Template for Submitting Patient Group Input to the Common Drug Review at CADTH

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Sofosbuvir – for chronic hepatitis C
Name of patient group	HepCBC Hepatitis C Education & Prevention Society
Name of primary contact for this submission:	
Position or title with patient group	REDACTED
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1.1 Submitting Organization

HepCBC is a non-profit society run by and for people infected and affected by hepatitis C. Our mission is to provide education, prevention and support to those living with HCV. Our office with our only paid employee (an office mgr.) is in Victoria, BC. We also have activities and groups in Nanaimo, BC and Surrey, BC. Our representatives attend provincial and federal-level conferences and we give information and support world-wide through our website. We publish a monthly bulletin, the hepcbull. We focus on providing "clean and sober" peer support groups, anti-stigma activities, prevention education to young people, and encourage testing among at-risk groups -- including those who are no longer at risk but may have contracted hepatitis C decades ago. We work alongside local HIV/AIDS organizations in support of co-infected people.

1.2 Conflict of Interest Declarations

a) *We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:*

HepCBC Hepatitis C Education & Prevention Society has received funding for hepatitis C-oriented projects such as publishing educational materials, organizing educational forums, attending and presenting at educational conferences, advertising in newspapers (events and hepatitis C patient awareness), and holding awareness activities from the following pharmaceutical companies over the last three years: Merck Pharmaceuticals, Hoffman-LaRoche, Vertex Pharmaceuticals, Gilead Sciences, Janssen Pharmaceuticals, Bristol Myers Squibb, Boerhinger-Ingelheim, and AbbVie.

b) *We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:*

The author of this report has attended several educational conferences and meetings for which registration and travel expenses were funded by the pharmaceutical companies listed above.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

This report was developed using data from
(1) a patient survey advertised through our website and our email list. In total there were submissions by eight patients (5 male, 3 female, all in 50s or 60s except one age 39

(2) Three of the above are volunteers who have actively manned HCV+ phone and email support systems for several years, and have extensive knowledge of patient concerns and experiences.

(3) Aggregate input from one of our monthly support groups has also been added.

2.2 Impact of Condition on Patients

The #1 problem mentioned was fear of losing our jobs, being debilitated, comatose, or dying prematurely, especially for those of us with family members who depend upon us. Patients mentioned they can no longer work – not even at desk jobs, carry groceries, garden, or play in a band.

Stigma was #2 problem mentioned by most patients:
"The anxiety from not wanting other to know about your condition and trying to function daily can make life hell at times."

#3 – Affects entire body, not just the liver: Fatigue, weakness, pain, brain fog, and lack of energy were mentioned by most. Some need to sleep 12 hours a day or more. When they wake up, they still lack energy or strength.

"I rarely feel good. I feel like I have a mild flu most of the time, poor energy and a dull ache in right side of my abdomen. Joints are always sore, especially back, shoulders and neck."

"Fibromyalgia and brain fog is episodic, so I don't have it all the time, but it makes life harder, painful, exhausting, and sometimes I can't do my job or drive because my cognition is severely affected. I'm genotype 1A, but only have Fibrosis Stage 2!"

"I am currently on long term disability due to lethargy, joint and back pain and reduced mental clarity. I am a software implementation consultant by trade, but am unable to 'keep up' with the demands of the job, either physically or mentally. I used to manage my time, but now I manage my energy levels."

"Progression of the disease and destruction of the organs and bones worried me. The disease caused me joint pains, fatigue, digestive difficulties and pain. Now that I've been cured, these symptoms are disappearing."

"I no longer have the attention span to read extensively as I once did. I have not worked for 2 years. Previous to HCV, I was fairly active and was in a white collar profession that was quite mentally demanding."

2.3 Patients' Experiences With Current Therapy

Genotype 1 patients are generally being treated with the current Standard of Care (triple therapy with Interferon, Ribavirin, and either boceprevir or telaprevir. However some of them have been on clinical trials because they live very close to a research clinic (Percuro) in Victoria, BC.

Genotypes 2 and 3 patients are same as above, except of course their current SOC does not include boceprevir or telaprevir.

We do not have any other genotypes other than 1-3 represented.

The current therapy has cured a few of us. Current SOC triple therapy is more effective than previous SOC for Genotype 1 patients. However, of course, those cured are still left with liver damage that can leave them at risk for liver cancer and failure for many years following the end of treatment. Early treatment is vastly more critical than many doctors assume.

ADVERSE EFFECTS:
"I was on interferon treatment in various forms 3 times; I am interferon-intolerant. I will never take interferon again. My current vision and auditory problems and fibromyalgia can be seen as immune responses that were triggered by interferon."

"The treatment I went through with interferon and ribavirin was worse than the disease for me. On top of the weekly injection that I had to give myself, which I dreaded, I also suffered from anemia (extreme), muscle wasting (weight loss of almost 30 lbs), rash, hair loss, dry mouth and throat, persistent cough, brain fog, insomnia....these are what I remember. I am not willing to try interferon or ribavirin again. Current treatment is another drug on top of the previous treatment. I am worried about my liver, but I do not have any option at this time. My need is to get an interferon-free or ribavirin-free drug with a better cure rate for genotype 1a."

"The current drugs interferon with teleprevir/boceprevir and ribavirin are very expensive and the side effects are so bad that many don't complete the program."

"During my original 48 week Pegatron treatment I was 100% compliant and did not miss a single pill or injection. It was necessary for me to complement this treatment with Neupogen, to allow me to continue. During the treatment, and for three years following it, my leg rash persisted."

ACCESSIBILITY:

"I no longer have private medical coverage, so I am not sure if it was going to be ODSP covering the medication, OHIP or if the health clinic applied to some other program."

"Had Merck Canada not given me the Victrellis on a compassionate basis and my husband's extended medical covered dual therapy, I would have had to wait as I did not qualify for coverage under BC Meds guidelines."

Cirrhotic woman on triple therapy: "Financial hardships accessing therapy, finally got help from manufacturer & Pharmacare because deductible was high"

NEEDS NOT COVERED:
1) Financial loss due to:
A) loss of productivity on treatment
B) over the counter side effect medication (you can spend a fortune on creams when you have a bad rash!!!)
2) Clear directives for primary physicians.
A) The only reason I got diagnosed is because I donated blood, and was tested by them. My family doctor would never have thought to test me.
B) I find myself educating my family doctor of over 10 years just left but he never once suggested a liver ultrasound, I had to ask for one after reading about its necessity online!"

ALTERNATIVE THERAPY:
Genotype 3 male who failed treatment and is now on Chinese therapy awaiting new treatments says this therapy is "Subtely controlling the rashes, makes me feel better, no adverse effects. It is a financial hardship, though: $900 for 4 months! And admittedly it is not a cure."

2.4 Impact on Caregivers

All patients commented on the financial impact on the entire family and the increased responsibility and stress all family members went through. Plus there was the emotional impact of not knowing if the treatment was going to work, coupled with the patient's terrible moods, particularly irritability or depression.

"I was infected for probably 43 years, and I had to pay for a housekeeper much of that time. I found many challenges dealing with the side effects related to IFN and RBV, since I had neutropenia and anemia. I was short-tempered, and this possibly caused the loss of my marriage and my work, directly or indirectly."

"When I went through the treatment, I was not able to do much for myself. I was running a high fever at night, achy, and couldn't sleep. My daughter did not work during this period and stayed home to take care of me. I was also depressed and moody, which I know was hard on those around me. It was their unconditional love and support that got me through."

"If the caregiver is a family member, then they will be forced to put up with a lot of abuse as the side effects of the current therapy are very hard on the whole family and the duration of 48 weeks will consume their lives for the whole year."

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

SAME AS IN SECTION 2.1

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had to Date With the New Drug?

The general consensus was that sofosbuvir will be a welcome improvement. Patients really stress they want interferon-free, and even ribavirin-free treatments, and they don't like telaprevir or boceprevir since they have such terrible side-effects.

a) Not having experience with sofosbuvir:
"In short my expectation is that it will cure me quickly and without major side effects."

"A year of treatment plus six months to a year of recovery seems too long to me to handle. A twelve-week treatment duration, pills only, higher success rate and fewer side effects sounds better than I could have ever hoped for. I almost 40 and desperately want to get on with my life. I feel like I am 70. I used to have a life (career, activities, financial security) and I want it back. As far as side effects go, it really depends on how severe (ie life-threatening) they are. 12 weeks of "intense" sickness sounds much better to me than 50 weeks of "pretty-bad" sickness.

"Had I not responded to a BMS trial recently, yes, I would be willing to go through difficult side effects if there were a good chance of responding, but I would prefer a treatment with no or few side effects. I have at least one friend who has taken sofosbuvir, and that person feels much

better and had few side effects, but is not sure of his/her status as far as SVR yet. The trials look very promising."

"I was recently on an interferon-free Abbvie drug which was practically side-effect free, and it worked! It looks like sofosbuvir also has excellent results, and if coupled with a non-interferon product it will be effective in helping cure this virus."

"Having witnessed the impact on a few friends who had treatment, and seeing how many problems they encountered during 6 months of treatment, I felt leery about dealing with an entire year of treatment with no support system and a poor housing situation…The possibility of a new treatment in the foreseeable future with a drastically shorter treatment period, milder side effects, potentially higher success rate and simpler way to administer treatment convinced me to decline current available therapy and wait to see how things would progress with sofosbuvir."

"My liver specialist has advised that I am now too ill to undergo the latest current HCV treatments (boceprevir and telaprevir) and has recommended that I receive a liver transplant before resuming any HCV treatments. I am currently taking Lactulose to help with elimination of toxins that contribute to my deteriorated mental capacity, and periodically undergo upper endoscopies to assess and 'tie off' esophageal varices. It would be great if using sofosbuvir could help get rid of HCV and also heal my liver."

"There needs to be a huge push to review and fast track some of the new drugs that are coming out so patients can cut down on the side effects and the duration of treatment so they can enjoy a better quality of life."

b) N/A – we did not have any patients who had been in a trial with sofosbuvir.

Section 4 — Additional Information

"I was just pulled from a (Merck) interferon-free trial because it seemed to exacerbate my atrial fibrillation. However I know the treatment was working!!! Within two days, the aches and fog I have been living with for years disappeared. My viral load had gone from several million to less than 100 when I was removed from the trial."

"I'm very happy that you are listening to patients. This is apparently one of the most promising drugs on the market for genotype 1a, and I hope it will be available to patients very soon!"

"There needs to be much more control on the abilities of drug companies to influence doctors. When I went in for screening for participation on the clinical trial, I was told that a certain drug was the one for me. After doing some careful checking, I found that this particular drug company has been providing research funding dollars as well as trips and paid speaking engagements to doctors endorsing their products. We need to have full disclosure for all doctors on financial assistance they receive from these companies. Even though there have been a lot of problems from current drugs on the market, companies have been allowed to hide or dismiss some of those problems. The new DAA treatments are so far ahead of the current therapy that the focus needs to be on getting these drugs to market for the sake of the patients that need them so desperately."

"In particular, more research for Genotype 3 is urgently recommended."