pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review
Patient Advocacy Group Input on a Drug Review

June 2012

RECORD OF UPDATES

Update	Version	Reported on pCODR Website
Original	April 2011	April 27, 2011
Revised	June 2012	June 4, 2012

INQUIRIES

Inquiries and correspondence about the pan-Canadian Oncology Drug Review (pCODR) should be directed to:

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About Completing This Template

- This *Patient Advocacy Group Input on a Drug Review* template should be used by patient advocacy groups to submit input at the beginning of a drug review. The input template starts after these instructions. Please note that there is a different template for providing feedback on an initial recommendation.

- Patient advocacy groups must also complete the *pCODR Patient Advocacy Group Conflict of Interest Declarations* template when providing input at the beginning of a drug review, located in Appendix A of this document and available on the pCODR website (www.pcodr.ca).

- Patient advocacy groups must be registered with pCODR to provide input on a drug review. To register with pCODR please go to "Submit and Contribute" on the pCODR website, complete the online registration request form and submit the completed form to pCODR (See the *pCODR Patient Engagement Guide* for information on eligibility and registration.)

- Please note that only one submission per patient advocacy group is permitted. This applies to those groups with national and provincial / territorial offices; only one submission for the entire patient advocacy group will be accepted. If more than one submission is made, only the first submission will be considered. Individual patients should contact a patient advocacy group that is representative of their condition to have their input added to that of the group. If there is no patient advocacy group for the particular tumour, patients should contact pCODR for direction at info@pcodr.ca.

- Please ensure that the input is in English, and that it is succinct and clear. Please use a **minimum 11-point font** and do not exceed **eight (8) typed**, 8 ½" by 11" pages. If a submission exceeds **eight pages**, only the first **eight pages** will be considered. Patient advocacy group input must be submitted to pCODR by **5 P.M. Eastern Time** on the day of the posted deadline.

- Patient advocacy groups should complete those sections of this input template where they have substantive comments and should not feel obligated to complete every section, if that section does not apply to their group. Similarly, groups should not feel restricted by the space allotted on the form and can expand / contract the tables in the template as required. **The page limit of eight (8) typed pages remains**.

- You may delete the instructions, questions and examples under each heading on the *Patient Advocacy Group Input on a Drug Review* template for more space. Appendix A is NOT included in the **eight (8) typed page limit** for the *Patient Advocacy Group Input on a Drug Review* template.

- In sections 2 and 3 of the *Patient Advocacy Group Input on a Drug Review* template, guidance or examples are provided to help identify the type of information that pCODR will find most helpful to understand the needs and preferences of the majority of patients. Objective, experiential information that is representative of the majority of the patient advocacy group is preferred.

- Patient advocacy groups are encouraged to address the questions posed in the input template as succinctly as possible and to communicate key messages.

- Scientific, published references are not required, as pCODR has access to current scientific literature through the manufacturer's submission and a rigorous, independent literature search. Published studies are reviewed by the clinical guidance panel and summarized in the Clinical Guidance Report.

- The patient advocacy group input must be submitted by the deadline date for this drug, posted on the pCODR website under "Find a Review" so that it can be available in time to be fully used in the pCODR review process.

- In addition to its use in the pCODR process, the information provided in your submission may be shared with the provincial and territorial ministries of health and provincial cancer agencies that participate in pCODR, to use in their decision-making. Any patient-specific personal information will be removed.

- Information about pCODR may be found at www.pcodr.ca. For more information regarding patient input into the pCODR drug review process, see the *pCODR Patient Engagement Guide*. Should you have any questions about completing this form, please email: info@pcodr.ca.

Patient Advocacy Group Input on a Drug Review

1 Information about the Patient Advocacy Group

Please expand / contract the tables in the template as required. Please use a **minimum 11-point font** and do not exceed **eight (8) typed, 8 ½" by 11" pages**. If a submission exceeds eight pages, only the first eight pages will be considered. This page limit does not include Appendix A or reference list. **You may delete the instructions and examples under each heading for more space.** Should you have any questions about completing this template, please email pCODR at info@pcodr.ca . Patient advocacy group input must be submitted to pCODR by **5 P.M. Eastern Time** on the day of the posted deadline.

Name of the drug and indication(s): Avelumab

Name of registered patient advocacy group: Save Your Skin Foundation

Contact person: Kathleen Barnard

Title: President

Phone: 604-842-5658

Email: Kathy@saveyourskin.ca

1.1 Information Gathering

Please briefly identify how the information to complete Sections 2 and 3 was obtained. Was it obtained, for example, through personal experience, surveys, focus groups, one-to-one conversations with a number of patients using current therapy, printed sources, etc?

Information was obtained by on line survey
Out of the 57 responded
-over 70% were male
-over 57% were between the age of 51 – 65 years, over 40% were over 66 years.
-over 36% of patients have had other non-MCC
-over 57% of patients were between 51 – 65 Years old when first diagnosed-
-over 80% of patients had mass removed by surgery
- over 60% of patients lymph gland were comprised

1.2 Confirmation of Authorship

I have the authority to declare this patient advocacy group has sole authorship of this submission and to confirm that no other parties have written or participated in the writing of the submission.

Oct 24th 2017

Signature

Date (YYYY/MM/DD)

2 Condition and Current Therapy Related Information

2.1 Experience Patients Have with This Type of Cancer

The diagnosis of cancer impacts all aspects of patients' lives. Furthermore, different cancers, and stages of cancer, affect patients in different ways. Recognizing this, the focus of the information requested in this section relates to the impact of the cancer for which the drug under review is indicated. What are the symptoms and problems associated with this cancer that impact a patient's day-to-day life and quality of life? Examples of the type of information that could be included are:

- Which aspects (e.g., cough, pain, edema, appearance) of this cancer are more important to control than others?
- How do ongoing symptoms affect day-to-day life?
- Describe any limitations as a result of the cancer.

You may delete the instructions and examples under each heading for more space.

Lack of information on this type of cancer

Lack of knowledge of this type of cancer to some physician which cause misdiagnosis

Fear of being diagnosed with a RARE deadly cancer

Scarring and disfigurement

Couldn't go to work

Being told surgery, radiation and chemo were the only option for treatment

Fatigue

Depression

Weight Loss

Barriers is receiving clinical trials

Psychological barriers

2.2 Patients' Experience with Current Therapy

How well are patients managing their disease with currently available treatments? Examples of the types of information that might be included are:

- What therapies are patients using to treat this type of cancer?
- How effective is the current therapy in controlling the common aspects of this cancer, e.g., pain, fatigue?
- What are common adverse effects and are some more difficult to tolerate than others?
- Would patients be willing to tolerate potential adverse effects resulting from treatment, if the benefits were only short-term?
- Are there hardships in accessing current therapy? Can patients readily access available treatments in their own communities?
- In addition to the drug cost, are there other financial implications to patients or caregivers (e.g., traveling costs, drug disposal issues, drug administration supplies)?
- Are there needs, experienced by some or many patients that are not being met by current therapy? What are these needs?

You may delete the instructions and examples under each heading for more space.

Previous treatment were limited to surgery, radiation and chemotherapy. 100% of patients surveyed realized this was a RARE skin cancer with very low survivorship and were willing to tolerate all potential adverse side effect from treatment even for a short term benefit.

For patients that went through radiation the experienced: nausea ,vomiting, diarrhea, fatigue dry mouth, and sores in mouth. All patient that had radiation said the side effects were temporary.

Patients that underwent surgery experience: Loss of work, mobility issues, disfigurement, depression.

Patients that were treated with chemotherapy were difference depending on dose. But all patients surveyed had at least 3 of the following: hair loss, loss of appetite, nausea and vomiting,, depression.

70% of patients interviewed had surgery to biopsy the mass
54% of patientshad surgery to remove the mass and surrounding tissue
60% of patients had surgery to remove the mass, surrounding tissue and lymphnodes
60% of patients had radiation
22% of patients had Immune therapy
18% had chemotherapy
16% participated in a clinical trial
61% have not had re-occurence

2.3 Impact on Caregivers

What challenges do caregivers face in caring for patients with this type of cancer? How do treatments impact a caregiver's daily routine or lifestyle? Are there challenges in dealing with adverse effects related to the current therapy?

You may delete the instructions and examples under each heading for more space.

Couldn't go to work

Caregiver had to take on a more active role with house hold duties

Living knowing that their loved one might not make it = suffered anxiety and depression

All caregivers interviewed were surprised at the lack of knowledge and awareness around this type of cancer.

3 Related Information about the Drug Being Reviewed

3.1 What Are the Expectations for the New Drug? Based on no experience using the drug:

- How much improvement in the condition would be considered adequate with this drug compared with current drug therapy?
- Is it expected that the lives of patients will be improved by this drug, and how?
- Is there a particular gap or unmet patient need in current therapy that this drug will help alleviate?
- What are the potential risks associated with the drug and do they outweigh the benefits?
- What other benefits might this drug have—for example, fewer hospital visits or less time off work?

You may delete the instructions and examples under each heading for more space.

All patients surveyed were glad to be part of a clinical trial and were willing to take the risk for any life gain whether short or long term.
All patients surveyed had heard about the new treatments coming to cancer and were thrilled that something was on the horizon for MMCC and that they had the opportunity to take part
All patients surveyed understood the survival benefit and the side effects but were willing to go through for a change at more time with their family and loved ones.
All patients felt this treatment gave them HOPE in a very bleak diagnosis
All patients are living with the anxiety of their MMCC coming back as they had been told at their first appointment that this type of cancer was rare and deadly..
All patient with MMCC understood that not a lot is known about this type of cancer and there was a high risk that they could develop other Skin Cancers.
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3.2 What Experiences Have Patients Had To Date with the New Drug? Based on patients' experiences with the drug as part of a clinical trial or through a manufacturer's compassionate supply or by paying for it out of pocket or through private insurance:

- What positive and negative effects does the drug have on the disease?
- Which symptoms does the drug manage better than the existing therapy and which ones does it manage less effectively?
- Does the drug cause adverse effects?
- Which adverse effects are acceptable and which ones are not?
- Is the drug easier to use?
- How is the drug expected to change patients' long-term health and well-being?

You may delete the instructions and examples under each heading for more space.

All patients surveyed had at least 3 of the following side effects (highest to lowest)

Fatigue/lack of energy

Diarrhea

Nausea

Rash

Decreased appetite

All patients surveyed said not only were the side effects manageable, they were also still able to have a good quality of life.

All patients surveyed said that the one side effect that they did not encounter with hair losee and that made them all extremely happy. All surveyed said that losing their hair during cancer was the hardest symptom they could have encountered, That they could deal with nausea and fatigue but not hair loss.

All patients surveyed that the administration of the treatment was generally uneventful and that they had a clear understanding of what to expect during and after treatment.

4 Additional Information

Please provide any additional information that would be helpful to pCODR. This could include suggestions for improving the patient input process, indicating whether the questions are clear, etc. **You may delete the instructions and examples under each heading for more space.**

This submission reminded me of the first submission we did for our Canadian Melanoma patients back in 2011. It was hard to find surviving patients to interview. But we also understood from this survey similar to the Melanoma submission we did in 2011, is that there is a lack of education of this type of cancer, there is little hope, and current treatment options are surgery, radiation and chemotherapy and that anything new and innovative gives these patients HOPE.

Appendix A: pCODR Patient Advocacy Group Conflict of Interest Declarations

Name of registered patient advocacy group: **Save Your Skin Foundation**

Name of drug and indication under review: **Avelumab**

Conflict of Interest Declarations

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. Patient advocacy groups must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. Conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the patient advocacy group input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry e.g., educational or research grants, honoraria, gifts, and salary;
- affiliations or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

1. Has this patient advocacy group received any payments over the previous two years from any company or organization that may have direct or indirect interest in the drug under review?

   □x Yes
   □ No

   If no, please go to Section B

2. What form of payment did this patient advocacy group receive? (Check all that apply.)

□	Operating Funds	x	Program Funding (e.g., website)
□	Royalties	x	Research/educational grants
□	Gifts	□	Sponsorship of Events
□	Honoraria	□	Other, please specify: _____

3. Please provide the names of companies and organizations and the amounts of the payments in the box below.

EMD	$20,000
Merck	$25,000
Novartis	$50,000
BMS	$75,000
Roche	$40,000

Section B: Holdings or Other Interests

Has this patient advocacy group received or is it in possession of stocks or options of more than $10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list in the table below.

NO

Section C: Affiliations, personal or commercial relationships

Does this patient advocacy group have personal or commercial relationships either with a drug or health technology manufacturer (including such manufacturer's parent corporation, subsidiaries, affiliates and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations and outline the nature of these relationships in the table below.

No

I hereby certify that I have authority to disclose all relevant information with respect to any matter involving this patient advocacy group with a company, organization or entity that may place this patient advocacy group in a real, potential or perceived conflict of interest situation.

Date: Oct 24th 2017 Name: Kathleen Barnard Signature:_____