

January 11th, 2011

Hello,

I am writing to follow-up on my communication of December 21st where I provided a summary of the feedback we received as a result of the information session we hosted with pharmaceutical manufacturers in late November. This communication is to let you know the results of the Steering Committee's deliberations around two specific issues raised during those sessions.

1. The first was a concern was about how two submission streams (i.e. one from pharmaceutical manufacturers and the other from tumour groups) will work. It is important that all stakeholders—pharmaceutical manufacturers, tumour groups and patient groups—are aware of the drugs under review. As noted, two submitter types may cause confusion or duplication of effort. pCODR will coordinate this activity, with input from the Provincial Advisory Group, as required. This will involve establishing a notification process so we can alert the appropriate parties if we see any duplications.
2. The second request was about involving members of the clinical and economic guidance panels in pre-submission planning meetings. We agree that having consistent information move from the pre-submission phase to the guidance panel review phase is very important. To that end, the pCODR Manager of Reviews will ensure that issues raised during the pre-submission meetings are provided to the guidance panel members when they begin their work (which could be some time later given that pre-submission work may occur several months in advance of the submission review.)

To recap my December 21st communication, pre-NOC submissions will be permitted and we are currently working with the Industry Oncology Working Group to determine how information clarification during a review will take place. As details on these two elements are available, I will be in touch.

As a reminder, we welcome your nominations for pERC Chair; these are due January 14th.

We look forward to our continued work together,

Sincerely,



Mona Sabharwal
Executive Director