Canada

Recent and planned developments in pharmaceutical policies

2015 Pre-launch activities: horizon scanning and forecasting

DEVELOPMENTS

Changes in pricing

Canadian patented drug prices are rising relative to their international comparators

Despite this change, patented drug prices in Canada still fall within the range of prices of the PMPRB comparator countries. In 2013, Canadian prices were just below the median of the prices in the seven comparator countries. Prices in France, the United Kingdom, Italy, Sweden and Switzerland were lower than Canadian prices, while those in Germany were slightly higher. As in previous years, prices reported for the United States were appreciably higher than in Canada.

The annual rate of growth in prescription drug spending in Canada has gradually declined over the last decade

This decline, which reached a new low of 1.2% in 2012, is the net result of several key opposing factors. The PMPRB is launching a new annual publication, the NPDUIS CompassRx report, which will shed light on the drivers behind the growth in prescription drug spending in Canadian public plans.

The 2012/13 edition of the CompassRx report identifies generic substitution and generic price reductions as key factors putting a downward pressure on drug expenditures, while the growth in the use of high-cost drugs, e.g., biologics, put an upward pressure on overall costs. Subsequent editions of this report will help to predict whether this trend will continue and will assist policy-makers and researchers in anticipating future cost pressures and expenditure levels.

Ratification of the Comprehensive Economic Trade Agreement will impact the Canadian Patent Act

Canada has reached a final text on the Comprehensive Economic and Trade Agreement (CETA) with the European Union. The upcoming implementation of CETA will require changes to the Patent Act to provide pharmaceutical patentees with up to two additional years of market exclusivity. These changes may precipitate a discussion as to whether the current balance between intellectual property rights and consumer protection is working as originally intended.

Canadian provinces and territories are strengthening collaborative initiatives to reduce the price of brand-name and generic drugs

- *The **pan-Canadian Pharmaceutical Alliance (pCPA)** was recently established as a forum for the provinces and territories to achieve greater value for brand-name and generic drugs for their publicly funded drug programs. The pCPA superseded the two previous negotiating initiatives: the **Pan-Canadian Pricing Alliance** (for brand name products) and the **Generic Value Price Initiative**. Through pCPA negotiations, 49 brand-name drugs are now subject to confidential Product Listing Agreements, with negotiations for an additional 18 drugs currently underway. Quebec, the only province that has not participated so far, has also signalled a desire to join the pCPA.*

- *In January 2013, all of the provinces and territories (except Quebec) used their combined purchasing power to lower the prices of the most common generic drugs sold in Canada. To date, the prices of 10 of the most common generics have been reduced to 18% of the brand name price, with four additional generics scheduled to be reduced to this level effective April 2015 and another four by April 1, 2016. The PMPRB's analytical work contributed to these efforts.*

- *In addition, the **Pan-Canadian Generic Pricing Framework**, which came into effect on April 1, 2014, provides a progressive tiered approach to price reductions for generics based on the number of drug manufacturers: from 75% to 25 % of the brand-name price.*

Changes in reimbursement

Each Canadian province or territory decides which drugs should be reimbursed under its public drug plan programs. Most jurisdictions maintain a formulary listing of drugs and prices. The Common Drug Review (CDR) at the Canadian Agency for Drugs and Technologies in Health aids in the decision-making process. The CDR conducts reviews of the clinical, cost-effectiveness, and patient evidence for drugs and provides formulary listing recommendations to Canada's publicly funded drug plans (except Quebec).

Other changes

- The Canadian Agency for Drugs and Technologies in Health (CADTH) is updating its previous (2014) Therapeutic Review for the treatment of chronic hepatitis C virus infection, examining the clinical and economic impact of new and existing drugs.

- Health Canada is developing an Orphan Drug Framework to provide a significant benefit to Canadians with rare diseases and spur innovation and research into new treatments for rare diseases. This framework will facilitate clinical trials and approval of rare disease drugs at the same time it happens in the USA and Europe. The framework has passed the legislature in Canada and is awaiting final approval.

- The Government of Canada has introduced new legislation called the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law), which will allow Health Canada to recall a drug already on the market and impose fines for promoters of unsafe products.

TOPIC

Pre-launch pharmaceutical policies: Horizon scanning and forecasts

- The Canadian Network for Environmental Scanning in Health (CNESH) was established in 2011 to identify and share information on new and emerging health technologies. The network is currently identifying top game-changing health technologies that have the potential to transform the delivery of health care through their impact on clinical effectiveness, patient survival, quality of life, patient safety, or costs to the health care system.

- Given the ongoing challenges related to high-cost medicines, the PMPRB is undertaking a number of analytical studies that monitor the international prices and utilization of pipeline drugs and new drug launches, including orphan drugs.