Patient Group Input to CADTH

Section 1 — General Information	
Name of the therapeutic review	Drugs for Chronic Hepatitis C Virus Infection
Name of patient group	Positive Living Society of British Columbia
Patient group's contact information:	Positive Living Society of British Columbia 1107 Seymour Street - 2nd Floor Vancouver, BC V6B 5S8 (604) 893-2200 / 1 (800) 994-2437 info@positivelivingbc.org www.positivelivingbc.org
Date of submission:	January 9, 2014

1.1 Submitting Organization

Vision Statement
People living with HIV in BC are healthy and free to lead purposeful and actively engaged lives in an accepting, inclusive community.

Mission Statement
The Positive Living Society of British Columbia exists to enable persons living with AIDS and HIV disease to empower themselves through mutual support and collective action. From our personal struggles and challenges come our courage and strength.

Full Membership is free and open to all HIV+ British Columbians.
As a Full Member of POSITIVE LIVING BC you have a unique opportunity to empower yourself fully and to make a difference in the HIV-positive community, and gain access to the wide variety of POSITIVE LIVING BC services and resources in order to manage the challenges of living with HIV/AIDS.

Associate Membership is available for anybody who does not meet the criteria for Full Membership.

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:

Program Funding comes (or has come in prior years, in the case of Pfizer) from the following pharmaceutical companies:

Abbvie
Janssen
Gilead
Pfizer
Bristol Myers Squibb
Merck
ViiV

We also have funding relationships with unions whose membership is drawn significantly from healthcare-related fields:

Hospital Employees Union
BC Government Employees Union
CUPE-BC

Lastly, we receive program funding directly from health authorities and their designates, specifically:

Vancouver Coastal Health
Provincial Health Services Authority
Fraser Health Authority
Providence Healthcare

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

NONE NOT PREVIOUSLY MENTIONED

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

One-on-one interviews conducted with several persons –including members from within as well as persons outside our own organization with personal knowledge of hepatitis C treatment and / or involvement in discussions regarding such treatment; plus, ongoing discussions within two different regular organizational Board of Directors Standing Committee meetings which both deal in issues directly related to our population-of-focus (**our members, a number of whom are co-infected**) and for which this submission author has Minutes duties (Health Promotion Standing Committee and Positive Action Standing Committee) and thus, at which discussions regarding HCV treatments often occur; HCV medication overview knowledge obtained through personal attendance by the submission author at a CCO Symposium on both HIV and HCV, held in April, 2013, in San Francisco, as well as regular contact with several Infectious Disease specialists working at the nearby Immunodeficiency Clinic; plus, contact with HepC BC (a group of individuals seeking to help one another through HCV illness in this province); discussions with knowledgeable staff persons at the Canadian Treatment Action Council, which regularly provides information updates for interested patients and organizations dealing with HIV and with HCV, and with whom our Society has a close relationship; information provided by individuals working at CATIE – an information service for HIV- and HCV-positive clientele and their representative organizations, as well (and

whom we also work closely with); departmental team meetings at our workplace, that are informed through Peer Navigator reports, because they work directly within the St Paul's Hospital's Immunodeficiency Clinic and in the field, locally, to offer direct-to-client services, often to individuals requiring complex care arrangements including not only HIV illness but, not infrequently, HCV illness as well.

2.2 Impact of Condition on Patients

What are the condition-related symptoms and problems that impact the patients' day-to-day life and quality of life?

The following are just <u>some</u> examples:

My partner is infected with Hepatits C and I therefore am affected by the virus in my personal life. He struggles, as it is now, in being able to function and be independent on his own due to multiple health issues. He therefore relies on me for assistance in his day to day life. I am happy to assist him in as much as I can, but it makes him feel demeaned and less of a man. And with the work I do in charity, running a organic coop, being a Board of Director member and doing Community Based Research I am extremely busy as it is and as these are all important causes to myself and many others, it is vital to my self care to continue with these projects. A slip in my partner's health takes me away from my peers and community that rely on me.

The newer drug regimes coming available for Hepatits treatment would be so much easier on his body and have higher success rates of cure that this could be a life saver for my partner. The Pegetron, we have been told by our doctors would be so hard on his system at this point, in combination with his other health issues that it could kill him. The newer drugs, without the Pegetron, he could handle and he could be cured - thereby being a much more functioning member of society. This could also keep my loved one with me longer and in better health.

As I do speak on the international stage in regards to HIV and Health and Housing and the work I do in community, I see day to day the negative effects of Hepatitis C and knowing that there are cures available to people that prevent transmission and prevent the horrible side effects of Pegatron, I am saddened and dismayed that this would even be considered.

Given the scope of this study and this day and age when we do not need Pegatron, please reconsider the use of it in your study, we know that it's time is over and it is time for brighter days.

Separately, another view point to consider:

If given the options of treatments the important side effects that have mattered to me in consideration are:

It is important to me to be able to continue to work without side effects such as nausea and fatigue. As a productive member of society, living with HIV and Hep C, I take great pride in the fact that I am able to function in my job and my personal life with minimal to no interruption caused by these illnesses. I know that with the current treatment programs for Hepatitis C, I would face potential issues in continuing to do so and may have to rely on medical EI and/or my disability available through my benefits provider. To do those creates several issues to me, one of them being the pride in continuing to work through my illnesses and remain productive, the other being able to support myself while working through a possible cure to the

Hep C. I have people who rely on me at work to do an exemplary job in my career and I would not want to let them down. I have family and friends, as well as pets, who rely on me to assist them in their lives. I would not want to be in a position that is putting me in their hands to assist me instead. Especially since the potential cures for the Hep C virus that are now becoming available do not require that I am fatigued or ill during treatment.

Pegatron is known to have many side effects that given the possibilities of the new treatments, need not be included in treatment. As a person living with Hepatitis C, I would prefer to be cured of the virus without the use of Pegatron. If there are options available that will not cause me to have these side effects that can take me away from a productive work schedule, that can keep me from relying on assistance from benefits programs and from family and friends, then it does not make sense to me to include Pegatron.

It is important to me to be cured of this disease, and as soon as I can be. I have already faced six years with Hepatitis C and of those, the past three seeking to be treated for it. I have faced nothing but road blocks in seeking this treatment though. My liver has not yet experienced damage from the Hepatits C or from the meds I take for HIV, and my liver enzymes remain stable, according to the Province, I therefore am not eligible for treatment. Instead, I need to wait to be treated until I have experienced enough damage that I require it, that is I need to be sick to be treated and therefore am putting my health and well being at risk. Not only is this potentially bad for my body, but it creates a low self esteem issue as well. I have to be constantly concerned about my health as well as the health of my loved ones. This is causing risk for my loved ones of contracting the virus as well.

There are so many costs to this virus that can be avoided, financial and personal. Why would the consideration of Pegatron, with all of its unpleasant side effects need to be included in those costs? As a possible patient of any treatment for Hepatitis C, I do not see the reasoning behind the inclusion of Pegatron, the new treatments becoming available from testing reports that I have read and been informed of, including by my Hepatits specialist, do not require the use of it. By including it in all aspects of this study, you are not moving the cause forward in any positive manner, rather holding back treatments for those that need it and want it in order to protect ourselves and those around us. With the epidemic spreading, this needs to be a priority to prevent further infections and increased costs to the medical system as well as the individuals.

Thank you for re-considering the use of Pegetron in this study.

2.3 Patients' Experiences With Current Therapy

How well are patients managing their condition with currently available treatments?

Current standard-of-care is, as is well known, the so-called 'gold standard' of peg-INF+RIBA + DAA, as adding in boceprevir or telaprevir is quite common, now. Some patients are now being advised to wait for newer, better, more tolerable medications if their Fibroscan scores are low enough and if they can wait for peg-INF+RIBA-sparing regimens, at least three of which are in registration trials. One nice advantage with telaprevir and boceprevir has been the earlier marker for improvement and the potential for d/c where sufficient log drops by early (4, 12-week) timepoints don't occur. One negative, though, is that these still have the same long-standing anemic issues connected with ribavirin treatment and the peg-INTERFERON is no easy ride, either. ***New DAAs that also continue to include the peg-INTERFEROM plus ribavirin***

are really improvements over cure rates and duration <u>but not the side-effect profile during treatment period</u>.

Cure rates of Types 1, 2, 3 and 4 are well-known. These standards appear to be – in some cases – almost doubled with some coming medications that include simeprevir, sofosbuvir, faldaprevir, daclatasvir, ledipasvir, and particularly in the prevalent and-hard-to-treat Type 1.

As was noted, farther above, <u>the debilitation common to enduring long treatments is one of the hardest factors for patients to face</u>. <u>This must be addressed</u>.

One definite hardship is that RCT Phase III drug-licensing trials rarely, if ever – by design – include HIV-HCV co-infected individuals for reasons of seeking best-case scenarios in their outcomes; however, this can (and, until recently, certainly did) easily inhibit decision makers regarding provincial formularies making informed decisions about listings for co-infected persons. This directly impacts our own population-of-focus. **Thus, one suggestion for improvement would be perhaps a caution to regularly monitor AST, ALT, BUN, total bili, in addition to pVL, but for CADTH to nevertheless recommend to provinces an indication to treat with newer DAAs, especially the future DAAs which include sofosbuvir and others (faldaprevir, ledipasvir, as well as either polymerase or other protease inhibitors) if they spare peg-INF+RIBA, and particularly where these newer treatments having fewer side effects: This may be particularly important where previous null or partial responders, relapsers or those re-infected, seek re-treatment. Sometimes, people in these latter categories don't get a second chance, but we may be more hopeful with these coming treatments?**

2.4 Impact on Caregivers

See above comments regarding this.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

See answer 2.1 – same.

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

a) Based on no experience using the drug:

The biggest expectations appear to be the reduction in treatment duration, the likely higher cure rates, the possibility to re-treat prior null, partial responders, relapsers and those re-infected with newer, better technology.

As to experiencing serious adverse effects: The medications should improve upon the side effect profiles experienced to date or they will not be seen as any real improvement, outside of higher cure rates, thus begging the question of whether to go through all of that, especially if a patient is treatment-experienced but

not experienced with the new medication(s). **Would somebody go through that same experience again?**

The QoL issue (i.e., time off work) is a major issue. With greater emphasis on improvement of individuals' lives, overall, one cannot improve treatment without also improving ability to tolerate treatment and conduct life – especially over a period of time of six months or longer.

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

Increases in treatment effect, decreases in treatment duration – these are the goals and the standards being met as newer generations of HCV medications are approved.

Most folks seem to be open to tolerating an initial period of relatively mild discomfort when starting a regimen. **They are not so embracing of long-lasting treatments whose effects continue throughout. This is what needs to be improved most. This is why peg-INF+RIBA-sparing regimens are the hopeful wave expected**.

Section 4 — Additional Information

Navigation of the CADTH website to re-locate information about this particular patient-group input review, especially, as to its scope and closing dates, was neither simple nor – actually – possible: The author attempted to verify the status of the review that's due to close on January 13th on the day of January 7th but was completely unable to do so – despite several guided attempts, and being helped by staff at CTAC – to locate this same information that had actually been posted and was visible before the holiday period. This is extremely frustrating and may inhibit the ability of CADTH to gather the information requested and needed for a thorough review in this process.