

Position Statement

PRICING OF HEPATITIS C MEDICINES IN CANADA

Action Hepatitis Canada (AHC) is calling on the government of Canada to review and update legislative and regulatory frameworks involved in the establishment of pharmaceutical pricing in Canada.

The AHC is also calling for a re-evaluation of the prices that have been established for curative Hepatitis C (HCV) medicines that came to market beginning in 2014.

Background

The announcement of highly effective curative HCV treatments in 2014 - twenty-five years after the discovery of the hepatitis C virus - brought tremendous hope. With these new therapies comes the possibility of eliminating this virus from our population, preventing needless suffering from end-stage liver disease and liver cancer, and saving lives.

Since that time, several other drugs have entered the market each with equally promising curative rates of approximately 95%ⁱ. These new medicines are taken daily for 8 to 12 weeks and have minimal side-effects. In Canada, they have been priced at an average of \$700 per pillⁱⁱ, making them unaffordable to most and causing many of our government bodies to limit financial coverage for treatment to people with advanced liver disease as a result of HCV^{iii,iv,v}.

Hepatitis C in Canada

HCV is a life-threatening virus that attacks the liver and can cause liver fibrosis, scarring of the liver (cirrhosis), liver cancer, and death from liver failure. As of 2011, approximately 250,000 Canadians were living with HCV, with thousands of new infections occurring every year^{vi}.

There is no vaccine for HCV, but it is curable. Ideally, treatment is taken at earlier stages of illness, before the progression of liver damage and other symptoms of HCV. Early treatment is recommended whenever possible as it contributes to improved quality of life and decreased health care costs^{vii,viii}. ([See Action Hepatitis Canada: "Access to Hepatitis C Treatment"](#))

Patented Medicine Pricing in Canada

The current regulatory pricing system in Canada consistently sets drug prices among the highest in the world^{ix,x}. In the case of new HCV drugs, the prices have been set so high that governments and private payers cannot afford to treat all those who would benefit^{xi,xii,xiii}.

Pricing of patented medicines are regulated in Canada by the Patented Medicines Price Review Board (PMPRB). The PMPRB determines the value of a medicine by looking at how well it works, the extent of negative side effects and the cost savings to the health system that the treatment will bring. Because of the largely curative nature of these new HCV treatments, the low degree of negative side effects and the

cost to the health system of advanced HCV illness, the value of these new HCV medicines is high^{xiv}. As a result, costs have been established at correspondingly high levels.

The pricing formula described above is used to set prices for ground-breaking new medicines typically developed to treat illnesses that affect a relatively small number of patients^{xv, xvi}.

In those cases, treatment would have a strong value and be affordable for governments because of the small numbers of patients requiring treatment with those high-priced therapies. However, this formula does not work for illnesses that are as prevalent as HCV – affecting about 1% of Canada’s population (more than 250,000 people)^{xvii}. In cases of prevalent illness, a new pricing formula is required.

Inflated Pricing –Rationing of Treatment

As a result of high prices, many of Canada’s provinces and territories have placed restrictions on access to HCV treatments^{xviii}, limiting eligibility to people whose virus has progressed to cause significant fibrosis and damage to their liver.

These restrictive criteria are not supported by clinical evidence or by recommendations made by expert bodies in the field of Hepatology. Bodies including the Canadian Association for the Study of the Liver^{xix}, the Canadian Agency for Drugs and Technology in Health^{xx}, the American Association for the Study of Liver Diseases^{xxi}, and the European Association for the Study of the Liver^{xxii} each recommend that all patients be considered for treatment regardless of fibrosis level.

Ethical profit margins

Manufacturers of new HCV treatments are profiting at rates that are vastly disproportionate to their investment or to any reasonable expectation of commercial gain^{xxiii,xxiv,xxv,xxvi}. These companies have benefitted from a regulatory system in Canada that is outdated and in need of extensive critical examination and revision.

Legislative and regulatory processes in Canada should be re-designed to better ensure affordable pricing and broad accessibility of medicines while safeguarding an ethical profit margin for pharmaceutical companies.

If prices were set with ethical profit margins in mind, eligibility restrictions would be unnecessary, all people diagnosed with HCV could be treated regardless of fibrosis score, and corporate profits could be maintained within reasonable limits^{xxvii,xxviii}.

Looking Forward – Systemic Change Required

It is essential that federal legislation and regulation be reviewed and updated in order to reduce the costs of essential medicines while continuing to ensure innovation and profit of pharmaceutical companies.

The AHC is calling on the Federal Government to take a stand on pharmaceutical pricing issues by establishing a regulatory process that strikes a better balance between encouraging development and investment while respecting the principle of equitable access within the Canadian healthcare system.

ⁱ RP Myers, H Shah, KW Burak, C Cooper, JJ Feld. *An update on the management of chronic hepatitis C: 2015 consensus guidelines from the Canadian Association for the Study of the Liver*. Can J Gastroenterol Hepatol 2015 In Press.

ⁱⁱ Canadian Treatment Action Council. *Treatment Access Map*. <http://ctac.ca/resources/treatment-access-map>.

ⁱⁱⁱ CADTH Therapeutic Review. *Drugs for Chronic Hepatitis C Infection: Recommendations Report*. Version 1.0; November 2015.

^{iv} Common Drug Review. CDEC Final Recommendation. Ledipasvir/Sofosbuvir (Harvoni – Gilead Sciences Canada, INC.). Accessed Dec 10, 2015 at https://www.cadth.ca/sites/default/files/cdr/complete/cdr_complete_SR0395_Harvoni_Mar_20-15.pdf

^v Common Drug Review. CDEC Final Recommendation. Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir (Holkira Pak – AbbVie Corporation). Accessed Dec 10, 2015 at <https://www.cadth.ca/sites/default/files/cdr/complete/SR0406-Holkira-Pak-July-22-15-e.pdf>

^{vi} Trubnikov M, Yan P, Archibald C. *Estimated Prevalence of Hepatitis C Virus infection in Canada, 2011*. Canada Communicable Disease Report: Volume 40-19; December 18, 2014. Available at: <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/14vol40/dr-rm40-19/surveillance-b-eng.php>.

^{vii} Max Trubnikov, Ping Yan, Jane Njihia, Chris Archibald. *Identifying and describing a cohort effect in the national database of reported cases of hepatitis C virus infection in Canada (1991-2010): an age-period-cohort analysis*. CMAJ OPEN, 2(4).

^{viii} Younossi ZM, Stepanova M, Henry L, et al. *Effects of sofosbuvir-based treatment, with and without interferon, on outcome and productivity of patients with chronic hepatitis C*. Clin Gastroenterol Hepatol. 2013.

^{ix} Springer International Publishing Switzerland 2015 25 Z.-U.-D. Babar (ed.), *Pharmaceutical Prices in the 21st Century*; Chapter 2: Drug Pricing in Canada DOI 10.1007/978-3-319-12169-7_2

^x Marc-André Gagnon. *A Roadmap to Rational Pharma-care Policy in Canada*. Canadian Federation of Nurses Unions.

^{xi} Jagpreet Chhatwal. *Direct-Acting Antivirals for Hepatitis C Treatment: Effectiveness vs Cost-Effectiveness*. Future Virology. 10.8 (Aug 2015): p929

^{xii} S. Trooskin, H Reynolds, J. Kostman. *Access to Costly New Hepatitis C Drugs: Medicine, Money, and Advocacy*. Clinical Infectious Diseases; 2015;61(12):1825-30

^{xiii} CADTH Therapeutic Review. *Drugs for Chronic Hepatitis C Infection: Recommendations Report*. Version 1.0; November 2015.

^{xiv} *Costly Cures*. The Economist. June 2014.

^{xv} Marc-André Gagnon. *New Drug Pricing: Does it Make any Sense?* Translated from Rev Prescrire. June 2015; 35 (380): 457-461.

^{xvi} Troyen Brennan, William Shrank. *New Expensive Treatments for Hepatitis Infection*. Journal of the American Medical Association. Aug, 2014; vol. 312. Number 6.

^{xvii} Troyen Brennan, William Shrank. *New Expensive Treatments for Hepatitis Infection*. Journal of the American Medical Association. Aug, 2014; vol. 312. Number 6

^{xviii} Canadian Treatment Action Council. *Treatment Access Map*. <http://ctac.ca/resources/treatment-access-map>.

^{xix} P Myers, H Shah, KW Burak, C Cooper, JJ Feld. *An update on the management of chronic hepatitis C: 2015 consensus guidelines from the Canadian Association for the Study of the Liver*. Can J Gastroenterology Hepatology; 2015 In Press.

^{xx} CADTH Therapeutic Review. *Drugs for Chronic Hepatitis C Infection: Recommendations Report*. Version 1.0; November 2015.

^{xxi} American Association for the Study of Liver Diseases. *Recommendations for Testing, Managing, and Treating Hepatitis C*. Accessed online October 1, 2015 at <http://www.hcvguidelines.org/>

^{xxii} European Association for the Study of the Liver. *Hepatitis C Clinical Practice Guidelines*. Accessed online, January 4, 2016 at <http://www.easl.eu/research/our-contributions/clinical-practice-guidelines/detail/recommendations-on-treatment-of-hepatitis-c-2015/report/4>

^{xxiii} Troyen Brennan, William Shrank. *New Expensive Treatments for Hepatitis Infection*. Journal of the American Medical Association. Aug, 2014; vol. 312. Number 6

^{xxiv} S. Trooskin, H Reynolds, J. Kostman. *Access to Costly New Hepatitis C Drugs: Medicine, Money, and Advocacy*. Clinical Infectious Diseases; 2015;61(12):1825-30

^{xxv} Wyden-Grassley Investigation finds Revenue-Driven Pricing Strategy Behind Gilead Hepatitis Drug. Accessed Dec 2015 at <http://www.finance.senate.gov/newsroom/ranking/release/?id=3f693c73-0fc2-4a4c-ba92-562723ba5255>

^{xxvi} Kevin B Laupland MD MSc FRCPC, Louis Valiquette MD MSc FRCPC. *The dollars and sense of chronic hepatitis C infection management*. Canadian Journal of infectious Diseases and Medial Microbiology. Vol 26 No 3 May/June 2015

^{xxvii} Jagpreet Chhatwal. *Direct-Acting Antivirals for Hepatitis C Treatment: Effectiveness vs Cost-Effectiveness*. Future Virology. 10.8 (Aug 2015): p929.

^{xxviii} US Senate Committee on Veterans Affairs. *Senate panel probes exorbitant prices for hepatitis C drugs*. Washington, DC, 2014. Available at <http://www.veterans.senate.gov/hearings/hepatitis-c-in-veterans>. Accessed Dec 2015.