Patented Medicine Prices Review Board | Conseil d'examen du prix des médicaments brevetés

CANADA

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

Pharmaceutical Pricing and Reimbursement Policies in the in- and out- patient sector

Health Canada – Drug Approval

Grants the authority to market new drugs in Canada once they have met the regulatory requirements for **safety, efficacy and quality**

Population: 37.6 Million
GDP per capita: CA$58,498 (2017)
Healthcare spending per capita: CA$6,839 (2018)
Share of healthcare spending on drugs: 15.7% (2018 forecast)

Pricing – National Level

The Patented Medicine Prices Review Board (PMPRB)

Regulates the price of all patented medicines sold in Canada to ensure that they are not excessive.
Reviews the prices charged to wholesalers, hospitals and pharmacie at the factory gate level.
Currently, drug prices are compared to prices of similar drugs in a therapeutic class and/or to prices in comparator countries. Drug products are categorized based on their degree of therapeutic improvement: breakthrough; substantial, moderate, or slight/no improvement. Yearly increases are limited to changes in the Consumer Price Index.
In August 2019, the Government of Canada introduced amendments to the *Patented Medicines Regulations* allowing for important changes to the regulatory process. Changes include:

- **An updated schedule of comparator countries** - The new framework includes countries with similar consumer protection priorities, economic wealth and marketed medicines as Canada.
- **Additional price regulatory factors** - The new regulatory framework adds new the factors that include the medicine's value to and financial impact on consumers in the health system.
- **Changes in reporting requirements** - The new framework requires the actual price obtained by the patentee to be reported to the PMPRB, taking into account any adjustments. This includes reporting the confidential rebates and discounts that manufacturers negotiate.

IN-PATIENT

All drugs administered in hospitals are fully funded by the Medicare system at no cost to the patients under the *Canada Health Act*.
Canadian Hospitals operate under fixed budgets, and procure medicines typically through purchasing programs that establish group contracts for set prices. The hospital then buys directly from the manufacturer at the contracted price.

OUT-PATIENT

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.

PUBLIC (42.7%)*	PRIVATE (35.6%)*	OUT-OF-POCKET (21.8%)*
Each of the 10 Canadian provinces and 3 territories provide coverage with a focus on seniors, lower-income earners and those with high drug costs in relation to their income. Federal coverage is provided for veterans, First Nations and Inuit, Royal Canadian Mounted Police and the armed services.	Most employers provide private insurance for working age beneficiaries and their dependants.	Individuals not covered by a public or private plan, or those with deductibles and co-payment costs.

*Source: Canadian Institute for Health Information, 2017 forecast

Public Reimbursement

HTA

Canadian Agency for Drugs and Technologies in Health (CADTH) and l'Institut national d'excellence en santé et services sociaux (INESSS)

Through the pCODR and CDR processes, the Canadian Agency for Drugs and Technologies in Health (CADTH) evaluates the clinical, economic, and patient evidence for cancer drugs (pCODR) and other drugs (CDR). Based on these evaluations, CADTH provides reimbursement recommendations and advice to Canada's federal, provincial, and territorial public plans (with the exception of Quebec), as well to the provincial cancer agencies. The recommendations are not binding, but are considered by the public drug plans when making formulary listing decisions.
In 2017, CADTH updated its Guidelines for the Economic Evaluation of Health Technologies. Manufacturer submissions should now include cost-utility analysis or a justification for their absence. CADTH also implemented a new streamlined its Health Technology Assessment (HTA) process for biosimilars that is expected to reduce the review period for these drugs to 3 months.
In the province of Quebec, the Institut national d'excellence en santé et services sociaux (INESSS) assesses the clinical advantages and costs of health technologies, medications and interventions used in the fields of health care and social services. It issues recommendations concerning adoption, use and coverage by the public plan of health technologies and services.

Pricing

Pan-Canadian Pharmaceutical Alliance (pCPA)

Starting in 2010, Canada's provincial territorial and federal governments have come together through the pan-Canadian Pharmaceutical Alliance (pCPA) to collectively negotiate the prices of brand name and generic drugs as a way to achieve greater value for publically funded programs.

Brand-name drugs

The pCPA enters into confidential Product Listing Agreements for brand-name dugs for publically funded drug plans. These negotiations are based on the health technology assessments conducted by a national review process: Common Drug Review (CDR) or the Pan-Canadian Oncology Drug Review (pCODR). As of August 31, 2019, 314 joint negotiations have been completed.

Generic drugs

In January 2018, the pCPA reached an agreement with the Canadian Generic Pharmaceutical Association to lower the price of the nearly 70 most commonly discpensed prescription generic drugs in Canada to either 10% or 18% of the equivalent brand-name drug.

Wholesale and pharmacy markups – Public and Private

About half of the provinces/territories regulate wholesale margins, while others are unregulated. Most public and private drugs plans reimburse a pharmacy markup. For public drug plans, markup ceilings ranges from 4% to 8.5% of the ingredient cost and are often capped for high-cost drugs.