A case study of the proposed amendments to patented medicine price review regulations in Canada

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BACKGROUND

Drug expenditures are increasing worldwide, with the entrance of high-cost specialty drugs to market being an important contributing factor. In response to growing concerns about drugs costs and the sustainability of healthcare systems, attention has turned to reducing drug prices to manage expenditures in Canada.

The Patented Medicine Prices Review Board (PMPRB) is engaged in an ongoing process to '*modernize*' the regulations governing patented medicine prices in Canada. A significant addition in these reforms is the use of pharmacoeconomic factors (i.e. a cost-utility threshold) to set price ceilings of new medicines. This new price control factor may have a disproportionately negative impact on orphan drugs.

METHODS

The objective of this policy analysis was to estimate the impact of the proposed PMPRB amendments on orphan drug prices. New Active Substances approved by Health Canada from 2016-2018 with an Orphan Drug Designation by the US Food and Drug Administration were selected for analysis. In the absence of official Guidelines from PMPRB implementing this test, we followed the methods detailed by PMPRB and Health Canada in the Regulatory Impact Analysis Statement published August 21, 2019. 'Pharmacoeconomic Value' (PV) ceiling prices were calculated for orphan drugs approved from 2016-2018 using best available data from published CADTH reviews, where available. **Willingness-to-pay (WTP) thresholds of $150,000**, **$50,000**, **and $35,000 per quality-adjusted life year (QALY)** were used.

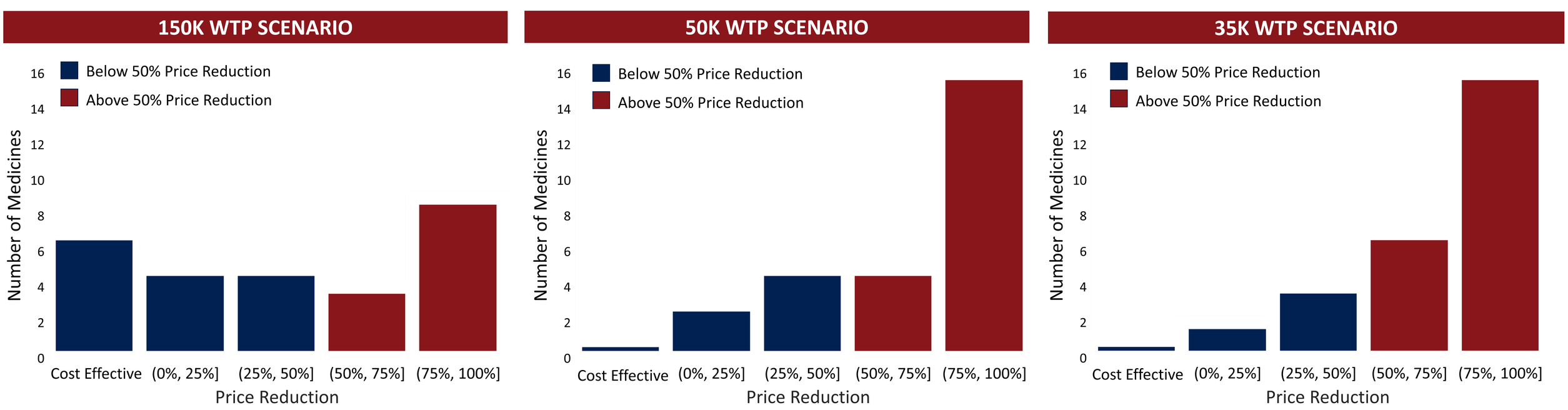
RESULTS

Of the 44 orphan drugs approved by Health Canada from 2016-2018, 31 had published CADTH reviews. 30 of these reviews could be utilized to calculate a PV price. Only 1 product was considered cost-effective at the submitted price under all WTP thresholds. For the remaining 29 products, PMRPB would require average **price reductions of 45%, 68%, and 74% using the three specified WTP thresholds.** 27% of orphan drugs sampled (8 drugs) would need to reduce prices by more than 80% under all WTP threshold scenarios.

DISCUSSION

There exists a substantial gap between the original price and the potential price under the proposed PMPRB regulatory changes. This is primarily due to the uncertainty inherent in conducting cost-utility analyses for orphan drug products. These results raise important questions: Will future global orphan drugs launch in Canada? Will current orphan drugs remain economically viable to remain in Canada?

These reforms could delay or put future launches of orphan drugs at risk.



References
Canada Gazette Part II, Volume 153, Number 17

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Conflict of interest
Brittany Humphries is an Associate, HTA and Health Economics at PDCI Market Access and a PhD student in the Department of Health Research Methods, Evidence and Impact at McMaster University.

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