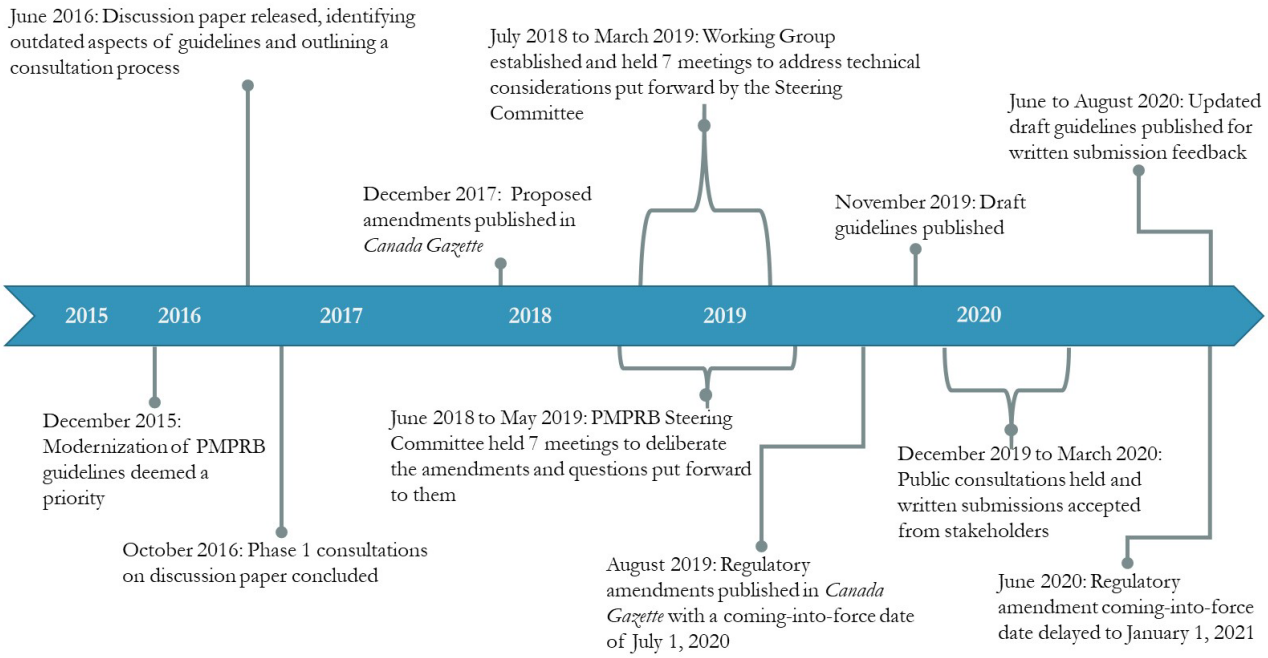
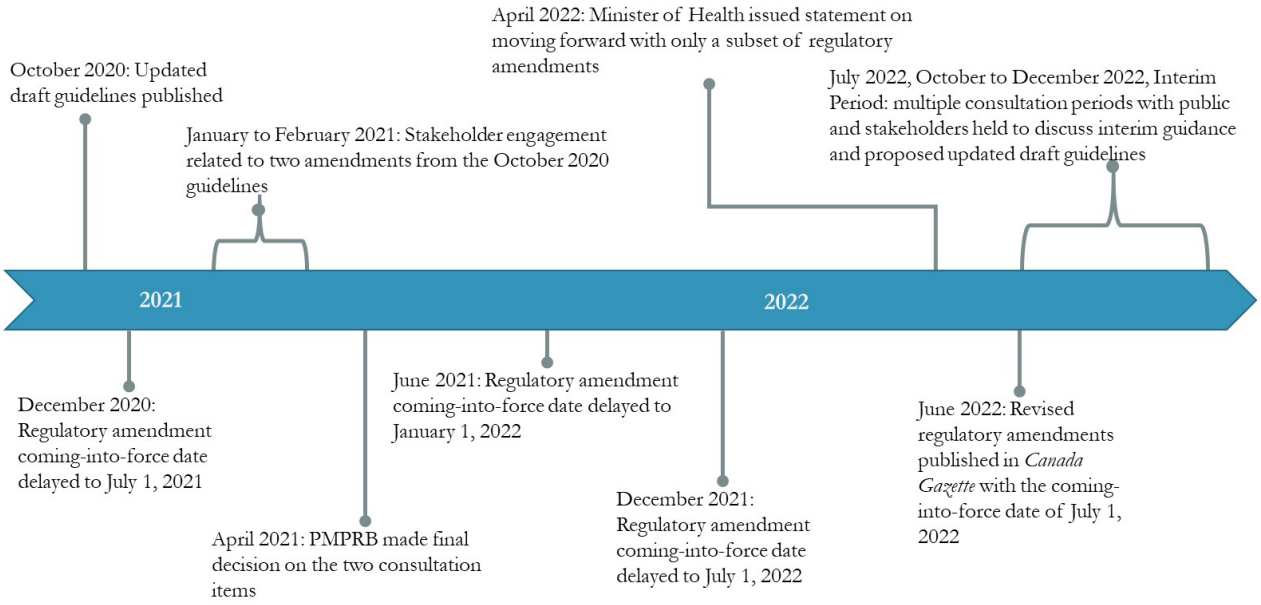
Appendix 1. The timeline and process of PMPRB regulatory amendments

The following Figures indicate the major milestones in the PMPRB regulatory amendment process. Specifically, the modernization of PMPRB guidelines was first identified as a strategic objective in PMPRB's Strategic Plan 2015-2018.[1,2] PMPRB released their guidelines modernization discussion paper in June 2016[3] and initiated the stakeholder consultation until October 31, 2016,[4] followed by the broad consultation conducted by Health Canada on the proposed amendments from May 16, 2017 to June 28, 2017[5] and the formal publication of the proposed amendments in the Canada Gazette on December 2, 2017.[6] A series of consultations were further conducted including the deliberations of a multi-stakeholder Steering Committee on Modernization of Price Review Process Guidelines who met and provided feedback from June 2018 to May 2019 and the associated recommendations of a Working Group who met and provided feedback from July 2018 to March 2019.[7–9] New regulatory amendments were approved by the Federal Minister of Health and published in the Canada Gazette on August 21, 2019 with a coming-into-force date of July 1, 2020.[10] The corresponding draft guidelines were then published on November 21, 2019,[11] revised on June 19, 2020,[12] and updated on October 23, 2020.[13] Intensive and far reaching public consultations on the draft guidelines occurred during this period.[12] Further consultation on the definition of Gap medicines and the timeline for compliance in the guidelines was conducted from January 15 to February 15, 2021 and final decision was made on April 16, 2021.[14]

However, the coming-into-force date of the amended regulations and guidelines has been delayed four times by 6 months to July 1, 2022 due to the COVID-19 pandemic, feedback from consultations, and successful challenges on the net of all price adjustments disclosure requirement in the Federal Court by an association representing Canada's brand name pharmaceutical industry, Innovative Medicines Canada.[1,15–18] On April 14, 2022, the Federal Minister of Health decided to proceed only with the amendments related to changing new basket of comparator countries but not those related to the requirements to file information net of all price adjustments and to new price regulatory factors.[18,19] The PMPRB then released its updated guidelines accordingly on October 6, 2022 and launched a 60-day consultation period until December 5, 2022.[20] The updated guidelines has not been finalized or implemented. During the interim period between the coming-into-force of the new patented medicines regulations and the final publication of the corresponding guidelines, the Interim Guidance issued by PMPRB on August 18, 2022 will remain in place.[19,20]





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