

Health Canada

**Health Products and Food Branch (HPFB)
Office of Consumer and Public Involvement (OCAPI)**

**Report on the Best Medicines Coalition (BMC)
Consultation Workshop**

**December 13, 2002
Ramada Hotel and Suites
Ottawa, Ontario**

Canada 

TABLE OF CONTENTS

Introduction / Overview	2
Getting Started.....	3
Opening Comments	3
Context/Boundaries	3
HPFB Issues Requiring Patient Involvement.....	4
Who in the Patient Community do we Need to Consult with?.....	6
How should we Consult	8
Principles for Consultation	8
Challenges / Obstacles to Effective Consultation	9
Potential Patient Involvement Approaches	9
Where to From Here / Next Steps	11
Appendix A	12
Appendix B	13
Appendix C	14

INTRODUCTION / OVERVIEW

The Best Medicines Coalition Consultation Workshop was held in Ottawa on Friday, December 13, 2002 to develop consultation options for involving the patient community (ies) in *relation* to the Therapies Review System and Health Products and Food Branch (HPFP) *policies*.

The delegates from the Best Medicines Coalition were:

- Kathy Kovacs Burns Canadian Diabetes Association, co-chair of the Coalition
- Denis Morrice The Arthritis Society, co-chair of the Coalition
- Deanna Groetzinger Multiple Sclerosis Society of Canada
- Cheryl Koehn Arthritis Consumer Experts
- Lynn Macdonald Breast Cancer Advocate
- Jean Légaré Canadian Arthritis Patient Alliance
- Rolph Calhoun Canadian Association for the Fifty-Plus
- Patrick McIntyre Canadian AIDS Society
- Jane Hamilton Best Medicines Coalition
- Shawna Krebs HepCURE
- Susan Jones Canadian Arthritis Patient Alliance

The delegates from Health Canada were:

- Roger Farley Director General, Office of Consumer and Public Involvement
- Sylvie Cantin Director, Public Involvement and Outreach – OCAPI
- Jacinthe Guindon Outreach Coordinator – OCAPI
- Mary Raphael Project Manager, Policy Bureau, Therapeutic Products Directorate
- Linda Searson A/Project Manager, Center for Policy and Regulatory Affairs, Biologics and Genetic Therapies Directorate
- Bill Leslie Senior Advisor, Marketed Health Products Directorate
- Tilak Gunawardhane Outreach Officer - OCAPI

Dr. Janet King, Senior Director General, Health Products and Food Branch, welcomed delegates on behalf of Health Canada.

The session was facilitated by Warren Wilson, Intersol Consulting Associates Ltd.

This report summarizes the discussions held at the workshop, the processes followed and outcomes achieved, and lists the action steps identified to ensure that the outcomes of the workshop are leveraged effectively within the Outreach Division management team.

GETTING STARTED

Opening Comments

Dr. Janet King, Sr. D.G. HPFB, opened the workshop and welcomed participants. Dr. King spoke to the workshop purpose and noted that Branch leadership was committed to developing more optimal approaches for consulting with Canadian patients. Dr. King welcomed the opportunity to develop a relationship with BMC.

Denis Morrice and Kathy Kovacs Burns welcomed participants on behalf of BMC. Both also welcomed the opportunity to work with HPFB/HC toward developing a model or strategy that will appropriately engage the patient community.

Context/Boundaries

Roger Farley, D.G. OCAPI, made a more formal opening presentation aimed at setting the context for discussions. Roger reviewed HPFB's mandate, role in HC, organizational architecture and challenges. A copy of Rogers' presentation was provided to participants and is included in Appendix A.

HPFB ISSUES REQUIRING PATIENT INVOLVEMENT

The group reviewed a current list of HPFB issues or initiatives. This list, which is included as Appendix B, represents broad, current areas of focus for the Branch. Following clarification of the list, patients were asked if there were any issues missing – additional areas where patient involvement might be advantageous?

The following issues were identified:

- Coverage/access to over-the-counter drugs and herbal products such as traditional Chinese medicine
- Research in all the categories – consent and ethical process for evidence-based decisions, qualitative and quantitative
- Process for practice-based research – qualitative evidence gathering
- Encouraging and facilitating knowledge transfer among practitioners – doctors, nurses, health providers (This is linked to point 14, communicating drug safety information to the public)
- Under number 11:
 1. Information on drug monographs that go to physicians – making sure that is given to patients; reporting on adverse reactions to products; marketed health products directorate
 2. Important to build in a patient information section
- Prescription process between physicians and patients: teaching patients and physicians how to interact better. It was suggested that Health Canada could have a significant impact in addressing a learning gap. There is another Branch in Health Canada that leads the work with practitioners, the Health Policy and Communications Branch, and would be better positioned to address this issue. The suggestion was made that OCAPI take the lead on dealing with issues like this one that cross over jurisdictions, because the public really doesn't care who it belongs to, they want their issues addressed.
- Design of clinical trials (linked to # 8, but separate)
- Communicating with patients about consultation – must communicate in a way that reaches them. Use real, plain language, not jargon.
- Information on the role of the Branch in the various areas of regulation, policy and inspection

The question of prioritization of issues was then explored. The following points were raised:

- Some initiatives are one-offs, others are ongoing. The one-offs require shorter, more intense involvement, possibly followed by communication to inform patients on the outcomes of the consultation.
- The relative importance of the initiatives depends on the individual – each of us will attach importance differently based on our advocacy group. There are some initiatives that would probably be identified as cross-cutting because they are of concern to many groups.
- OCAPI could use BMC as a sort of review body or clearing house, so that as each issue comes up, you have a body that can say – should we go to citizens, how important is it? BMC could be the group that Health Canada consults to ask about consultation. BMC would not be authoritative on all of these, some are outside of our area of expertise, such as #40. That doesn't say we can't be an umbrella group for best practices for consultation. BMC can be the alarm button – we're in touch with the community, we can connect OCAPI with the groups for whom this is most important.

This is an emerging recommendation from the group: use BMC as an umbrella group as an element of its patient consultation strategy – not the exclusive source of advice.

- There is no direct link between the importance of the issue and where it fits in the consultation continuum.
- Consultations that have worked in the past are those where target groups were brought in at the beginning to help shape the consultation, as opposed to back-end consultation with no involvement. Input to the consultation process should also be meaningful. Question: Who gets to determine the lesser and the greater degree of consultation? If BMC is not a part of that determination, can we be?
- Another suggestion to prioritize the list was analogous to Maslow's hierarchy of needs. The most *basic* issues are linked to patient safety and access to medicine. Next in the hierarchy are *proactive* actions to prevent increasing problems with a disease and finally *research*. Initiatives 1-26 appear to link well and belong in the basic level.

Participants were also asked to individually prioritize the list of issues as additional information for HPFB to help them in identifying high priority issues for consultation. The idea behind lists and prioritization is to try to deal with "consultation fatigue", and talk to the right people at the right time.

BMC agreed to take the list to their meeting the next day and come back with a common response to the questionnaire.

Once the list of initiatives is prioritized, additional dialogue may be required to identify specific issues or processes, which will be of particular interest for BMC.

WHO IN THE PATIENT COMMUNITY DO WE NEED TO CONSULT WITH?

The group next dealt with the question of *Who* in the patient community (ies) HPFB would need to consult with on the issues identified. A partial list of so-called “umbrella” patient organizations was identified as follows. This list includes organizations currently being consulted by OCAPI:

- Consumers Association of Canada
- Canadian Council on Multicultural Health / Canadian Ethno-cultural Council
- Consumers Council of Canada
- Option Consommateurs in Québec
- Women and Health Protection, linked to Centers of Excellence for Women
- UCAN
- Fédération des communautés francophones et acadiennes
- Québec Community Network Group

This led to a discussion on the definition of *patient*:

- For Best Medicines *Coalition*, the definition is “Individuals who are trying to access best medicines in terms of treating chronic illnesses or conditions”. Chronic in this context is *long term*, incurable illness, i.e. years in duration, in many cases life-long. The BMC is “Committed to people-centered access to the best medicines”

The group differentiated chronic patients from:

- *Acute* patients - Patients with illnesses that are of some duration (medium term – months/years), but who generally have illnesses that are more curable than chronic patients. eg. Cardio vascular patients
And
- People with *short* term illness – curable illness eg. The flu
And
- Healthy people trying to prevent illness (by taking medicine/health products)

Participant’s advice to Health Canada is to consult with people from all of these patient groups to get the best perspective.

Who speaks for whom can be contentious. Each group has a mission. There is no group representing the broader patient population not suffering from a chronic illness, which will make it hard to consult with them.

BMC’s vision and mission is specific to the patient consultation topic, and this may make BMC more appropriate to represent the Canadian patient population. There are differing points of view, however, as to whether BMC could / should represent all of the groups described above.

BMC can represent chronic and acute patients, and a sub-set of the short term and even healthy patient groups, but its members may have a different view from people who are not dealing with chronic or acute illness.

- Patients with chronic illness often have to deal with acute illness, and take the same medicines as patients who only deal with acute illness. They may, however, have a different perspective – there appears to be a philosophical split in the general population in terms of risk tolerance, with chronic patients tending to tolerate higher levels of risk because of their condition.

- An example where patients of chronic illness might differ from the general population is in the introduction of new drugs sometimes labelled “Me-too” drugs – drugs that fit in the same category as other drugs because they treat the same illness: the general public might want to genericize them or resist the introduction of a new drug, but patients dealing with chronic illness would want the new drug because they have had experience where one drug works with one patient but not another and vice-versa.
- What do we define as risk? Side effects? If defined in specific ways, it might be easier to differentiate. *Trade-offs* may be a better term than *risks*. People with chronic illness have to weigh everything. Some days they may not feel ready to take a risk either – their risk tolerance can vary over time.

BMC has a stake in many of the issues HPFB is dealing with, whereas the general consumer would have a stake in a smaller number of issues. Some of the points made in this respect include:

- One example of an issue which would interest the general public as well as BMC would be direct consumer advertising.
- There are drugs that are breakthrough, leading edge, versus others that are taken by the general public. This might be another criteria for differentiating consultation. Almost like therapeutic classes; general population, then disease-specific.
- Biologics and genetic therapies, therapeutic products, natural health products and marketed health products appear to be of particular interest to BMC, but these involve many processes.
- BMC represents 10-15 million chronically ill patients in Canada.

With regards to consulting the broader public, a participant asked why Health Canada would consult people on something that they are not using, not directly concerned with. The people who care about medication for chronic illness are those living with the illness. In these cases, Health Canada should not concern itself with the others nearly as much. To manage resources and get meaningful input, they should talk to groups that are affected by the specific drug or product, people who have a direct stake in the policy or product.

The point was made, however, that part of consultation is an education process, and there is a value in working with the “healthy” group to get their perspective and get information out to them, even on issues where they might not appear to have a direct and immediate stake.

HOW SHOULD WE CONSULT

Sylvie Cantin, Director – Public involvement and Outreach – OCAPI, made a presentation that informed the ensuing discussion on how to involve patients. Sylvie’s presentation outlined *the HC Public Involvement Continuum* and presented several consultation mechanisms or options for patients. Sylvie’s presentation was provided to participants and is attached as Appendix C.

Following Sylvie’s presentation, the group identified the following Consultation *Principles*. There was a high degree of consensus around the principles. They were viewed as guiding elements that could be/should be used in selecting consultation options.

Principles for Consultation

1. **Meaningful participation**
If the strategy is engagement, there needs to be meaningful participation in the process from beginning to end: stakeholders are integrally involved in developing the process, have a vote and their vote gets counted, are listened to and have an opportunity to influence, and something happens as a result.
2. **Targeted consultation**
Clear purpose, clear goals
3. **Trust**
We need to build trust, define mutual expectations. This is particularly necessary for the engagement level. You need time and resources to build trust.
4. **Commitment to action**
Where the goal is to effect implementation of policy, there should be more engagement of stakeholders. Conversely, there should be a commitment by Health Canada to implement before they engage. An engagement strategy can help ensure effective implementation.
5. **Transparency**
Those being consulted have to be able to trust that they are being told the truth
6. **Innovation**
We have to get out of the idea that there’s only one way to consult, and investigate hybrid models; we should also be innovative on solutions.
7. **Evaluation / Accountability**
Decisions should be examined down the road to make sure they are still appropriate.
8. **Dealing with constraints**
We need to recognize that they exist, and make them visible; where necessary, BMC should try to influence – we can play a role in helping to lift some constraints by putting pressure on HPFB to make changes that internal staff could not effect from within.
9. **Mutual respect:**
For the consultation process, and for the people at the table and the expertise they bring. We can agree to disagree without discounting the other person.
10. **Patience**
Consultation takes time and energy, and you have to let it unfold.
11. **Appropriate communications:**
Ensure that participants are well equipped to participate effectively; sometimes the amount and complexity of information provided can be overwhelming and impedes meaningful participation. There is a shared responsibility to ensure participants are well prepared to participate in consultations.
12. **Sustainability**
When consultation is initiated, resources have to be allocated at the right level so that time and cost constraints do not interrupt the process along the way.

For BMC, meaningful consultation will mean that they are consulted on the issues on which they will be most impacted, taking into account HPFB resource constraints.

It is also important for HPFB to state clearly which initiatives will not be opened to active engagement by BMC, either because they are too far along in the process, or for any other reason.

If there is an issue that deserves an engagement type of consultation, but resources will only allow for feedback, it may be better to put the initiative on hold until the right resources can be allocated to ensure the proper level of consultation.

One of the roles of OCAPI is to ensure that public consultation is taken seriously within the Department and is given equivalent weight with expert advice in the departmental decision-making process.

Challenges / Obstacles to Effective Consultation

The following are real challenges, perceived or otherwise, to achieving a successful level of consultation.

- **Time**
- **Cost**
- **Culture:**
(There may be resistance in some government circles to implement meaningful consultation. There may be an opportunity to educate about the consequences of not consulting effectively.)
- **Legal Issues**

Potential Patient Involvement Approaches

Participants then offered the following advice to HPFB to guide the selection of consultation approaches/mechanisms:

- Make sure there are appropriate bi-laterals between Directorates and BMC on issues that are important to patients. If OCAPI has a partnership with BMC, we would have regular discussions about specific topics to determine the best consultation approach on each, before they become an issue and before the broader consultation begins. Direct to Consumer Advertising (DTCA) and Canadian Coordinating Office of Health Technology (CCOHTA) are examples of issues on which BMC would have important insights to contribute.
- All the options identified could be appropriate. The option selection should be guided by the outcomes desired on each of the specific issues.
- Use option 3 to gather information from different groups, and use option 1 for ongoing consultation.
- When you put these options into place, you must have a plan; it may be that you have a consultative committee in place who has already helped you develop a plan for the specific consultation. Each of the options will provide very different outcomes.
- Would patient advocates like to have separate patient approaches or mechanisms, or would you like to only participate in mixed groups? It would be easy to add BMC members in existing standing committees, and this would allow for addressing patient consultation on a broader base, but BMC has specific expertise on some of the issues identified earlier for which they should be consulted separately.
- BMC should be one of the HPFB standing committees, operating at a very high level of engagement. It could be an incredible vehicle for building capacity within the patient community, since it has flexible membership, can solicit additional members, and can become a vehicle for other groups to get involved.

- Participants agreed that a mechanism should be found to consult BMC on a regular basis on the consultation process, on specific issues, and on the people and groups which should be consulted.
- On another note, OCAP will provide a list of standing committees to BMC to help them determine which ones are of interest to them, and conversations can proceed from there to see what is feasible.

WHERE TO FROM HERE / NEXT STEPS

The following action steps were identified to follow up on the workshop:

Action	Who	When
1. Present the idea of BMC playing a "standing committee" role to the executive committee of the Branch.	Roger Farley	Ongoing
2. Review list of standing committees and let HPFB know which standing committees are of interest.	BMC	End of January
3. Prioritize HPFB initiatives based on degree of interest in being involved and communicate priorities to HPFB.	BMC	December
4. Develop a strategy for BMC to assist Roger in advancing the idea of ongoing involvement of BMC with the Branch.	Kathy & Denis with input from Roger	Ongoing
5. Organize a follow-up meeting to further the agenda.	HPFB to lead	May/June 2003
6. Pursue opportunities for bilateral conversations on specific issues.	Kathy & Denis & HPFB	Immediately & ongoing
7. Develop and provide draft of the workshop report to HPFB and Kathy.	Intersol	December 20
8. Provide feedback on the first draft of the report.	Kathy and HPFB	Early January
9. Finalize report.	Intersol	Mid-January

APPENDIX A

Insert Roger Farley's presentation

APPENDIX B

Insert current list of HPFB issues or initiatives

APPENDIX C

Insert Sylvie Cantin's presentation