

# PATIENT INPUT INFORMATION

*This section was summarized by CDR staff based on the input provided by patient groups. It has not been systematically reviewed. It has been reviewed by the submitting patient groups.*

## **1. Brief Description of Patient Group(s) Supplying Input**

Two patient groups submitted input.

The Canadian Treatment Action Council (CTAC) is a national non-governmental organization whose mandate is to address access to treatment, care and support for people living with human immunodeficiency virus (HIV) or hepatitis C virus (HCV). Full membership is limited to persons living with HIV/AIDS or organizations with a substantial HIV/AIDS mandate. CTAC has received unrestricted organizational and educational grants from Abbott/Abvie, Boehringer-Ingelheim, Gilead Sciences, Janssen, and ViiV Healthcare. CTAC made no statement with regards to possible conflicts of interest in the preparation of their submission.

The Hepatitis C Education and Prevention Society (HepCBC) is a non-profit organization run by and for people affected by HCV in British Columbia. HepCBC focuses on providing peer support groups, anti-stigma activities, prevention education, general hepatitis information, and encouraging testing among at-risk groups. HepCBC has received funding to support educational and advertising activities and attendance at conferences from Merck Pharmaceuticals, Hoffman-LaRoche, Vertex Pharmaceuticals, Gilead Sciences, Janssen Pharmaceuticals, Bristol Myers Squibb, Boehringer-Ingelheim and AbbVie. Other support has been received from Rx&D. HepCBC indicated that the author of this submission has attended several educational conferences and meetings for which registration and travel expenses were funded by the pharmaceutical companies listed above.

## **2. Condition and Current Therapy Related Information**

The information contained in this section was gathered through surveys and written contributions from patients, caregivers and service providers, and based on aggregated input from monthly support groups, telephone conversations and email support systems.

HCV is a serious and potentially life-threatening liver disease that may lead to liver fibrosis, cirrhosis, cancer, liver failure and even death. HCV infection can remain asymptomatic for several decades, and many patients only find out that they are infected once liver damage is severe. Conversely, some patients experience symptoms much earlier after initial infection. The number, type and severity of symptoms vary between individuals, and often lead to a misdiagnosis when injection drug use is not suspected. No symptom is universal across all patients. The most frequently reported symptoms include fatigue, headaches, muscle or joint pain, slower motor reflexes, digestive problems, weight loss, suppressed appetite, hair loss, insomnia, irritability, depression, and reduced cognitive functioning (e.g., memory, word recall, concentration and attention span, speed of thought, fluency of speech, ability to learn). Other reported symptoms include digestive problems (e.g., lack of appetite, inability to digest common foods, Crohn's disease, esophageal bleeds, acid reflux), electrolyte and iron imbalances, water-retention, hypothyroidism, gall bladder attacks, sexual dysfunction, sensory disturbances (e.g., detection of chemical odors, rapid eye deterioration, sensitivity and avoidance of light and noise), and anxiety and rage. These symptoms lead to other health problems (e.g., inactivity leading to weight gain and overuse of painkillers leading to more liver damage) and to difficulty engaging in social and family activities, and maintaining employment.

The impact of the patient's disease on caregivers is also evident. Caregivers find it difficult to support their loved one during treatment and often experience poverty, a sense of isolation and uncertainty about the future. Poverty ensues as medical expenditures increase, as the patient is unable contribute to family responsibilities, and as caregiving requirements disrupt the caregiver's own work. These increased demands on the caregiver contribute to the caregiver's sense of isolation - a feeling that is also influenced by the social stigma of HCV and an ignorance regarding how the disease is spread. The unpredictability of the disease also leaves caregivers uncertain about how long their loved one will be able to live independently or remain alive at all. Caregivers expressed concern for their capacity to educate themselves about the virology of the disease, to stay informed of new treatments and treatment availability across provinces, and their ability to navigate the health care system. It is recognized that these concerns may be even more challenging for caregivers who are aging and may need care themselves.

The social stigma associated with HCV infection is of concern for patients and their caregivers. Driven by the emergence of promising treatments, patients in the baby-boom cohort have become more willing to be open about their infection; however, patients co-infected with HIV experience increased stigma and treatment challenges.

Patients mention that current treatment has become diversified over the past year depending on a patient's genotype, stage of liver disease, and if the patient has private insurance. While it is recognized that the early treatments interferon and ribavirin are necessary in some cases, there is an overwhelming consensus from patients that when possible, interferon and ribavirin should no longer be used due to their debilitating side effects and low efficacy. Patients cite interferon as "a very taxing, difficult drug" and at least two patients called ribavirin "poison". Administering interferon can also be a source of anxiety for patients with a history of injection drug use. Boceprevir and telaprevir were noted by patients as later generation therapies that increased sustained viral response (SVR) and had shorter treatment durations, but patients were still aware of their side effects. Simeprevir was noted as causing fewer side-effects; however its administration with interferon and ribavirin limited its use for many patients.

Patients indicated a need for interferon-free treatments with increased SVR rates, shorter treatment durations, fewer side effects, and effectiveness across all genotypes, stages of liver disease and previous treatment responder types. One patient group indicated that a large percentage of patients they come into contact with were being "warehoused", either by doctors or by themselves, rejecting the idea of taking current therapies, knowing vastly superior drugs are so close to being approved. There is an overwhelming sense of "desperation and despair" from patients. Time is of the essence and patients indicate that "they know life-saving drugs are out there if they can just hold on long enough..." .

### **3. Related Information about the Drugs being Reviewed**

Patients expect that the new drugs will require a shorter duration of treatment, and be more efficacious and tolerable. They are optimistic about the safety and efficacy of the drugs, but are concerned about availability and accessibility. Patients tend not to differentiate the various new drugs from one another since they are all so much better than the existing ones, and share the characteristics of being mostly tested on genotype 1, have far greater efficacy, a far shorter treatment time, no interferon or needles, very few side effects, and extremely high prices.

Many patients had experience with the new direct acting antivirals (DAAs) as part of clinical trials. All DAA treatment-experienced patients had successful outcomes except one patient who had to discontinue treatment due to a possible drug interaction. One patient group indicated that no side effects were reported from the use of these drugs, and the shorter durations of treatment were valued by patients and their caregivers. Patients responding to consultations about Holkira Pak, which requires multi-pill administration, suggested that if a treatment is more effective and offered a shorter duration of treatment, patients would accept the increased burden of multiple pill administration.

### **4. Additional Information**

Patients are concerned that the prices of these drugs will be so high that CADTH (and/or provincial Pharmacare plans) will either not approve the treatment at all, or implement coverage criteria requiring patients to undergo and fail very challenging standard treatments (with both interferon and ribavirin) before having access to newer DAAs. Delaying treatment until liver disease is more advanced impacts patients' physical and mental well-being. It is frustrating for individuals, especially those who are experiencing multiple barriers, to be told that they are not sick enough to qualify for treatment. Patients worry about the liver damage that may be caused by delaying treatment and suggest that extrahepatic manifestations be considered in treatment decisions. The sooner a person is effectively treated (i.e., cured), quality of life is improved, and the less chance they have of inadvertently infecting someone else. Improved treatments for hepatitis C have the potential to reduce social system and healthcare costs for patients with severe liver disease. Delays in the funding decision process will mean that some patients' time will run out. One patient indicated that there are no other diseases in which a patient has to prove significant damage to his/her bodily organs in order to get treated. And there are no others in which a patient has to take such clearly inferior - even harmful – treatments simply because of price. Thus, there are concerns that this treatment will not be accessible because it is either not covered by public drug plans or the criteria for coverage will limit access.

One patient group suggested that compensation for HCV infection should include diagnostic procedures and medication for managing side effects. They also suggest that CADTH address equitable pricing, and recommend that drug costs be amortized over time to show a clear justification for funding.