Patented Medicine Prices Review Board | Conseil d'examen du prix des médicaments brevetés | PPRI Pharmaceutical Pricing and Reimbursement Information | WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

CANADA

Recent and planned developments in pharmaceutical policies 2018

Special topic: national incentives and derogatory procedures for orphan medicines

CHANGES IN PRICING

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 2016, the federal government and Quebec joined the pCPA. 241 joint negotiations have been completed since September 30, 2018.

As of April 1 2018, based on an agreement between the pCPA and the Canadian Generic Pharmaceutical Association (CGPA), the price of the nearly 70 most commonly dispensed prescription generic drugs in Canada have been lowered to either 10% or 18% of the equivalent brand name drug.

The Patented Medicine Prices Review Board regulates the prices of medicines to ensure that they are not excessive. In the first half of 2018, the prices of 10 drug products representing 6 molecules were reduced via the PMPRB's Voluntary Compliance Undertaking process. The molecules affected were brimonidine gel, evolocumab, levofloxacin, methotrexate sodium, panitumumab and travoprost – timolol.

CHANGES IN REIMBURSEMENT

In 2017, the Canadian Agency for Drugs and Technologies (CADTH), which makes non-binding health technology assessment (HTA)-based reimbursement recommendations to Canada's public drug plans, updated its Guidelines for the Economic Evaluation of Health Technologies. Manufacturer submissions should now include cost-utility analyses or a justification for their absence. CADTH also implemented a new streamlined HTA process for biosimilars that is expected to reduce the review period for these drugs to 3 months.

In addition to the price agreement reached by the pCPA in February 2017 with the manufacturers of six hepatitis C drugs, Canadian public drug plans now cover these drugs for all hepatitis C patients, regardless of genotype or level of liver fibrosis, starting in 2018.

On January 1, 2018 the Government of Ontario (Canada's most populated province), introduced the Ontario Health Insurance Plan Plus (OHIP+), providing free coverage for residents age 24 years and under without private insurance. OHIP+ provided coverage for about 1.2 million Ontario residents who were previously uninsured.

OTHERS CHANGES

In 2017, the federal government committed to an investment of $140.3 million over five years to improve access to pharmaceuticals, lower drug prices and support appropriate prescribing (the 3 A's – access, affordability, and appropriate use). The federal government also committed $950 million over five years towards the development of innovation superclusters, including in the life and biosciences sector.

As part of the federal government's commitment to the 3 A's to better address health care system needs, in December 2017, Health Canada proposed amendments to Canada's Patented Medicine Regulations which would enable the PMPRB to consider new factors when accessing the excessivity of a drug's price. These new proposed factors include considering a drug's pharmacoeconomic value, its market size in Canada, Canada's GDP and GDP/capita and a change in the basket of countries used as part of an international price comparison. The Health Canada is proposing dropping the US and Switzerland from the basket of PMPRB7 countries, and adding: Australia, Belgium, Japan, the Netherlands, Norway, South Korea and Spain. The regulatory changes will also require patentees to report confidential third party rebates, allowing the PMPRB to know the actual prices being paid for medicines in Canada. Finally the changes would see the reporting by manufacturers of patented generics on a complaints basis, thus reducing their regulatory burden.

Since June 2018, the PMPRB has been consulting with its stakeholders over how best to implement Health Canada's proposed regulatory changes. Two consultative bodies have been struck to assist in the development of new Guidelines. The mandate of Steering Committee on Modernization of Price Review Process Guidelines is to assist the PMPRB in synthesizing stakeholder views on key technical and operational modalities of new draft Guidelines that would give effect to the regulatory changes. The Steering Committee's work will be based in part on the analysis and recommendations of a technical Working Group, which will examine certain issues that the Steering Committee believes would benefit from the review of experts in health technology assessment and other economic and scientific matters. It is expected that the work of the two groups will continue through the winter 2018/19 to be followed by the release of draft Guidelines. A larger consultation will be held on the draft Guidelines in the spring of 2019.

SPECIAL TOPIC: National Incentives and Derogatory Procedures for Orphan Medicines

Canada's Regulatory Approach

In 2014, the Canadian government passed the *Protecting Canadians form Unsafe Drugs Act*. Also known as Vanessa's Law, this act improved Health Canada's ability to collect post-market safety information and take appropriate action when a serious risk to health is identified. Coming out of this new legislation, Health Canada has embarked on the Regulatory Review of Drugs and Devices Initiative designed to make the regulatory processes more efficient and effective in meeting health care system needs, including the needs of Canadians with rare diseases.

An orphan drugs-specific approval framework does not currently exist in Canada. Drugs for rare diseases are authorized for sale in Canada under the Food and Drugs Act and Part C of the Food and Drug Regulations. Expected changes resulting from this initiative include:

- making greater use of the reviews and decisions of trusted foreign regulators;
- working with health technology assessment organizations to reduce the time between Health Canada approvals and reimbursement recommendations;
- building a program to provide early parallel scientific advice with health technology assessment organizations to assist new drug development;
- expanding the priority review policy to decrease review time for products needed by the health care system;
- using existing and new real world evidence to support regulatory decision-making across a drug's life cycle; and
- renewing the Special Access Programme (SAP) to improve access to products that are not currently authorized for sale in Canada.

Consultations on this initiative are expected to continue through to 2021.

In 2017, 16 of the 36 new active substances authorized in Canada were classified as orphan drugs in Europe or the United States. Many of these drugs were reviewed using accelerated processes. All of 7 new active substances approved under our Priority Review Policy are orphan drugs. Priority reviews of drug submissions are granted for new therapies, preventatives and diagnostic agents for serious, life-threatening or severely debilitating diseases or conditions. Of the 6 new active substances approved under our Notice of Compliance with Conditions Guidance, 4 are orphan drugs.

Incentives

The Canada Revenue Agency (CRA) administers the Scientific Research and Experimental Development Tax Incentive Program (SR&ED) – the largest single source of federal government support for encouraging research and development (R&D) in Canada. The program includes refunds and/or tax credits for expenditures on eligible R&D investment in Canada. There are other programs that aim to incentivize R&D investment for rare diseases:

Advancing therapies

The federal health research granting agency, Canadian Institutes of Health Research (CIHR) includes funding opportunities for research on rare diseases. In addition, CIHR also plays a leadership role internationally, such as participating in the International Rare Disease Research Consortium (IRDiRC). The Consortium aims to accelerate medical breakthroughs for people affected by rare diseases and includes more than 40 organizations from 17 countries. Since 2016, the Consortium has yielded medicinal products and therapies for 222 rare diseases and has set new goal of delivering 1000 new therapies has been set for the next 10 years.

Advancing diagnostics

CIHR and Genome Canada are also investing in the Care for Rare Project. This project aims to use new gene sequencing technologies to identify the genes implicated in many rare diseases. By advancing genomic research, this project will support the continued development of personalized medicine—the tailored treatment of patients based on their unique genetic makeup. This project has recruited over 4000 patients and family members to participate in research. They have studied 950 different rare diseases, have provided a diagnosis to over 1500 patients, have identified 135 novel rare disease genes, and are developing three experimental therapies.

Advancing collaborative research

Canada is also engaged in E-Rare, the European Union's main instrument for funding research in areas related to rare diseases. This initiative enables scientists in different countries to collaborate on a common interdisciplinary research project, with a clear translational approach. The European Research Area Network (ERA-Net) "E-Rare" for research programs on rare diseases has been extended to a third phase, "E-Rare-3" (2014 to 2019), to further help coordinate the research efforts and to implement the objectives of the IRDiRC. CIHR is a member of E-Rare-3, and has supported 25 projects since 2012 through its participation in 5 Joint Transnational Calls.

Advancing resource hubs

Canada is an active member of Orphanet. This online resource offers a directory of specialized information for people with rare diseases and health care providers. It includes information gathered from all over the world about: biobanks, registries, researchers, clinical trials, expert centres, specialized clinics, medical laboratories, and patient organizations.

Provincial Reimbursement

In Canada, reimbursement decisions in public drug plans are made at the provincial/territorial level. Federal plans cover specific populations including Indigenous populations (First Nations and Inuit), and military (members of the Canadian Armed Forces). Five provinces have established special access programs for drugs for rare diseases (DRDs). These programs take the form of coverage plans enabling access to a defined set of DRDs on a separate formulary (Alberta and New Brunswick) or dedicated reimbursement decision-making processes for DRDs (British Columbia, Ontario, and Saskatchewan).

Province	Coverage description	Application process	Drug Approval Criteria	Deliberating body
Alberta	Defined Formulary	Physician submitted request	For the treatment of Gaucher, Fabry, MPS II (Hunter Syndrome) and Pompe disease.	Advice from Alberta Rare Diseases Clinical Review Panel
British Columbia	Dedicated Reimbursement Process	Physician submitted request	For the treatment of non-cancer-related diseases with a prevalence of <1.7/100,000 Canadians, costing >$50,000/patient annually.	British Columbia EDRD Advisory Committee
New Brunswick	Defined Formulary	Physician submitted request	For the treatment of MPS I, MPS II, Cryopyrin-Associated Periodic Syndrome, Pompe disease and Niemann Pick Type C	Ontario Drugs for Rare Diseases Working Group
Ontario	Dedicated Reimbursement Process	All patients for whom the drug is indicated	For the treatment of diseases with an annual incidence of <1/150,000 individuals	Ontario Drugs for Rare Diseases Working Group
Saskatchewan	Dedicated Reimbursement Process	Physician submitted request	For the treatment of non-cancer-related diseases with an prevalence of <1/150,000 individuals	Saskatchewan Drug Plan and its Drug Advisory Committee