# New Patented Medicine Regulations in Canada: Updated Case Study. (EN/FR)

## Description

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### Abstract

The Canadian federal government is imposing sweeping changes for the price review guidelines of the Patented Medicine Prices Review Board (PMPRB), the quasi-judicial agency whose role is to set ceiling prices for patented medicines sold in Canada. The revisions are due to come into effect in July 2020. The objective of this article is to examine the planned changes in the draft PMPRB guidelines and to apply them to a hypothetical case study of the decision-making process that the pharmaceutical manufacturer of a new medication for a rare disorder is likely to go through when assessing whether to seek regulatory approval in Canada under the new regulations. The case study demonstrates that the changes in the PMPRB's draft guidelines will create a high level of uncertainty among manufacturers of drugs for rare disorders due the major price reductions that will be forced upon them. Manufacturers will be faced with a decision of whether to delay the introduction of a new product into Canada or not launch it at all. The high level of uncertainty being generated by the changes in the PMPRB's draft guidelines will imperil the launch of all new medicines in Canada because it will significantly decrease the attractiveness of the country as a jurisdiction in which pharmaceutical companies seek regulatory approval for new products. The uncertainty will especially impact manufacturers of new specialty high-cost medications, but it will not be limited to them. The result will be long delays in patient access to important new therapies. In some cases, manufacturers may not seek regulatory approval in Canada if they decide that the market is not worth the risk of failing to secure a reasonable price in both Canada and other jurisdictions. This would eliminate access for all patients, even those with private insurance. Access to drugs for rare disorders with private and (especially) public insurance coverage is already difficult, if not impossible, to obtain for many Canadian patients. The changes in the PMPRB's regulations will make the situation much worse.

### References

1. Health Canada (2017). Remarks from the Honourable Jane Philpott, Minister of Health, to the Economic Club of Canada – May 16, 2017. Ottawa: Government of Canada. https://www.canada.ca/en/health-canada/news/2017/05/economic_club_ofcanada-may162017.html.

2. PMPRB (2018). Mandate and jurisdiction. Ottawa: Government of Canada. http://pmprb-cepmb.gc.ca/about-us/mandate-and-jurisdiction.

3. Rawson NSB (2018). New patented medicine regulations in Canada: case study of a manufacturer's decision-making about regulatory submission for a rare disorder treatment. Can Health Policy. Toronto:

Canadian Health Policy Institute. https://fko.wzo.mybluehost.me/products/new-patented-medicine-regulations-in-canada–case-study-of-a-manufacturer—s-decisionmaking.html.

4. PMPRB (2019). PMPRB Guidelines 2019. Ottawa: Government of Canada. https://www.canada.ca/content/dam/pmprbcepmb/documents/consultations/draft-guidelines/draft-guidelines-en.pdf.

5. PMPRB (2018). Guidance document on changes to the Guidelines. Ottawa: Government of Canada. http://www.pmprbcepmb.gc.ca/view.asp?ccid=1376&lang=en.

6. Government of Canada (2017). Regulations amending the Patented Medicines Regulations: regulatory impact analysis statement. Canada Gazette I: 151. http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html.

7. Rawson NSB (2018). Regulatory, reimbursement and pricing barriers to accessing drugs for rare disorders in Canada. Vancouver: Fraser Institute.

8. Richter T, Janoudi G, Amegatse W, Nester-Parr S (2018). Characteristics of drugs for ultra-rare diseases versus drugs for other rare diseases in HTA submissions made to the CADTH CDR. Orphanet J Rare Dis 13: 15.

9. Pettitt D, Raza S, Naughton B, Roscoe A, Ramakrishnan A, Ali A, Davies B, Dopson S, Hollander G, Smith JA, Brindley DA (2016). The limitations of QALY: a literature review. J Stem Cell Res Ther 6: 4.

10. Canadian Diabetes Association (2011). Diabetes: Canada at the tipping point. Toronto: Canadian Diabetes Association. https://www.diabetes.ca/CDA/media/documents/publications-and-newsletters/advocacy-reports/canada-at-the-tipping-point-english.pdf.