the PMPRB as well as generate risks of inconsistencies and conflict between federal, provincial and FPT agencies. To this day, Teva is not aware of any country that has attempted to establish a maximum non-excessive price for a medicine based on Health Technology Assessment (HTA). Furthermore, in all of the countries that use

HTAs, only two apply a fixed cost-per-QALY threshold but only to provide advice to be used in subsequent negotiation on price and coverage criteria. Teva supports the use of HTA in assessing the relative clinical effectiveness, costs and benefits of a new therapy. However, considering budget impact via the PMPRB channel would unnecessarily overlap and duplicate the work done to manage affordability, as well as providing access by the existing key provincial payer and HTA bodies, namely CADTH, INESSS and the pCPA. PMPRB resources and efforts would not be optimized by addressing the same issues already handled by these bodies.

2. Updating the list of countries used for price comparison

Although Teva believes that the methodology undertaken by the PMPRB has worked well to ensure that Canadians have access to the medicines they need, it is open to work in concert with the different stakeholders to review the basket of countries. Since this is the first time in 30 years that a review of the basket of countries is done, Teva, in line with BIOTECCanada, recommends that a criteria for country selection be determined before selecting the countries.

The country selection criteria should be aligned with Canadian provincial healthcare systems/payers and economic development policy goals. Teva is aligned with the recommendation made by BIOTECCanada to add the following criteria:

- Innovation policies
- Policies to promote and improve health outcomes
- Trading relationship with Canada through established agreements such as NAFTA and CETA
- Geographic proximity

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. It is recognized in the literature that international reference price methodologies have led to drug shortages in Europe. In addition, as the United States are Canada's most important trading partner, removing it from the basket of reference countries may refrain the industry from bringing innovative therapies to Canada.

3. Formalization of a move to a complaints-based system of oversight for patented generic drug products

Consistent to the positions of BIOTECCanada, Biosimilars Canada and the Canadian Generic Pharmaceutical Association, Teva recommends that the proposal to reduce the regulatory burden for patented generic drugs should be extended to all multiple source drugs as well as biosimilars in order to bring greater consistency in the price regulation in these various markets.

4. Setting out the pricing information required of patentees to enable the PMPRB to operationalize the new pricing factors

Information on cost-effectiveness and budget impact is already provided to CADTH/INESSS and pCPA by patentees. They serve to inform the pricing and coverage negotiations as per specific requirements to meet their needs and using tools precisely designed to achieve these objectives and not to set maximum prices. Teva firmly believes that the introduction of such a measure by the PMPRB would engender additional unnecessary regulatory burden for patentees and even more importantly would likely mislead the PMPRB pricing assessments.

5. Requiring of patentees to provide the PMPRB with third party information related to rebates and discounts on domestic prices

Teva also supports the view of BIOTECanada that if patentees are to report third-party rebates to PMPRB, provinces and territories risk losing some of the value they receive from this system and that the pCPA already acts on their behalf to ensure that their buying power is optimally leveraged.

In recent years, private payers have also implemented a variety of measures to allow for the negotiation of confidential rebates and conditions in selected markets to ensure cost containment and the sustainability of private drug benefit plans.

Teva also recommends that non-excessive prices of existing medicines be grandfathered and appropriate transition measures be considered for new medicines.

Teva looks forward to collaborate closely with the trade associations, the PMPRB and other interested stakeholders on the implementation of the guidelines to better meet health care system needs and improve the sustainability of the pharmaceutical industry and patients' health in an affordable way.

Sincerely,

/s/ Ori Warshavsky

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/s/ Penny S. Levin, M.S.

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