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

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information

# CANADA

## Recent and planned developments in pharmaceutical policies 2017/2018

## Special topic: patient involvement in pricing and reimbursement of 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.

In January 2018, the pCPA reached an agreement with the Canadian Generic Pharmaceutical Association (CGPA) to lower the price of the nearly 70 most commonly dispensed prescription generic drugs in Canada to either 10% or 18% of the equivalent brand name drug. This agreement comes into effect April 1, 2018.

In September 2017, the Patented Medicine Prices Review Board found that the price of Soliris (eculizumab) was and is excessive in Canada. The maker of Soliris, Alexion, was ordered to pay back several million dollars in excess revenue to the government of Canada and lower the list price of Soliris in Canada to the lowest of the seven countries Canada compares itself to for pricing purposes.

### CHANGES IN REIMBURSEMENT

In 2017, the Canadian Agency for Drugs and Technologies (CADTH), which makes non-binding 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.

Further to a 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 introduced a new expanded universal drug plan that provides free drug coverage to residents 25 and under, affecting approximately 4 million people.

### OTHERS CHANGES

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. Budget 2017 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 improve the affordability, accessibility and appropriate use of prescription drugs to better meet health care system needs, in December 2017, Health Canada proposed amendments to Canada's Patented Medicine Regulations which would enable the PMPRB to consider cost effectiveness and budget impact in setting ceiling prices for patented drugs in Canada. That same month, the PMPRB released a scoping paper explaining how it intended to operationalize the regulatory amendments through changes to its pricing guidelines. While the details of the framework remain to be worked out through consultation, its basic structure can be described as a risk based approach to pricing review that is broken down into five main parts:

1. An interim international price reference test;
2. A screening phase; (high, medium and low risk of excessive pricing)
3. For a high risk drugs, The application of a QALY-based threshold as well as a secondary adjustment for high market impact drugs;
4. A therapeutic reference and complaints based approach for medium and low risk drugs and;
5. Periodic re-assessment of introductory price ceilings – a life cycle approach to price regulation responsive to changes in market conditions and RWE

The new regulations and guidelines are expected to be in place by January 2019.

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## SPECIAL TOPIC: Patient Involvement in Pricing and Reimbursement of Medicines

**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. 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.

In Canada, due to the decentralized decision process, there are a variety of opportunities for patients and groups to have their voices heard. The following are the principle fora for patient involvement.

**HTA organizations**

**CADTH** - Patients are important participants in Canada's drug reimbursement recommendations processes. Patient group input is used by the Common Drug Review (CDR) and the pan-Canadian Oncology Drug Review (pCODR) programs to identify patient-important outcomes and expectations for new treatments, and inform the development of the research protocol. Patient input is sought on each drug that is reviewed by CDR and pCODR. The patient submissions received are discussed during committee deliberations and reflected within the final reimbursement recommendations. Within the pCODR program, there are a few additional opportunities for patient input, including an opportunity to provide feedback on an initial recommendation before it is considered final.

Typically, CADTH seeks input from patient groups, rather than from individuals, to encourage diversity of voices and experiences. In October 2015, CADTH announced that in the limited instances where no Canadian patient group exists, individual patient and caregiver input will be accepted for CDR and pCODR programs.

Manufacturers are required to provide CADTH with notification of a pending CDR submission or resubmission before formally filing with either CDR or pCODR. Calls for patient input and the respective deadline are posted on the CADTH website 20 business days in advance of the applicant's anticipated date of filing. A total of 35 business days are provided for preparing and submitting patient input.

All patient groups along with CADTH staff, experts involved in the review, and committee members are required to disclose any real, potential, or perceived conflicts of interest. Declarations made do not negate or preclude the use of the patient group input.

Public and patient members also hold positions on CADTH's Board of Directors (public members), Canadian Drug Expert Committee (public members), pCODR Expert Review Committee (patient members), Health Technology Expert Review Panel (public member) and Patient Community Liaison Forum.

**INESSS**- During the 30-day period that the work plan for a product review is posted, health professionals, consumers and patients, as well as their associations or groups are invited to send INESSS feedback or observations on the drug products under consideration. INESSS recognizes that patients and caregivers have first-hand knowledge of life with a disease or specific health condition. They can describe the benefits and drawbacks of currently available treatments, which are not always reported in the published literature, and assess new treatments. Their feedback and observations are then shared with all members of the standing scientific committee on entry on the list of medications, who will evaluate the drug product in question.

In the interest of transparency, INESSS asks that all participants in the evaluation procedure, whether individuals or organizations, disclose any conflicts of interest they may have in order to ensure an objective and credible procedure.

**Provincial organizations**

**Ontario** - The Committee to Evaluate Drugs (CED) is the Ministry's independent expert advisory committee on drug-related issues. Its key functions are to establish, maintain, and apply criteria to evaluate the quality and therapeutic value and cost of drug products and to recommend to the Minister, including the executive officer, those products which should be considered for publicly funded drug programs, and the conditions under which such products should be funded..

Two of the CED's 12 members represent the public. To be considered for the two positions, applicants must not have been employed by any pharmaceutical or related companies; be able and willing to comply with Conflict of Interest and Confidentiality requirements of the Government of Ontario.

Since 2016, the CED no longer reports on those drugs reviewed by CADTH. The committee meets at least once a month to carry out its mandate with respect to drug product reviews, formulary reviews, ODB cost saving initiatives, and individual requests under Section 16(1) of the Ontario Drug Benefit Act.

**Ontario** – The Ontario Citizens' Council is an advisory body of 25 Ontarians, from all walks of life, that meet to discuss and provide their values and opinions that reflect the needs, culture and attitudes of Ontario citizens on the tough decisions that need to be made on drug policy in the province. The Council meets up to two times a year for 2 to 3 days at a time. Groups, such as healthcare professionals, paid employees of health charities, employees of companies in health industries, elected officials, or Ministry of Health employees that already have a strong voice in making their opinions known to decision makers may not be members of the Council.