Patented Medicine Prices Review Board Canada

Conseil d'examen du prix des médicaments brevetés Canada

CANADA

Pharmaceutical pricing and reimbursement policies / in- and out-patient sectors

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.**

PRICING factory gate 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 pharmacies.** The PMPRB published its Strategic Plan for 2015-2018, which will enable the PMPRB to better advance its goal of a sustainable health system in Canada. In spring 2016, the PMPRB will launch consultations with Canadian stakeholders that are expected to result in the creation of a new regulatory framework to be implemented in January 2018. For information on legal matters currently before the Board, as well as complete documentation on past matters, please visit:http://www.pmprb-cepmb.gc.ca/en/hearings/the-hearing-process

IN-PATIENT

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

OUT-PATIENT

Prescription drug costs in Canada are covered by a blend of public and private drug plans, as well as out-of-pocket payers.

PUBLIC (43%)*

Each of the 10 Canadian provinces and 3 territories provide public coverage with a focus on seniors, lower-income earners or 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 military.

PRIVATE (35%)*

Most employers provide private drug insurance for working-age beneficiaries and their dependants.

OUT-OF-POCKET (22%)*

Individuals not covered by a public or private plan, or those with deductible or co-payment costs.

*Source: Canadian Institute for Health Information, national health expenditure trends

PRICING

pan-Canadian Pharmaceutical Alliance (pCPA)

Since 2010, provincial and territorial governments have implemented individual policies aimed at reducing the price of drugs. More recently, through the pCPA initiative, they have been working together to achieve greater value for brand-name and generic drugs. Through these policies and the pCPA initiative, the prices of generic drugs have been reduced to levels as low as 18% of the reference brand-name prices.

Brand-name drugs
The pCPA conducts joint provincial/territorial negotiations and enters into confidential Product Listing Agreements (PLAs) for brand-name drugs for publicly funded drug plans. These negotiations are based on the health technology assessments conducted by the national review processes: Common Drug Review (CDR) or Pan-Canadian Oncology Drug Review (pCODR). As of February 29, 2016, 93 joint negotiations have been completed.

Generic drugs
The pCPA also conducts joint negotiations for top-selling generic drugs. The Pan-Canadian Generic Value Pricing Framework was implemented effective April 1, 2014. As of April 1, 2016, 18 commonly-used generic drugs have been reduced to 18% of their brand-name prices. In addition, a pan-Canadian Tiered Pricing Framework was developed that sets the prices of new generic products based on the number of products available in the Canadian market (if a generic drug is sold by one manufacturer, the framework allows for 75-85% of brand price; for generics produced by two manufacturers, the percentage drops to 50% of brand, and for three, the percentage of brand falls to 25% for oral solids and 35% for other dosage forms). In 2014, the average generic price in Canada was 36% of their brand-name counterpart.

Brand-name drugs
Private plans do not negotiate the prices of brand-name drugs collectively and do not benefit from the discounts/rebates available for public plans.

Generic drugs
The generic prices that are negotiated by the pCPA are available to both the private and out-of-pocket markets.

Manulife DrugWatch
DrugWatch responds to the climbing prescription drug prices through the implementation of a new approval process, which ensures new drugs meet a clinical effectiveness standard in relation to their price.
The scrutiny of drugs in the DrugWatch program is intended to give Manulife more leverage to negotiate prices with drug manufactures. Nearly 3.8 million Canadians have drug coverage through one of the company's plans. The program is unique to Canada in that it will be the standard process for all Manulife's clients, without them opting in or out.

Wholesale and pharmacy markups
No policies exist. These may be negotiated by individual insurers (e.g. Preferred Pharmacy Networks).

REIMBURSEMENT

Wholesale and pharmacy markups
About half of the provinces/territories regulate wholesale margins, while others are unregulated. Most public and private drug plans reimburse a pharmacy markup. For public drug plans, the markup ranges from 4% to 8.5% of the drug ingredient cost.

Private plans generally cover all prescription drugs, although private formulary plans do exist, in which case, private drug plans make their own listing decisions.

The Common Drug Review (CDR) and pan-Canadian Oncology Drug Review (pCODR)

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 drug plans (with the exception of Quebec), as well as to the provincial cancer agencies. The recommendations are not binding but are considered by the public drug plans when making formulary listing decisions. As of April 1, 2016, CADTH will no longer accept confidential submitted prices for the CDR and pCODR reviews. The submitted price will be disclosed in all applicable reports.

Cost-sharing
Cost-sharing structures take the form of co-insurance, co-payments, deductibles, and maximums. Recent concerns over the long-term sustainability of private plans in Canada have resulted in an increased use of cost management mechanisms, such as mandatory generic substitution, greater use of managed formularies, prior authorization and multi-tiering (promoting the use of more cost-effective medicines), preferred pharmacy networks, increased cost sharing, pooling of high-cost beneficiaries, and the elimination of retiree benefits, among others.

Patient eligibility and cost-sharing
These vary widely according to the plan design. Some public plans provide income-based coverage, while other focus on seniors and lower-income earners. Cost-sharing structures also vary depending on the plan design, with a blend of deductibles, co-insurance and/or co-payments.

Recent analysis of select Canadian public drug plans calculated that of the $7.7 billion in prescription drug expenditures in 2012/13, drug costs accounted for 74.4%, pharmacy dispensing fees for 21.4% and markups for the remaining 4.2%. Prescription drug expenditure levels differ widely among provincial drug plans. This is mainly due to variations in the size of the beneficiary populations, but also reflects the demographic and disease profiles of the populations, as well as differences in plan designs. On average, public drug plans paid 82.0% of the overall prescription drug cost for their beneficiaries, with the remainder being paid by the beneficiaries either out-of-pocket or through a third-party private insurer.

Canadian Drug Insurance Pooling Corporation
Twenty-four insurance companies across Canada share the costs of very expensive and recurring drug treatment claims. This approach is intended to set affordable premiums for fully insured employer drug plans as well as shelter their employees from the full financial burden of prescription drug treatments. Since 2013, the new pooling mechanism paid more than $4,000 prescription drug claims of over $25,000. Several individual claims exceeded $500,000. One was over 1.2 million.

Canada