CANADA

Recent and planned developments in pharmaceutical policies in 2023

CHANGES IN PRICING

National Price Ceilings for Patented Medicines

On July 1, 2022 the Government of Canada announced that it will proceed with the implementation of a new basket of comparator countries. The new basket includes: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden and the United Kingdom (the "PMPRB11").

In the fall of 2022, the PMPRB consulted on a new set of guidelines to operationalize these regulatory amendments. Following feedback from stakeholders, the PMPRB is considering next steps. In the meantime, the price review process continues under a set of Interim Guidelines established in the summer of 2022, until such time as new guidelines are finalized.

On February 1, 2023, the Government of Canada announced the appointment of a new Chairperson for the PMPRB, Thomas J. Digby, effective January 27, 2023.

Federal, Provincial and Territorial Price Negotiations

Canada's federal, provincial and territorial governments collectively negotiate the prices of brand name and generic drugs as part of the pan-Canadian Pharmaceutical Alliance (pCPA). As of February 2023, the pCPA has completed 579 negotiations.

The pCPA Governing Council released the pCPA 2022-2024 Strategic Plan, following the in-depth evaluation of the pCPA's current and prospective future roles. Since then, a stand-alone pCPA corporation has been created, which was a key recommendation of this new plan.

The pCPA and the Canadian Generic Pharmaceutical Association (CGPA) are currently negotiating a new multiyear agreement on access and pricing for generic pharmaceuticals. It is the third time the two parties are engaging in negotiations, after previous agreements were signed in 2014 and 2018. The current deal expires March 31, 2023.

CHANGES IN REIMBURSEMENT

Health Technology Assessment

In 2022, the Canadian Agency for Drugs and Technologies in Health (CADTH) released its 2022-2025 strategic plan designed to advance its leadership in evidence-informed health care and reinforce its status as the hub of health technology assessment in Canada.

The CADTH Post-Market Drug Evaluation (PMDE) Program launched on September 1, 2022. The program provides evidence-based responses to questions and concerns raised by federal, provincial, and territorial decision-makers about drugs approved for use in Canada.

In November 2022, CADTH launched a consultation on Real-World Evidence (RWE) Reporting Guidance. Regulators and health technology assessment (HTA) agencies have recognized the need to integrate high-quality RWE to help address evidence gaps for decision-making. The consultation wrapped up on January 6, 2023, and CADTH will host a webinar in March 2023 to summarize and share the type of feedback provided through the consultation process.

Federal, Provincial and Territorial Public Payers

Since 2020, a number of Canadian provinces have instituted policies reimbursing only biosimilar versions of approved indications for adult patients. In December 2022, Ontario announced that beginning March 31, 2023, recipients who are on an originator biologic will begin to transition to a Health Canada approved biosimilar version of the drug at no cost. The province joins Alberta, British Columbia, New Brunswick, Nova Scotia, Quebec, Northwest Territories in establishing such policies.

Federal Initiatives

Drug access and affordability

Prescription drug costs are not covered by Medicare in Canada but are covered by a blend of public and private drug plans, as well as out-of-pocket payers. Each of the 10 Canadian provinces and 3 territories provide varying levels of coverage, with the most comprehensive coverage generally focused on more vulnerable populations, e.g., social assistance recipients, seniors, households with high drug costs relative to income. The federal government provides drug coverage to registered First Nations and recognized Inuit populations, federal inmates, Canadian forces, veterans, and refugees.

The Government is taking steps towards a national pharmacare program. Progress to date includes:

- Working with the Province of Prince Edward Island to improve access to medications for Island residents and inform the advancement of national universal pharmacare;
- Receiving advice on the development of a potential pan-Canadian formulary that would include a broad range of safe, effective, evidence-based drugs and related products to meet the health care needs of Canada's diverse population.

In 2023, the Government has committed to:

- Continuing to work with provinces, territories, and other stakeholders to conduct analysis and develop options to advance a Canadian Drug Agency;
- Launching a national strategy for drugs for rare diseases to help Canadians get better access to the effective treatments they need; and
- Tabling a Canada Pharmacare bill as outlined in the 2022 Federal Budget.

Drug Regulation

The Government of Canada is proposing amendments to its Food and Drug Regulations to add agility, modernize and increase emphasis on pharmaceutical life cycles. Proposed areas of amendments include expanded scope for terms and conditions, rolling reviews, and modernization of biologic requirements.

SPECIAL TOPIC: Developing and implementing pharmaceutical policies in view of the current challenges

Inflation and Price Increases

The Consumer Price Index rose 6.8% in 2022, up from 3.4% in 2021 and 0.7% in 2020.

In reviewing the prices of patented medicines in Canada, the PMPRB takes into account the changes in the CPI and in the past has allowed patentees to take price increases in accordance with the PMPRB CPI-Adjustment Factors, provided that the Canadian price did not exceed the highest price in the comparator countries. Under the Interim Guidelines, increases in list price trigger an investigation into the price of a medicine.

According to the CPI methodology, price increases are capped by the lower of cumulative CPI over a maximum of the last three years and 1.5 times the increase in CPI of the most recent year. To provide manufactures with predictability on the allowable price increase, a two-year lag is used (e.g., 2018 CPI is used for 2020).

Drug Shortages

The Food and Drug Regulations (FDR) contain provisions that help to safeguard the Canadian drug supply. Since March 2017, manufacturers have been mandated to report actual and anticipated drug shortages and discontinuations to the third-party website Drug Shortages Canada.

In addition, the FDR create a framework for the exceptional importation and sale of drugs that are not otherwise licensed for sale in Canada. This framework developed initially to respond to shortage caused by the COVID-19 pandemic is intended to help address critical drug shortages. The drugs identified for import are those that are not fully compliant with Canadian regulations but are manufactured according to similar standards.

Established in November 2022, the Drug Shortages Task Force is leading the development of a strategy considering medium and long-term actions that supports shortage prevention and mitigation measures.

In September 2022, the PMPRB released a study on Drug Shortages in Canada under the National Prescription Drug Utilization Information System.