



## Canada

### Recent and planned developments in pharmaceutical policies 2014

#### Policies related to high cost medicines

<b>D E V E L O P M E N T S</b>	<b>Changes in pricing</b>	<b>Changes in reimbursement</b>
	<p><i>Nationally, the price of patented drugs is regulated by the Patented Medicine Prices Review Board. The PMPRB is responsible for regulating the prices that patentees charge for patented drug products sold in Canada to ensure that they are not excessive. The PMPRB has no authority to regulate the prices of non-patented drugs and does not have jurisdiction over prices charged by wholesale or pharmacies, or over pharmacists' professional fees. The regulation of any of these prices or fees is under the jurisdiction of the provinces and territories.</i></p> <p><i>In September 2014, Canada signed the Comprehensive Economic and Trade Agreement (CETA) with the EU. The Patent term restoration provisions of the agreement will provide innovative pharmaceutical companies the ability to restore up to two years of patent protection that have been lost by regulatory processes. This extension will delay the arrival of generic completion for individual drugs.</i></p> <p><i>In January of 2013, all of Canada's provinces and territories (except Quebec) joined together to form the Pan-Canadian Pharmaceutical Alliance (PCPA) to use their combined purchasing power to lower the generic prices on six of the most common generic drugs sold in. Since then, this buying group has negotiated reduced prices on a total of 48 drugs, both branded and generic, and has begun negotiations on a further 9 products.</i></p>	<p><i>Each provincial/territorial jurisdiction makes decisions about which drugs it is willing to reimburse. Most maintain a positive formulary of those drugs it will reimburse and at what price. The jurisdictions are aided in their decision process by the Common Drug Review (CDR) at the Canadian Agency for Drugs and Technologies in Health. CDR conducts reviews of the clinical, cost-effectiveness, and patient evidence for drugs and provides formulary listing recommendations to Canada's publicly funded drug plans (except Quebec).</i></p>
	<b>Other changes</b>	
	<ul style="list-style-type: none"> <li>• <i>Effective April 1, 2014, generic drug prices in the province of British Columbia for oral solids were reduced to 20% of the brand-name list price. All other generic drug forms were priced at 35% of the brand-name list price.</i></li> <li>• <i>On May 1, 2014, The New Brunswick provincial government introduced its new catastrophic drug plan. It is an income based plan designed to assist those residents without drug insurance.</i></li> </ul>	
<b>S P E C</b>	<b>High cost medicines</b>	
	<ul style="list-style-type: none"> <li>• While patented drug prices are regulated at the national level by the Patented Medicine Prices Review Board, reimbursement is managed in a mixed public/private insurance model.</li> </ul>	



I A L T O P I C	<ul style="list-style-type: none"><li>• To assist in the national discussion on the impact of high cost drugs on the sustainability of the healthcare system in Canada, the PMPRB has initiated a number of studies looking at the prices and utilization of these drugs both internationally and domestically.</li><li>• The Pan-Canadian Pharmaceutical Alliance has included in its list of negotiated products a number of high cost drugs, including Gilenya (fingolimod), Orencia (abatacept) and Solvaldi (sofosbuvir).</li><li>• In April 2012, Canada's private life and health insurance industry announced an agreement to collectively protect fully insured private drug plans from the full financial impact of high cost drugs through the development of a pooling framework.</li><li>• Currently Canada does not official have a mechanism to recognise orphan drugs. Health Canada is considering a new regulatory framework for orphan drugs. While this initiative will contribute to Canadian access to these important treatments, an orphan designation for a particular drug has the potential to increase its price.</li></ul>
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