Patient Organizations Cautiously Optimistic with New pCODR Process

By DEB MASKENS

The pCODR (pan-Canadian Oncology Drug Review) process was long anticipated by patient groups as an opportunity to provide early and meaningful input into a more open, transparent review process for cancer drugs.

December 2011 marked a first for pCODR, with the completion of its first drug review—pazopanib (Votrient)—for advanced kidney cancer. While other oncology drugs are currently under review, we believe that patient groups and the public have every reason to be encouraged.

Where the former process (the Joint Oncology Drug Review—JODR) was perceived as a black-box closed process, pCODR has openly invited and clearly incorporated patient input and feedback. The first patient group to experience the full process, Kidney Cancer Canada, strongly supports the new process. Through the Canadian Cancer Action Network (CCAN) Drug Review Working Group (DRWG), patient advocates are committed to working to strengthen and improve the patient voice in the pCODR process. We remain hopeful that a pan-Canadian drug review with strong support from the provinces will contribute to greater consistency in coverage between provinces and reduce unnecessary duplication of effort across our provincial health systems.

The Evolution of pCODR

pCODR is the review body established through interprovincial collaboration to conduct clinical and economic reviews of cancer drugs and to provide recommendations about funding to the participating provinces (all provinces except Quebec). pCODR has gathered the best talent in Canada to establish a high quality review process, including experts in the clinical and economic aspects of cancer drugs. Patient input is also an important component of pCODR.

pCODR was launched in July 2011. Its structure was based on experiences gained from the interim JODR process, which had been in place since 2007. Throughout the development of the new pCODR, patient organizations including CCAN provided substantial input into how the pCODR process should be structured and how it should function in terms of transparency and communication with patient organizations.

Many cancer advocacy groups identified the need for the patient and caregiver experience of the disease and drug treatments to be directly presented and equally considered early in the review process.

The architects of pCODR welcomed many of these suggestions. Three patient representatives now sit on the pCODR Expert Review Committee, which is responsible for reviewing drug submissions.

Patient groups are invited to make two formal submissions for specific drugs under review. These submissions include a qualitative and quantitative summary of the patient experience with the drug, including side effects, quality of life, treatment alternatives, and views on the specific disease and treatment options. A second submission gives patient groups an important opportunity to provide feedback on pCODR’s initial recommendation. Patient groups must pre-register with pCODR and must meet certain funding requirements that work to ensure a balanced and objective submission.

CCAN and pCODR Working Together

On behalf of its member organizations, including national cancer patient organizations, provincial and population groups, CCAN created the DRWG to promote the interests of cancer patients with pCODR. The DRWG represented a major strategic area of focus for CCAN in 2011 and also in 2012.

The Drug Review Working Group identified that one of the main barriers to patient groups being perceived as credible contributors to the process is the perception by some reviewers of influence by pharmaceutical sponsors, through the grants given to groups. Indeed, many patient organizations reach out to corporate sponsors, including pharmaceutical companies, for unrestricted education grants to fund patient meetings, conferences, materials and core operating costs. The truth is that with no public healthcare funding available to support patient advocacy organizations in Canada, these valuable organizations simply could not exist without private donations and corporate support. Independent patient advocacy organizations are especially important in light of the fact that many organizations or agencies that receive federal government funding are strictly prohibited from advocating at the federal level (e.g., for a national catastrophic drug plan).

To address the issues of any real or perceived biases, the CCAN DRWG created and implemented a standardized Code of Conduct Governing Corporate Funding for CCAN member organizations. The Code was based upon international standards for patient organizations including the European Cancer Patient Coalition and the International Association of Patient Organizations. The Code launched in January 2012 to clearly delineate the boundaries and conditions of financial relationships between patient organizations and their commercial sponsors. Organizations displaying the
To answer these questions, patient organizations must first find the patients who have had early access to the new drug (most often through a clinical trial). Due to privacy issues, patient organizations cannot simply obtain a list of patients who participated in trials. Recruitment for the patient survey may be unrealistic unless a) trials have been conducted in Canada and b) oncologists encourage their patients to contribute to the drug review process by offering their personal experiences.

3. Broadening the Conflict of Interest Disclosures to Promote Fairness
The Drug Review Working Group strongly believes that a singular focus on pharmaceutical funding as the only source for bias in the process is not sufficiently comprehensive and misses other significant potential conflicts of interest. Patient organizations have other sources of funding and other sources of potential biases. In addition, other stakeholders in the process have significant biases that are neither declared nor itemized to the same degree of detail. Our recommendation is for all groups to openly disclose all potential sources of support (in-kind, charitable donations, and grassroots effort) in addition to the singular dimension of industry funding.

4. Monitoring Provincial Reimbursement Decisions
Whether pCODR is successful in reducing provincial disparities remains to be seen. We will be watching carefully for provincial decisions to adopt the pCODR recommendation for each drug reviewed. Given the stated commitment from the provinces to support pCODR, we expect shorter decision cycles that will allow cancer patients access to the therapies they need.

DRWG will continue to work on forging a strong relationship with pCODR and to mutually find ways to strengthen the patient voice in the drug review process. We welcome your comments.

Through pCODR, we have a unique window of opportunity for Canadians to work together to develop a world-leading cancer drug review process. Our experience has been that pCODR is open to input and recognizes the unique value of the patient perspective. We will continue to work with pCODR to maximize opportunities for the patient voice to be heard.

Deb Maskens is Chair of the CCAN Drug Review Working Group www.ccanceraction.ca and Chair and Co-Founder of Kidney Cancer Canada www.kidneycancercanada.ca.

Members of the CCAN DRWG include: Marjorie Morrison, Vice Chair (Canadian Cancer Action Network); Tanny Nadon (Canadian Skin Patient Alliance); Sue Robson (Lymphoma Foundation Canada); Aldo Del Col (Myeloma Canada); Colleen Savage (Cancer Advocacy Coalition of Canada); Lauren Dobson Hughes, (Canadian Cancer Society); and Susan Turner (Facilitator).

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