

**You can complete this Patient Group questionnaire only once.** If you submit multiple questionnaires, only your most recent submission will be sent to the Drug Benefit Council for consideration.

**Submissions must be received by the Ministry before midnight  
on December 5, 2011.**

Mandatory questions are flagged with an asterisk (\*). You do not need to answer all of the questions but some questions must be answered so we can consider your input.

*Would you prefer to answer this questionnaire online?*

Select the drug name from the list available at [www.health.gov.bc.ca/pharmacare/yourvoice/pagroups/drug-list.html](http://www.health.gov.bc.ca/pharmacare/yourvoice/pagroups/drug-list.html) to go to our online questionnaire.

*If you answered "No" to this question, you are not eligible to provide input using this questionnaire. You may be eligible to complete a different questionnaire if you are a resident of B.C. and:*

*a patient who has the condition for which this drug is used, or  
a caregiver for someone who has the condition for which this drug is used.*

*If this is the case, visit [www.health.gov.bc.ca/pharmacare/yourvoice](http://www.health.gov.bc.ca/pharmacare/yourvoice) to select the appropriate questionnaire.*

#### COMPLETE THE CONFLICT OF INTEREST DECLARATION

The Conflict of Interest guidelines for the drug benefit review process as a whole are on the PharmaCare website at [www.health.gov.bc.ca/pharmacare/formulary/pdf/DBC-COI-Guidelines.pdf](http://www.health.gov.bc.ca/pharmacare/formulary/pdf/DBC-COI-Guidelines.pdf).

**When does a conflict of interest exist?** A conflict of interest may exist whenever an organization has a direct or indirect interest or relationship, financial or otherwise, with an entity that may affect, or reasonably appear to affect, the objectivity or fairness of the participant in the drug review process. An example of an indirect interest is if the organization owns stock in a company that makes a drug for the same condition for which the drug under review would be used.

In this part of the questionnaire, you will be asked about:

payments the organization you represent may have received from pharmaceutical-related companies  
any holdings or interests the organization you represent may have in pharmaceutical-related companies

**If the organization I represent has a conflict of interest, can it still give input to drug coverage decisions?** Yes. Your organization's input will be considered as long as you declare the conflict of interest in your answers to the questions.

Please complete the questions below to the best of your ability. All information you provide is protected under the Freedom of Information and Protection of Privacy Act.

## PART 1 – PAYMENT RECEIVED

2. Has the organization you represent received any payments **over the previous three years** totalling **\$2,000 or more per year** from any company, organization or individual that may have direct or indirect interest in the drug under review?

YES NO

*If you answered "Yes" to Question 2, please complete Questions 3, 4 and 5. Otherwise, go to Question 6.*

3. What form of payment did the organization receive?  
(Check all that apply.)

Salary

Royalties

Research

Honoraria

Payment for services rendered

Other, please specify

4. What was the total amount received from all sources?  
(Enter total from all sources.)

- a) Received \$1200 grant in last 18 months from Merck towards publishing educational pamphlets. In the they have occasionally provided us with minor funding for refreshments and publicity for public forums
- b) Received \$1,000 grant from Merck payable to sponsoring agency for World Hepatitis Day2011.
- c) Received \$3,000 grant from Merck for partial costs of web site reconstruction 2011.

5. Who are the companies/organizations/individuals that provided the payment?  
(Enter the names of all companies / organizations / individuals who provided payments.)

Merck Frosst Canada Ltd.

16711 Trans-Canada Highway  
Kirkland, Quebec, H9H 3L1  
Canada

## PART 2 – HOLDINGS OR OTHER INTERESTS

6. Do any of the following statements apply to the organization you represent with respect to any company, organization or individual that may have direct or indirect interest in the drug under review?

Shares and/or value of stock (excluding mutual funds) that total \$2,000 or more?

Current ownership interest (for non-publicly traded entities)?

Employment or appointment to the Board of Directors within the last three years?

Any other financial arrangements, interests, affiliations, or relationships that may create, or be reasonably perceived to create, a conflict of interest?

YES

NO

*If you answered "Yes" to Question 6, please complete Questions 7 and 8. Otherwise, go to Question 9.*

PROVIDE PATIENT GROUP INFORMATION

**You must complete this section of the questionnaire.**

Your organization's contact information will be used to retrieve your submission if you submit an access request under the Freedom of Information and Protection of Privacy Act (FOIPPA). It will not be used for any other purpose.

Your organization's name, however, will be included as part of your submission.

**9. Patient Group name**

*HepCBC Hepatitis C Education and Prevention Society*

**10. Representative's first and last names**

*REDACTED*

**11. Organization's Street address (Number and name)**

*PO Box 46009-2642 Quadra St*

**12. City or town**

*Victoria*

**13. Postal Code**

*V8X 1V2*

ANSWER THE QUESTIONS ON BOCEPREVIR (VICTRELIS™)

*The questions on the following pages ask for information about*

*the impact of condition and outcomes that matter most to patients in your group*

*patients' experience with other therapies*

*patients' experience with the drug under review*

*other information*

*You do not need to answer all of the questions. You need only answer those that you think apply to the patients your group represents.*

*If you need extra space, use the blank page at the end of the form. Enter the question number in the space provided.*

***To protect your privacy and the privacy of the patients in your group, please do not include in your response names of individuals or companies, locations, or any other information that might identify you or anyone else.***



## IMPACT OF CONDITION AND OUTCOMES THAT MATTER MOST TO YOU

14 How does chronic Hepatitis C affect the day-to-day life of the patients your group represents?

I) In order of frequency, members reported the condition-related symptoms below. No symptom was universally reported; some people exhibit more symptoms than others.

(1) Most frequently reported: Fatigue, digestive problems, muscle and joint pain, brain fog, irritability, depression, cognitive failure (concentration/attention span, speed of thought to motor reflex, fluency of speech, learning and memory), insomnia, slower motor reflexes, and general fear of social interaction (coupled with a fear of being stigmatized). Lower self-esteem and lower HRQOL indices.

(2) Also reported: Water-retention, acid reflux, gall bladder attack, lack of appetite, inability to digest many common foods, sensitivity to/avoidance of noise or light, sexual dysfunction, rapid eye deterioration, electrolyte imbalance, iron overload/imbalance, detecting chemical odors (in sweat, urine, stool, breath), anxiety, rage, hypothyroidism, IBD and IBS, seizure disorder, metabolic syndromes (fatty liver, pre-diabetes), toxic encephalopathy, ascites, and esophageal bleeds.

(3) Loss of productivity and function disables many, and this happens as a result of damage on multiple levels of systemic functions. Peripheral neuropathy is indicated and dementia has been indicated to continue, even after SVR, as a result of damage to the brain. 12 to 36 different sub variants of the virus have been identified in brain biopsy. Apoptosis of infected cells block aminogeric transporters causing loss of serotonin function.

II) Day-to-day life is affected by all of the above, but in order of frequency and importance:

Fatigue, muscle/joint pain limit general activity and job productivity/effectiveness.

Cognitive failure, fear of stigma and fear of social interaction limits both job effectiveness and general social interaction.

Pain during movement can lead to either overuse of painkillers (which can damage liver) or to avoidance of movement (which can lead to weight gain and other degenerative problems)

Digestive and iron-overload problems limit how one shops for and cooks food, one's diet vs. the family's diet, and when (how often) one cooks or eats, affecting this important part of family life and social interaction.

Financial difficulties ensue due to limited job possibilities coupled with the cost of controlling the disease: special food, supplements, and treatment drugs.

Feeling one must keep ones' HCV status secret, or to lie about it in order to preserve one's job or relationships is debilitating to one's spirit.

III) Activities patients report they now avoid or are unable to do at all:

Fulltime work

Work that involves a lot of physical activity

Work that involves speed (either physical or mental)

Work that involves a lot of social interaction

Work that involves possibility of cuts or other blood-to-blood contact

Contact sports

Public speaking

Eating in restaurants

Meeting new people

Job changes

Medical and dental work in which one should disclose one's HCV status

Dating – due to fear of stigma and social interaction along with sexual dysfunction

Travelling – due to fears of digestive upset, inability to communicate about one's condition, to cross borders with ones' medications, or to follow the diet one is used to, or possible non-availability of food or medicine one might need.

Active physical play with kids, grandkids

Computer work and reading – due to eye and/or concentration problems

15. What are the most important aspects of chronic Hepatitis C that they would most like to see improved with treatment?

I) Most of us in our group either failed treatment or are treatment naïve. We tend to deal with our condition through diet, exercise and supplements/alternative treatment which, though they DO make us feel better and probably slow the progression of the disease, are not going to cure us, and our disease continues its deadly progress.

(1) Our diet changes may include limiting amounts of such things as...

complex fats, refined grains, dairy products, simple sugars, animal proteins, iron, soy products, and chemical dyes and preservatives.

They may also include using large amounts of such things as...

organic fruits and vegetables, whole grains, fibre, protein (often involving legumes, eggs, and fish rather than red meat), simple oils (such as olive or grape-seed), complex sugars (such as molasses or maple syrup), liver-friendly teas and spices (such as turmeric), and sours (such as citrus juices, vinegar, plain yogurt, sauerkraut, kefir, or kimchi).

(2) Exercise members of our group do:

Walking, running, bicycling, dancing, golfing, gardening, yoga, tai-chi, and using elliptical trainer. Not being able to afford a car has actually helped some of us develop good walking and bicycling habits.

(3) Supplements and alternative treatment used in our group included: Cod-liver and other fish Oils, Milk-thistle, Co-enzyme Q10, SAME, selenium, L-glutamine, NAC, Chinese herbs, and acupuncture.

II) The current Standard of Care we have generally used for our condition, of course is dual therapy, pegylated interferon plus ribavirin. Those of us who have gone through SOC reported the following side-effects:

(1) Those who had been asymptomatic developed symptoms.

(2) Symptoms we had experienced before treatment tended to get worse - particularly fatigue, muscle and joint pain, depression, concentration, irritability and digestive upsets.

(3) These additional problems developed for some of us during treatment, in order of frequency...

Flu symptoms – fever, chills, dizziness

Weakness

Muscle and joint stiffness and slowness

Fatigue

Muscle and joint pain

Anemia (low red cell count)

Shortness of breath  
Irritability  
Depression  
Anorexia and extreme weight loss  
Nausea and vomiting  
Hair thinning, even loss  
Rash  
Itchiness  
Failure of anti-depressant, need to change type or dose coupled with greater intensity of depression  
Inability to concentrate  
Susceptibility to infection (low white cell count)  
Susceptibility to bleeding (low platelet count)  
Lack of interest in outside world  
Headache  
Detecting strange tastes and smells (in both food and self)  
Suicidal thoughts  
Constipation/lack of peristalsis  
Malabsorption  
Ischemic colitis  
IBS

(4) The side-effects that were severe enough to cause us to go off treatment (or strongly consider it) were...

Severe depression or rage  
Suicidal thoughts  
Severe anemia  
Lack of peristalsis and malabsorption

(5) The treatment side-effects tended to go away after 6 months or so. However, even several years following treatment, several of us still experience these symptoms, whether the treatment was successful or not...

Joint stiffness, swelling, pain (actually worse in those who went through treatment successfully)

Fatigue  
Depression  
Insomnia  
Fear of social interaction  
Inability to concentrate  
Double vision and general vision deterioration

We all still have to deal with the fear of stigma, whether we are considered 'cured' or not.

### III) Hardships in Accessing Current Therapy (in British Columbia)

(1) **Current treatment criteria disallow treatment for many symptomatic HCV+ people with low ALT counts.**

What good is advancing medicine if this disqualifier is used against those who manage their symptoms well enough to keep ALT low. Also, early treatment is much more effective earlier in infection but ALT is unlikely to be elevated in acute or early chronic stages.

(2) Pharmacare does not pay for EPO and other supplements which may help more people stay on treatment. Strangely, it does pay for transfusion and even transplant, which are far more expensive and could be avoided.

(3) Lack of healthcare worker knowledge about HCV transmission, progression, and treatment. They assume if you have it you are an IVDU.

(4) A multi-disciplinary treatment team is a real plus, but is not available in our city (Victoria) unless one is a 'street person'. The ACCESS/Cool Aid Health Centre has an excellent team and has a great track record for success in



supporting street people throughout treatment.

(5) Due to stigma, those on treatment who need to take time off work may be unable to do so as it would involve disclosing their condition to their employer.

(6) Due to lack of knowledge about the problems HCV+ people can develop over time, British Columbia's rules for granting Temporary Disability and Long-term Disability to HCV+ individuals are very arbitrary and inappropriate. People who are in the middle of treatment and suddenly find themselves unable to work are faced with a bureaucratic nightmare, and this stress can lead to treatment failure.

(7) Poor outcomes in rural area due to several reasons which could be resolved with education and support.

16. Victrelis™ is used to reduce the amount of the Hepatitis C virus in your body.

Studies looked at the following factors to assess if Victrelis™ is helpful and safe for the treatment of chronic Hepatitis C:

Sustained virologic response (undetectable Hepatitis C virus level for 24 weeks after the completion of therapy)

Disease relapse (durability of response)

Quality of life

Serious bad reactions (e.g. Blood problems: low red blood cell counts (anemia) which may lead to tiredness, headache and low white blood cell counts (neutropenia) which may lead to increased risk of getting infections)

We'd like to know which of these factors are important for the patients in your group. Please explain

Eradication of the virus would bring us back to healthy, effective, and productive members of our community.

The indolent nature of this virus has given the impression that it can be pushed to the back burner.

We have watched others who have completed successful treatment who experience a complete reversal of symptoms. The liver health improves, the symptoms are reduced in 80% of the clients, and the energy and vitality return after time off of the treatment. With the potential to have a shorter treatment time, the economic barriers become less substantial.

This hope is based on the idea that treatment decisions will be based on a improved level of patient centered care as recommended by the Consensus Guide for Management of Hepatitis C by Canadian Association for the Care of the Liver, not the provincial government which leads to worsened outcomes.

Shortened treatment times will lead to fewer psychiatric stresses endured from SOC. Other stresses from SOC include fatigue, brain fog, mood disturbances including depression, anger, sadness, and learned hopelessness which endures after treatment.

## EXPERIENCE WITH OTHER THERAPIES

Do **NOT** include experiences with boceprevir (Victrelis™).

17. List the common drug(s) the patients in your group have tried and **stopped taking** for chronic Hepatitis C. Please tell us why they have stopped taking them.

Chinese herbal formulations. ALT was successfully lowered however HCV RNA was not.

Unpegylated interferon ribavirin. Rapid virological response was obtained but not sustained to end of treatment.

Pegylated interferon ribavirin. Relapse after treatment.

Pegylated interferon with ribavirin. Viral load not substantially reduced and fertility rules applied.

Pegylated interferon with ribavirin and polymerase inhibitor; two successful drug trial candidates.

Pegylated interferon with ribavirin. Successful treatment for two group members.

18. List the common drug(s) the patients in your group are **currently taking** for chronic Hepatitis C and describe their experience with them.

Medical marijuana. Reduction of insomnia, reduction of depression, stimulation of appetite, reduction of nausea.

## EXPERIENCE WITH THE DRUG UNDER REVIEW

19. Have any of the patients in your group ever tried boceprevir (Victrelis™)?

YES

NO

*If you answered "Yes" to question 19, go to Question 20; otherwise, go to Question 21.*

20. Describe the experience the patients in your group have had with boceprevir (Victrelis™).

*Screening for the IL28B gene would determine if Boceprevir was necessary for people with other risk factors. There is no public health coverage for this genotyping, a \$405 cost to determine the need for an extra \$34,000 treatment. Our members have been going to the US to get this done although it was offered as a self-pay option for a brief period.*

Four weeks PRV and 44 weeks Boceprevir for all those in cirrhosis.

RNA should be measured at 12 weeks for previous non-responders.

IL28B testing should be available for patients with other auto immune problems; the preclusion of people with auto immune problems should not be a consideration for treatment OR for trials.

There should be a dermatologist who deals with rashes; the 'go to' person.

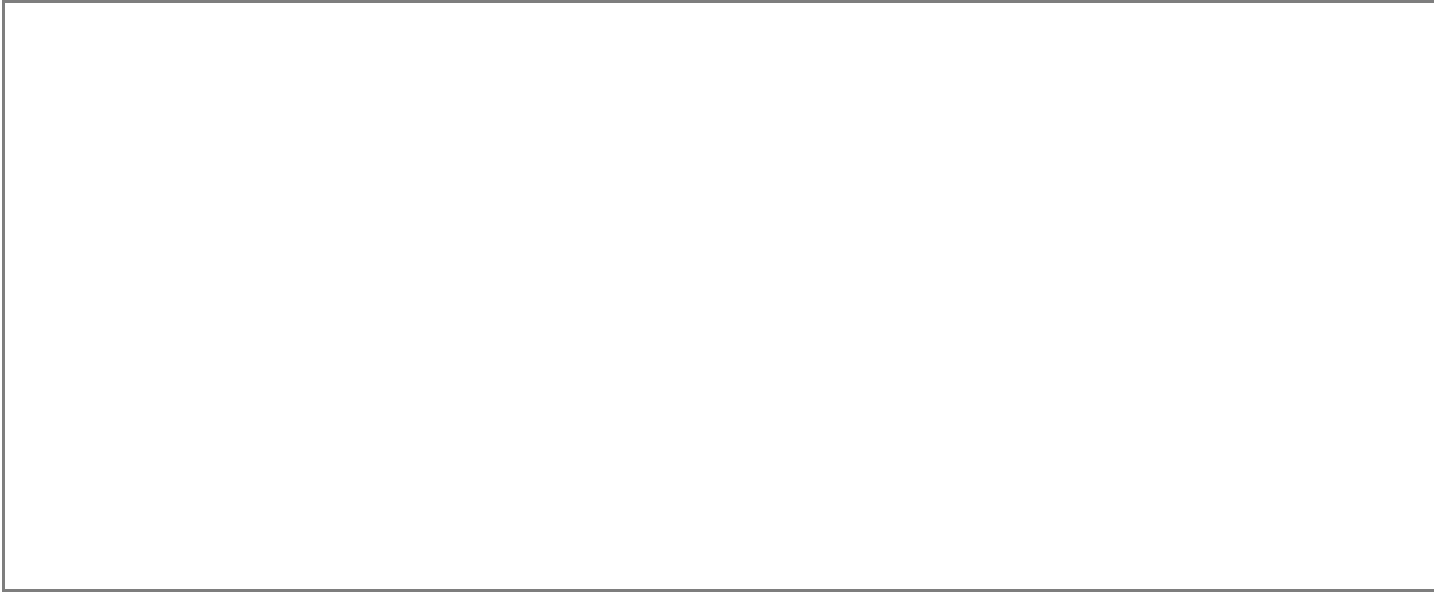
Internet access to diagnosis from rural areas should be encouraged and accessible.

Internet peer access should be encouraged and supported.

Anorectal symptom management should include fibre, loperamide, hydrocortisone, or paramoxine topical cream.

Erythropoietin should be offered rather than discontinue (and waste) treatment. Use transfusion for cirrhotic or

Depression screening should be administered and ecitalapram considered prior to treatment to stabilize depressed prone clients rather than on an as needed basis. Rather than waiting for 14 days after symptoms, start it two weeks before treatment.



## OTHER INFORMATION

21. If a new drug becomes available for chronic Hepatitis C, what aspects of their condition would the patients in your group want the new drug to improve?

The drugs that are being developed should go straight to market when they are approved at the Federal Level. There is a time when we know that approval is likely and we expect that the provincial drug review would not wait to do a review seen as a deliberate attempt to prompt the private health care providers to take the lead ahead of our public health care system.

There will be a rapid move away from treatment with the standard of care (SOC) pegulated ribavirin (PRV). We expect there are many patients who will not want to retreat until the SOC is not in the formula. Hopefully the Pharmacare will improve the response time to get those new treatments to us in a more timely manner.

22. What practical, financial or other factors (if any) would the patients in your group like to be considered in the review of boceprevir (Victrelis™)?

There are major problems with access to treatment for HCV clients as well as HIV/HCV infected.

Employment Insurance only allows for 15 weeks medical leave. The interruption of financial stability is traumatizing.

Mental health support has to be added to the team of hepatology practitioners, who also need incentives to take up this specialty. There has been little change to the level of treatment support workers since the start of pegulated interferon support groups are a major asset yet there is no support from provincial levels of government. We see our work could be combined with additional research to help curb this epidemic. Treatment alone cannot get ahead of the curve in the next few years, which will cost more if ignored now.



USE THIS PAGE IF YOU NEED MORE SPACE IN WHICH TO ANSWER QUESTIONS

A large, empty rectangular box with a thin black border, intended for providing answers to questions. It occupies the upper portion of the page below the instruction text.



MAIL YOUR COMPLETED QUESTIONNAIRE

Make sure that your last name and first initial appear on every page.

Clip or staple the pages together and mail to:

Public Input Formulary Management Pharmaceutical Services Division Ministry of Health Services 3-2, 15  
15 Blanshard Street Victoria BC V8W 3C8

THANK YOU FOR YOUR ORGANIZATION'S INPUT TO B.C. PHARMACARE'S REVIEW OF THIS DRUG

*Before your input is forwarded to the Drug Benefit Council, we will remove all personal information, including the name(s) of patients and any other identifying details. The name of your organization, however, will be included as part of your submission.*

*Would you like to learn more about the drug review process?*

Visit the PharmaCare website at [www.health.gov.bc.ca/pharmacare/outgoing/drugrevproc2.pdf](http://www.health.gov.bc.ca/pharmacare/outgoing/drugrevproc2.pdf)