



Canada

Recent and planned developments in pharmaceutical policies 2017

Special topic: Hospital Medicines

RECENT DEVELOPMENTS

Since 2010, Canada's provincial and territorial governments have come together through the pan-Canadian Pharmaceutical Alliance (**pCPA**) initiative to collectively negotiate the prices of brand name and generic drugs as a way to achieve greater value for publicly funded drug programs. In January 2016, the federal government formally joined the **pCPA** initiative.

As of September 2017, the **pCPA** has completed 170 negotiations for new brand name drugs and reduced the price of the 18 most commonly prescribed generic drugs to 18% of the brand price. Effective April 2017, the **pCPA** generics initiative further reduced the prices of six generics to 15% of the brand reference products.

Further to a price agreement reached by the **pCPA** in February 2017 with the manufacturers of six hepatitis C drugs, Canadian public drug plans will begin covering these drugs for all hepatitis C patients, regardless of genotype or level of liver fibrosis, starting in 2018.

In April 2016, the **pCPA** issued guidance to manufacturers on how it will approach price negotiations for the reimbursement of biosimilars, following Health Canada's approval of a number of these drugs, including infliximab, filgrastim, insulin glargine and etanercept. Principles contained in the guidance include:

- All biosimilar and reference biologic manufacturer proposals will only be considered through the national **pCPA** negotiation process rather than individual or selected jurisdictions.
- The introduction of a biosimilar must provide a reduction in the drug's transparent price to benefit all Canadians.
- Proposals from reference biologic manufacturers will only be considered if they provide at least similar listing value overall compared to the biosimilar, and must include similar or better transparent price reductions if equivalent status is sought.

In May 2017, as part of the Government of Canada's commitment to affordability, accessibility & appropriate use of prescription drugs, then Minister of Health, Jane Philpott, announced plans to amend Canada's Patented Medicine regulations to equip the **PMPRB** with more effective regulatory tools to better protect Canadians from excessive prices for patented drugs. The proposed changes were released as part of a discussion paper over May and June. Proposals include the addition of 3 additional factors that the Board can use to assess the excessiveness of a drug's price. If approved, the 3 new factors will include pharmacoeconomic measures, market size and GDP. The official regulatory process towards their approval begins at the end of November. The **PMPRB** will begin consultations on how to implement the new factors over the winter.

In April 2016, The Canadian Agency for Drugs and Technologies (**CADTH**) announced it would no longer accept confidential submitted prices for the purpose of conducting its economic evaluations of new drugs. The submitted price will be disclosed in all applicable reports. In March 2017, **CADTH** updated its Guidelines for the Economic Evaluation of Health Technologies. Company submissions should now include cost-utility analyses or a justification for their absence. Quebec receives advice from the Institut National d'Excellence en Santé et en Services Sociaux (**INESSS**), and the two bodies are working together to better align the timing and recommendation wording.

The Canadian Association of Provincial Cancer Agencies (**CAPCA**) has launched the pan-Canadian Cancer Drug Funding Sustainability Initiative to strengthen how decisions are made to fund cancer treatments, with plans to more effectively consider clinical, operational and implementation issues.

In October 2016, Canada and Europe signed off on the Comprehensive Economic and Trade Agreement (**CETA**). The **CETA** implementation bill (Bill C-30), which includes amendments to Canada's Patent Act to extend pharmaceutical patents by up to two years, was introduced into Canadian Parliament on October 31, 2016. **CETA** came into effect September 21, 2017.

PENDING DEVELOPMENTS

In Budget 2017, the federal government committed to invest \$140.3 million over five years to improve access to pharmaceuticals, lower drug prices and support appropriate prescribing. This funding is earmarked for **Health Canada**, **CADTH** and the **PMPRB**. Details on how the funding will be spent to advance this commitment have not yet been announced. Budget 2017 also committed \$950 million over five years towards the development of innovation superclusters, including in the life and biosciences sector.

In December 2016, the federal government announced that it would spend an additional \$65 million over five years for national measures to respond to the opioid crisis and implement the government's Opioid Action Plan. In addition, the federal government will provide \$10 million in urgent support to British Columbia to assist with its response to the overwhelming effects of the emergency in that province. Canadian public drug plans are consulting on and implementing policies focused on opioids, including the delisting of a range of high-strength opioids from their formularies (e.g. Ontario).

In September 2016, the House of Commons Standing Committee on Health asked the Parliamentary Budget Officer (**PBO**) to provide a cost estimate of implementing a national Pharmacare program. The Committee provided the program's framework, including the inclusive list of drugs to be covered by Pharmacare based on Quebec's formulary, eligibility requirements, co-payment levels, and eligibility requirements for co-payment exemptions. The **PBO** released its findings in September 2017. After taking into account the costs currently born by various payers across the country and expenditures already paid by the federal government, the net cost of a national pharmacare program was estimated to be approximately \$19B, with saving being realized in the cost of drugs and in out of pocket costs to beneficiaries.

The process to rewrite the North American Free Trade Agreement began August 16, 2017. Five rounds of negotiation are planned, with the final talks expected in early December. A number of topics are expected to affect health related issues, such as period of patent life and harmonization of standards.



BACKGROUND

In Canada, pharmaceutical pricing and reimbursement is a shared jurisdictional responsibility between the federal, provincial and territorial governments. At the federal level, Health Canada reviews new drugs for safety, efficacy and quality and the Patented Medicine Prices Review Board (PMPRB) sets their ceiling price for as long as they are patented. The Canadian Agency for Drugs and Technologies (CADTH), an independent, not-for-profit agency funded by federal, provincial and territorial governments, conducts economic evaluations of new drugs and makes reimbursement recommendations to participating public payers. The recommendations are not binding but are considered by the public drug plans when making formulary listing decisions. At the provincial and territorial level, health ministries and drug plan managers decide which drugs to reimburse for their beneficiary populations and negotiate prices directly with pharmaceutical manufacturers. Outside of government, private health insurers manage employer-sponsored drug plans and also negotiate prices directly with manufacturers. The rules governing whether and to what extent private insurers are bound by reimbursement decisions by public drug plans, or benefit from their price negotiations, vary by province.

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HOSPITAL MEDICINES

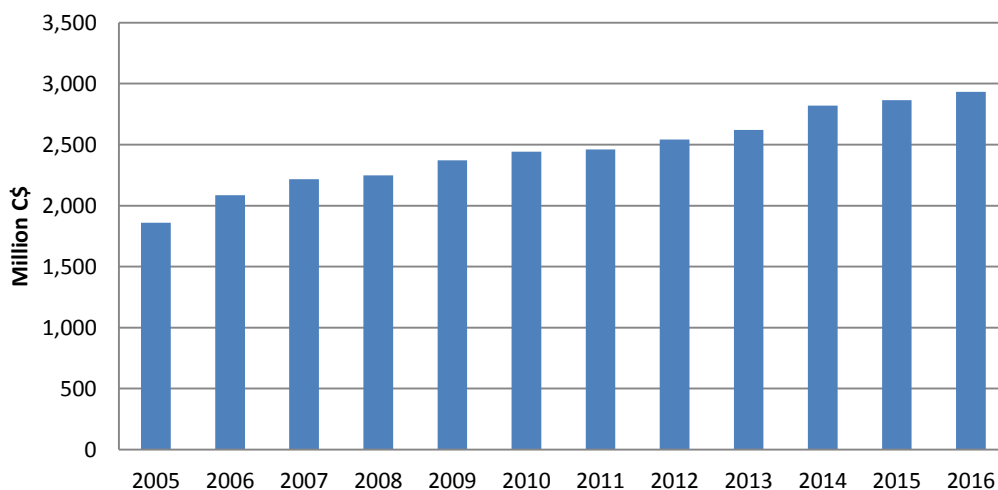
Hospitals negotiate prices with manufacturers for both branded and generic drugs. Group Purchasing Organisations (GPOs) enable groups of hospitals to leverage their purchasing power and secure higher discounts/rebates from manufacturers. GPOs typically use competitive tenders for the purpose of procuring multi-source drugs (ie off-patent originals and generics). The supplier offering the lowest price and guaranteed supply usually wins the tender which tend to run for three to five years. In some instances, provinces and territories have joined forces to secure lower prices for hospital drugs in their respective jurisdictions. For example, Alberta, British Columbia and Saskatchewan signed in 2009 a joint procurement agreement as part of the broader New West Partnership Trade Agreement. The pan-Canadian Pharmaceutical Alliance is another interprovincial collaborative initiative intended to cut the prices of hospital drugs. The prices negotiated through hospital procurement groups are considered confidential and are not available to the public

Public hospitals have traditionally been funded via block grants allocated by the relevant provincial/territorial government. However, this funding mechanism has been criticised as increasingly outdated in the face of high clinical volumes and need for innovation. Some provincial governments have as a result moved towards activity-based funding models similar to the diagnosis-related group (DRG) systems used in the US and much of Western Europe. Notably, activity-based funding mechanisms have been introduced for certain hospital services in Ontario, British Columbia and Alberta. In addition, the health ministers (as well as medical societies) of New Brunswick and Quebec have voiced interest in switching to such a system.

There are two primary HTA organizations in Canada, CADTH and the Institut national d'excellence en santé et en services sociaux (INESSS) in Quebec. Hospital Pharmacy and Therapeutics Committee (P&TCs) make formulary decisions based on recommendations made by these two organizations where available, supplemented with information and recommendations from other sources such as NICE (UK), Cochrane Reviews, and expert opinion. Traditionally, health authority or hospital Pharmacy and Therapeutics Committee (P&TCs) make formulary decisions for hospitals, independent of the public drug plans. In recent years, some jurisdictions have seen a growing collaboration between the public drug plans and the hospitals and health authorities to ensure consistent drug coverage for patients.

Over the past decade, expenditures on pharmaceuticals in the hospital sector have been driven by a combination of cost increases related to the increased use of newer more expensive products and an increasing demand fuelled by an aging population. The imposition of provincial cost-containment policies beginning in 2010 has helped to arrest expenditure growth. The loss of patent exclusivity of a number of hospital drugs in 2016 and 2017 should further help to contain costs related to the increased use of high cost/ low volume drugs.

Hospital purchases at actual prices, 2005 to 2016



Quintiles IMS, Canadian Pharmaceutical Market, Drug Store and Hospital Purchases, December 2016