Mood Disorders Society of Canada
La Société Pour Les Troubles de L'Humeur du Canada

ENSURING *MEANINGFUL* PATIENT INPUT

Response to request for stakeholder feedback on Patient Group Input guidelines and template from the Canadian Agency for Drug and Technologies in Health (CADTH)

From:

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Recommendation 4: Your request for patient input may serve CADTH's needs but it ignores the reality of the limited resources most patient groups have. Completing the template is, in fact, highly labour-intensive and it requires considerable specialized expertise to frame our remarks in the context demanded. If CADTH wants patient input, and it seems that you do, you must design processes that speak to our reality and provide a choice of pathways for us to participate.

Recommendation 5: The conflict of interest declaration must be crafted in the context of the actual relationships patient groups have with the pharmaceutical industry.

Recommendation 6: Your communication has to be much clearer regarding exactly what information you want from patient groups. There are numerous points of internal contradiction in both the guideline and the template. You need to consult patient groups about what information they want to provide.

Recommendation 7: If you want patient groups to hold focus groups, conduct individual interviews or survey their membership to find out who has participated in a clinical trial for the drug under review, you have to give us the funding and the time to do so. Otherwise, scope your requirements in light of our reality.

Recommendation 8: You need to be precise about what you will do with the information you are requesting along with the weight you will give it and how and when it will impact the decision-making process. You also need to be clear about what method you will use to let us know how our input has been used.

Recommendation 9: Include patients and caregivers – right at the outset - in crafting the processes and communications that relate to them. You will get communications that are clear, a process that works and the input you need.

1. INTRODUCTORY REMARKS

Patients, more than any other group, have a profound stake in what drugs are approved in Canada as their lives are seriously affected, often in life or death situations.

For a number of years now, patients have been advocating for their meaningful involvement in the drug review process and, most important, in the decision-making regarding drug approvals so that their perspectives can be taken into account.

In the field of mental health, consumers and families have been involved in developing, delivering and evaluating services for approximately 25 years. We also sit on Boards of Directors, government task forces, research committees and other bodies of influence. As a result of our presence, the manner in which decisions are made about mental health services, research and government policies has been transformed.

Our involvement was initially met with tremendous resistance and, once recognized as inevitable, with multiple barriers to our meaningful inclusion.

In preparing to respond to your call for our input, I was reminded of the early days of patient involvement in the mental health field.

Note that I am going to be using the word "meaningful" repeatedly because that is the crux of the matter. Our participation has to have real meaning and impact or it is worse than useless for you to ask us for our views.

2. BARRIERS WITHIN THE PROPOSED PROCESS THAT PREVENT PATIENT GROUPS FROM PROVIDING MEANINGFUL INPUT

a) The drug review process itself

Those intimately involved in the drug review process will likely admit that it is complicated – and critics argue that it is opaque. Certainly, it takes considerable research to obtain even a cursory understanding. Patients who attempt to inform themselves are met with a heavy barrage of jargon, acronyms, and complicated graphs (as the one contained in the Guidance document, for example).

In order for patients to have meaningful input they need communication that is straightforward and in language that is easily understood. You can look to the tenets of knowledge transfer in the research world to inform yourselves.

What clear language *does not* mean is dumbing down communications. What it does mean is clear explanations of the processes and identification of openings for meaningful patient input, along with an explanation of how the input will be taken into account and how patients will *know* that it's been taken into account.

As an illustration, groups like the Consumer Advocare Network take upon themselves the work of translating missives from CADTH (and others) so that their members can have an idea of what you are talking about. It should not be the patients' job to climb over this mountain of complexity to have their voices heard. Insider jargon-

ridden communication regarding the subject or process patients are being asked to comment upon constitutes a barrier to patient participation.

Recommendation 1: All communication needs to be purged of jargon and insider language. Processes upon which comment is requested need to be clearly explained.

b) Tone

In your template and guideline, there is considerable space devoted to the rules of engagement. For example, no individuals can participate, only patient groups. There are a variety of types and sizes of patient groups – not all organized around a shared disease or condition. Which patient groups do you mean, exactly? Why are individuals excluded?

You invite patients (in groups) to provide any information they want to regarding living with their condition but it must be in six pages only (11 point font) – no page beyond six will be read and this must be done within 15 business days.

These admonitions may have a sensible rationale behind them but they read as curmudgeonly finger waving at patients who are prone (you seem to be saying) to taking too much time to tell their long-winded stories of suffering. You're busy people. You don't have time for that sort of patient input.

Recommendation 2: Pay attention to the tone of your request for input from patient groups. Presently, your criteria for submissions are serving only your needs. There needs to be more pathways for patients to provide input and more time for them to do so.

c) Creating a level playing field

One of the barriers to meaningful patient input is utilizing structures and communication pathways developed by and for professionals, researchers, drug companies and CADTH itself – without regard for the needs of the people from whom you are requesting input.

For example, if patients are going to be succinct and to the point, they need much more information on what they are to comment upon. Your guide says they can go to the data base and find out which drugs are under review but these drugs are listed in alphabetical order - by drug name not by condition. Patient groups would have to scroll through all 186 to find a drug relevant to their condition upon which to comment. An easy fix is a second data base where the drugs under review are sorted by condition.

A related problem is, where are patient groups to obtain unbiased and objective information on the supposed benefits of the drug under review? In order to provide meaningful commentary that is useful to the review process, patients will need an understanding of what difference the new drug is promising to make in their lives, along with associated risks and side effects.

Patient groups must subscribe to receive emails regarding drugs under review. Does this mean that you will alert, for example, the Mood Disorders Society of Canada when a new (or a new use for an old) psychiatric medication is under review. Or

does this mean you will send generic alerts to all registered patient groups and let them sort out whether or not there is anything of interest to them?

The navigability of the CADTH website is itself an issue - for anyone. Why visitors are required to fill out a short questionnaire every time they want to look at a document is a barrier to usership with no obvious utility.

Recommendation 3: While it is a step forward to request patient input into the drug review process, there are numerous unrecognized and thus un-addressed structural barriers to our participation in the one and only proposed process.

d) Resources

Large patient groups may have dedicated staff to respond to calls for input (noting that these calls come from multiple sources – all with their own complexities to be understood) but most patient organizations are small, with few resources other than dedicated volunteers. The federal government provides very little funding to such groups while the provinces are somewhat more generous. How are patient groups, without compensation, to find the resources to respond to your call for input? How are they, without compensation, to develop and nurture the necessary expertise so that our remarks can be framed within the context of substantial knowledge about the drug review process, provincial/territorial formularies and the purported promises made for the therapeutic value of the drug under review? And do this in 15 business days and in six pages. Would it not make sense to have other, less costly avenues for input?

Canadians are the highest per capita users of psychotropic medication in the world.[1] It follows that mental health consumer and family groups (we do not use the word patient) have a considerable stake in the drug approval process. In addition, people with mental illness are over represented among the poor, disabled and the elderly, meaning that they are dependent on medications approved for the provincial/territorial formularies. Yet the groups that represent their interests remain small and have very few resources. The process proposed for including patient input in the drug review process, as it is presently designed, would mean that we will not be able to participate – not because we don't want to but because we literally cannot.

Recommendation 4: Your request for patient input may serve CADTH's needs but it ignores the reality of the limited resources most patient groups have. Completing the template is, in fact, highly labour-intensive and it requires considerable specialized expertise to frame our remarks in the context demanded. If CADTH wants patient input, and it seemsn that you do, you must design processes that speak to our reality and provide a choice of pathways for us to participate.

[1] Rehm, J., and Weeks, J. (2005) Abuse of controlled prescription drugs. In Substance abuse in Canada: Current challenges and choices. Ottawa: Canadian Centre on Substance Abuse. Available at: www.ccsa.ca.

3. BARRIERS WITHIN THE TEMPLATE THAT PREVENT PATIENT GROUPS FROM PROVIDING MEANINGFUL INPUT

a) The conflict of interest stipulation

Given recent public concerns regarding the obvious conflict of interest among contract researchers, the revelation that academics often lend their name to articles that were actually written by pharmaceutical company employees and the reality that 90% of drug trials are designed and funded by the same pharmaceutical companies that intend to market them,[2] it is understandable that there is a heightened sensitivity at CADTH regarding real or perceived conflict of interest.

The strong language in the conflict of interest stipulation for patient groups is crafted, I assume, in response to the above sensitivity. However, it should be customized in light of the *actual* relationship patient groups have with pharmaceutical companies. Patient groups pursue grants from pharmaceutical companies for the purpose of general education. They make it clear verbally and in writing that they will not promote any product but, in the service of educating their constituents, will offer general information about all relevant medications through brochures and conferences - typically. In many cases, pharmaceutical companies provide grants for educational activities that have nothing whatsoever to do with medication. Patient groups also stipulate that their name can not be used in any commercial marketing material and that grants are only accepted if they are provided on an unconditional basis.

The Mood Disorders Society of Canada's published policy is as follows:

"Specifically, we ask – and receive assurances – that:

- Corporate and organization partners provide donations free from encumbrances or restrictions.
- Our corporate partners and MDSC jointly agree that it is not in our mutually best interests for Mood Disorders Society of Canada to support, endorse or advertise any product or service.

MDSC honours its corporate supporters and partners through public acknowledgement on its website and through its various projects and publications."[3]

I agree that patient group input could be placed in the context of declaring the grants they have received from specific pharmaceutical companies but this statement must be accompanied by a copy or a link to their policy that describes the unconditional circumstances under which grants are sought, received and used. Providing this information serves the goal of transparency as it shows clearly that patient groups have addressed the issue of conflict of interest head-on and have responded proactively with clear policies that are accepted by the pharmaceutical industry. This declaration also shows that how patient groups do business with the pharmaceutical industry is very different than how researchers, physicians and academics do business.

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[2] Silversides, A. (2006). Women and health protection policy brief. Available at: http://www.whp-apsf.ca/en/documents/trans_policy.html

[3] Available at: http://www.mooddisorderscanada.ca/page/corporate-support

Recommendation 5: The conflict of interest declaration must be crafted in the context of the actual relationships patient groups have with the pharmaceutical industry.

b) What are you asking us for, exactly?

The template implies you want two levels of information. First, you seem to want general statements on how the condition affects people and their caregiver's on a day-to-day basis in the context of drugs currently available and second, how the lived experience would change if the drug under review became available. As per previous comments, how are we to respond to your second requirement when we have not been provided with objective information on what the new drug is supposed to do – along with its attendant risks? If you were to consult with patient groups, they might tell you that they would like to provide additional valuable information.

Recommendation 6: Your communication has to be much clearer regarding exactly what information you want from patient groups. There are numerous points of internal contradiction in both the guideline and the template. You need to consult patient groups about what information they want to provide.

c) Expectations regarding the methods of gathering this information

Given resource constraints, holding focus groups or conducting individual interviews is out of the question for most patient groups. And if a lack of resources weren't barrier enough, the timeline (15 days) is completely unrealistic. That said, these sorts of demands are not unique to CADTH where organizations routinely assume that patient groups, uncompensated and at lightening speed, will respond to any and all demands for information and input. In your case, you add to your demands by stating that you'd like to hear from people who have been on clinical trials or in receipt of manufacturer's compassionate supplies. How do you suppose we are to find out who among our membership has had these experiences (assuming they want to disclose) and then collect their opinions for your needs?

Recommendation 7: If you want patient groups to hold focus groups, conduct individual interviews or survey their membership to find out who has participated in a clinical trial for the drug under review, you have to give us the funding and the time to do so. Otherwise, scope your requirements in light of our reality.

d) What will you do with this information?

Your rationale for needing this information is insufficiently explained. You say it will help in your decision-making but you leave it at that. At what point in your decisions will it be taken into account? How will it be analyzed and summarized – noting that we have a long history of providing our experiences only to have them misunderstood and mis-interpreted. What weight will you give our perspectives? How will we hear about what sort of influence we've had. At present, this appears to be one-way communication – we submit, you receive and we don't hear from you until you want another submission. Gone are the days where patient groups participate blindly based only on vague assurances that what they have to say will be taken seriously.

Recommendation 8: You need to be precise about what you will do with the information you are requesting along with the weight you will give it and how and when it will impact the decision-making process. You also need to be clear about what method you will use to let us know how our input has been used.

4. Conclusion

At MDSC, we are glad you have responded to patient advocate groups' requests for input into the drug review process. That is the first step. The more difficult steps are related to how to include our voices and experiences in a meaningful way that has (and is seen to have) real impact on decision-making. With limited funds and staff, MDSC must constantly balance priorities. Engaging in time consuming processes where we can reasonably predict little or no possibility of achieving positive change for Canadians living with depression, bipolar disorder is, understandably, a low priority for us.

Recommendation 9: Include patients and caregivers – right at the outset - in crafting the processes and communications that relate to them. You will get communications that are clear, a process that works and the input you need.