



Best Medicines Coalition

Submission to the House of Commons Standing Committee on Health

March 29, 2012

Patient Position Summary:

Disruptions in drug supply put patient health at risk and are costly to the health care system. The current drug shortage situation is critical, demanding an urgent approach to fully understand its scope and causes and a strong regulatory framework to protect patient health. It is paramount that the development of effective solutions must involve all stakeholders, especially patients.

Issue Overview: Patient Perspective

The Best Medicines Coalition (BMC) is a national alliance of patient organizations and individual patient advocates with a shared vision of equitable and consistent access for all Canadians to safe and effective drugs. Within this broad goal, the BMC first identified drug shortages as a priority issue in 2010 and began voicing its concerns to decision-makers in early 2011, calling for government action. Government leaders have responded, welcoming patient suggestions but there has yet to be any progress on developing significant strategies to address this issue.

While ongoing, intermittent drug shortages have always existed to some extent, since 2010, this issue has evolved and escalated. For Canadian patients, especially those with chronic conditions and those with diseases that have complex treatment regimens which rely on a safe and secure supply of much-needed medications, this is a critical situation. Disruptions in the drug supply can jeopardize patient safety, increasing the risk of adverse events and hospital and physician visits, and can potentially lead to life-altering complications, and even death. Protracted effects can last long after correction of a supply disruption. In addition to health risks, there are increased costs to individual patients, health care organizations, and governments.

Drug shortages are an urgent matter and decision-makers in the federal government, in cooperation with the provinces and territories, must take an active leadership role to address this issue. A robust regulatory framework must be put in place to maximize consumer protection by extending surveillance, reporting, and regulations to ensure that once a drug has been approved in Canada, every effort is made to ensure that a consistent supply is available.

A critical issue of this magnitude demands leadership and a concerted effort from governments. It is imperative that patients and patient groups be involved in all aspects of this process, from fact-finding through to designing solutions.

Drug Shortages: Impact on Patient Care

The media is chronicling some of the most dramatic examples of drug shortages, beginning in 2010, throughout 2011, and escalating into 2012. Supply interruptions have touched most disease areas, some with serious negative results.

Following are testimonials from BMC members outlining how shortages impact those in their communities:

Epilepsy (full case study in appendix):

“Recent anti-epileptic drug (AED) shortages have led to some people being switched to a different formulation (if available) or being switched cold-turkey to an alternate drug. It is not known if others affected by shortages simply stopped taking their AED when it ran out without seeking medical care. Some people who were switched to an alternate AED have experienced episodes of prolonged seizures (status epilepticus) that have been life-threatening.”

~Gail Dempsey, Canadian Epilepsy Alliance (www.epilepsymatters.com)

Breast Cancer

“Breast cancer patients, especially those with aggressive forms of cancer and whose disease has metastasized, need timely access to the most effective therapy in order to increase their chances of survival and management of their disease. When there are shortages in access to chemotherapy drugs, this can have significant detrimental effects on the lives of these women and men. In addition, patients rely on anti-nausea medication to make some of these aggressive treatments bearable and help manage their quality of life. A large number of breast cancer patients are women who are still the primary caregiver in their family; access to these medications often allows them to continue to support and care for those dependent on them. A breast cancer diagnosis is devastating enough to face without having to worry about whether the appropriate treatments are going to be available.”

~Cathy Ammendolea, Canadian Breast Cancer Network (www.cbcn.ca)

Drug Shortages: Impact on Patient Care (continued)

Gastrointestinal Disease:

“In the gastrointestinal area, many ulcerative colitis patients have been on a generic 5-aminosalicylic acid (5-ASA) medication that releases in the gastrointestinal tract at a specific pH level. In late 2006 and early in 2009 for about 4-6 months each, there were repeated supply issues with the generic drug, so patients had to switch from generic to brand and back a few times during the year. This problem is recurring in 2012. Evidence shows that the generic product releases into the digestive tract at a different area from the brand product. Because of the different release point, when these patients experienced disease flares, the physicians could not tell whether it was truly new disease activity or if it was resulting from inconsistent medication supply. The extra cost to the healthcare system was in increased physician visits, diagnostic testing, and escalating to additional or more costly medications to re-stabilize the patient.”

~Gail Attara, Gastrointestinal Society (www.badgut.org)

Inflammatory/Rheumatoid Arthritis:

“There can be dismal results when a drug is suddenly not available. With inflammatory arthritis (as well as many other conditions) when you are on a treatment that works well, any change in medications can negatively impact disease outcome. If you stop a drug, often there is a long adjustment period until a new drug takes effect, during which the disease progresses. Also, when you resume the original drug, it often doesn't work as well as before, or sometimes not at all. For those with serious and difficult to treat conditions, options are limited.”

~Linda Wilhelm, rheumatoid arthritis patient advocate

Hepatitis C:

“Living with chronic health conditions is challenging at the best of times and when years of trial and error to find the medications that produce the best treatment outcomes is interrupted or altered, it causes a chain reaction of negative events. Drug supply shortages have lead to worsening of my health. Lack of continuity in my medication has resulted in less effective treatment results with drugs that used to work well no longer working. This affects the quality of my life (as well as my daughters'), and has meant more trips to the hospital emergency department, seeking care for deteriorated health associated with not receiving medication regularly.”

~Lisa Mortell, Hepatitis C patient advocate

Moving Forward: Patient-Driven Recommendations

The Best Medicines Coalition has developed the following preliminary recommendations for consideration:

1. *Patient Involvement:*

Ultimately, the group most affected by drug shortages are patients. Patients' needs must be front and centre in all discussions and decision-making related to the drug supply. Patients and patient advocates must be actively involved in all stages of this process, alongside other stakeholders.

- The government must mandate meaningful patient representation on all working groups or commissions, to ensure valuable front-line input into solutions that meet patients' needs.

2. *Independent Review:*

There is a strong need to conduct a thorough, independent, and credible review of drug shortages in Canada. This is so that stakeholders can fully understand the broad context within which shortages are occurring, determine the scope and nature of the problem, and choose sound policy options to prevent future shortages.

- While the current focus is on manufacturing challenges and raw material shortages, we recommend a more in-depth exploration of all factors, including commercial issues, and an exploration of the Canadian situation within the global context.

3. *National Leadership:*

The current drug shortage situation is a national health issue and patients expect the federal government to take a leadership role to address the issue by using all avenues available under its authority to ensure a safe, consistent supply of medications for Canadians now and in the future.

- Canadians need a regulatory framework that enables officials to prevent shortages and protect patient safety to the greatest extent possible.
- The premise – that *approval* to market a drug includes an *obligation* to ensure a consistent supply of that drug – is of paramount importance to patients. The regulatory environment must include provisions to monitor this.
- We suggest exploring effective oversight models, with mandatory reporting considered as a possibility, but only pursuing measures that will truly address and improve patient care and safety.

Appendix: Drug Shortage Case Study

Implications of drug shortages for people living with epilepsy

Epilepsy treatment background

People with chronic conditions, such as epilepsy, require consistent access to medication. Epilepsy is a chronic neurological disorder characterized by recurrent seizures. The main treatment for epilepsy, anti-epileptic drugs (AEDs), must be taken daily (or several times per day) to prevent seizures. Epilepsy medications have a narrow therapeutic range, require careful titration and are not interchangeable. If a medication change is required, either a change in dosage or switching to a new medication, this is typically done gradually over weeks or months. The greatest danger of sudden changes or suddenly stopping AED treatment is the risk of recurrent seizures. When AEDs are stopped or changed abruptly recurrent seizures can be more severe, or more prolonged than the previous seizures. Prolonged seizures (lasting longer than five minutes) require emergency medical care and can be life-threatening.

Risks associated with treatment interruptions or inconsistencies

When remission has been achieved with epilepsy treatment, it is important to avoid even a single breakthrough seizure. Adherence to a daily treatment plan is also critical for people with drug refractory epilepsy to minimize the risk of seizures as much as possible. There are significant personal and societal costs associated with breakthrough seizures, or a worsening of someone's seizure control, including fatalities due to prolonged seizures, injuries, accidents (e.g. motor vehicle accidents, drowning, severe burns), increased risk of SUDEP (Sudden Unexplained Death in Epilepsy), loss of a driver's licence, loss of employment, emergency department visits, hospitalizations, increased visits to health care providers in the short term and possibly over the long-term if the person does not regain the same degree of seizure control when they resume their regular AED therapy. Publications in the medical literature clearly identify the adverse events associated with abrupt but voluntary changes in AED treatment, such as suddenly stopping an AED. There is also literature pertaining to adverse events associated with inconsistency in supply, such as being switched to a different formulation. There are only anecdotal reports related to abrupt changes in treatment due to AED shortages because this is an unprecedented situation.

Recent and ongoing AED shortages

Between late 2009 and now there have been shortages of at least five different AEDs. Some of these medications are manufactured by a single pharmaceutical company. The AED shortages have led to some people being switched to a different formulation (if available) or being switched cold-turkey to an alternate drug. It is not known if others affected by the shortage simply stopped taking their AED when it ran out without seeking medical care. Some people who were switched to an alternate AED have experienced episodes of prolonged seizures (status epilepticus) that have been life-threatening. Physicians who specialize in epilepsy report that they have had patients with previously good seizure control who have experienced breakthrough seizures. Even when people have had enough medication on hand to see them through a shortage, or have been able to find a pharmacy that still had stock of their drug, there has been a tremendous amount of stress because they did not know how long their AED(s)

would be in short supply and whether they would run out. People with good seizure control have been worried about the potential impact of breakthrough seizures on their health but also on their independence (e.g. their driver's licence) and their career. Parents, spouses and other family members have been very concerned about the safety of their loved ones. People have been extremely frustrated and upset by the lack of information about drug shortages. Individuals affected by shortages do not have a place to go for general information pertaining to drug shortages, for information about specific drugs, or for advice on what they should do. Some people have had very good support from their health care provider &/or their pharmacist but they have still been seeking an authority on drug shortages for additional information.

One AED, ethosuximide (Zarontin) capsules, has been in short supply since 2010¹. People who rely on this medication have either been switched to a syrup formulation²; switched to a medication that may not be as effective; or they have been seeking out alternate ways to obtain the drug - going from pharmacy to pharmacy (when there was still some supply available), by obtaining the drug at a compounding pharmacy in Canada, or by travelling repeatedly to the US to purchase the drug at a considerable financial and personal expense.

In addition to the above concerns, Dr. Richard McLachlan (Professor of Neurology, Epilepsy Program, London Health Sciences Centre in London, Ontario) has shared these current concerns related to drug shortages and epilepsy: "We have three or four patients whose surgery is delayed because of unavailability of amytal and etomidate. The biggest problem we (both patients and physicians) are facing is not knowing what drug will be next - imagine if phenytoin³ suddenly became unavailable".

Many people with epilepsy who have been affected by drug shortages are initially shocked when they learn that their AED is unavailable, angry when (or if) they find out that there is no regulation to ensure the supply and desperate to see their drug back on pharmacy shelves.

~ Canadian Epilepsy Alliance (www.epilepsymatters.com)

March 21, 2012

¹ Apparently there was a short production run of ethosuximide capsules in January 2011.

² The syrup formulation of ethosuximide is not suitable for all patients who rely on this drug for the treatment of absence seizures. Children on the ketogenic diet can not take the syrup formulation because the carbohydrate content is too high. The syrup is not an acceptable formulation for many teenagers and adults.

³ There were shortages of some formulations of phenytoin (Dilantin) in 2011, but there has not been a widespread unavailability of this drug. Some people affected by the Dilantin shortage were able to find a pharmacy that still had their drug in stock while others were switched to an alternate formulation of phenytoin. It is important to recognize that switching to a different formulation is a potential cause of medication error and could result in adverse outcomes.

About the Best Medicines Coalition

The Best Medicines Coalition (www.bestmedicines.ca) is a broad-based alliance of organizations and individuals with a shared vision of equitable and consistent access for all Canadians to safe, effective, and good quality drugs which improve patient outcomes. Within this context, the BMC's areas of interest span from approval and reimbursement through patient safety and supply concerns. As an important aspect of its work, the BMC strives to ensure that Canadian patients have a voice and are meaningful participants in health care policy development and pharmaceutical review.

All participation in the BMC and the process for developing positions and activities are clearly delineated in its Terms of Reference. All positions and activities are developed by patient members all of whom are volunteers to the organization. Key decisions are made by a five-member Operating Committee, lead by a Chair, in consultation with Working Groups. All committees and working groups are comprised exclusively of patient representatives, with no representation from external funding organizations, and representatives of funding organizations do not participate in BMC policy meetings. All positions taken are solely in support of the organization's mission and are patient driven.

In order to sustain the organization, the BMC solicits funding from a variety of sources, both private and public. The pharmaceutical industry is a major supporter, including both trade associations and individual companies. In the past, the BMC has also received government grants to fund special projects. In addition, government funding is regularly reimbursed to cover travel and accommodation expenses where BMC patient representatives participate in policy consultations. While the BMC does not charge mandatory fees to members, some member organizations do contribute financially and some appoint a staff representative, which is viewed as in kind support.

Operations Committee 2011-2012

Gail Attara, President & CEO, Gastrointestinal Society (BMC Chair)
Linda Wilhelm, Independent Member (Past Chair)
Denis Morrice, Canadian Epilepsy Alliance (Treasurer)
Harlon Davey, Independent Member
Dr. Katharina Kovacs-Burns, Independent Member

Safety and Supply Working Group 2011-2012

Denis Morrice, Canadian Epilepsy Alliance (Chair)
Gail Attara, Gastrointestinal Society
John Bachynsky, Creating Synergy Health Coalition
Marjorie Harris, Independent Member
Lisa Mortell, Independent Member
Suzanne Nurse, Independent Member

Best Medicine Coalition Member Organizations:

Arthritis Consumer Experts: Cheryl Koehn	www.arthritisconsumerexperts.org
Asthma Society of Canada: Robert Oliphant	www.asthma.ca
Better PharmaCare Coalition (BC): Rennie Hoffman	www.betterpharmacare.org
Canadian Arthritis Patient Alliance: Sue Borwick	www.arthritis.ca/capa
Canadian Breast Cancer Network: Cathy Ammendolea	www.cbcn.ca
Canadian Epilepsy Alliance: Denis Morrice	www.epilepsymatters.com
Canadian Hemophilia Society: Michael Whelan	www.hemophilia.ca
Canadian Pain Society: Dr. Barry Sessle	www.canadianpainsociety.ca
Canadian Skin Patient Alliance: Christine Clarke	www.skinpatientalliance.ca
Canadian Society of Intestinal Research: Kimberly Skulsky	www.badgut.org
Canadian Treatment Action Council: Robert Reinhard	www.ctac.ca
Cancer Advocacy Coalition of Canada: Colleen Savage	www.canceradvocacy.ca
CARP, A New Vision of Aging for Canada: Holly Vengroff	www.carp.ca
Creating Synergy Health Coalition (AB) John Bachynsky	www.creating synergy.ab.ca
Gastrointestinal Society: Gail Attara	www.badgut.org
Hepatitis C Council of British Columbia: Deb Schmitz	www.bchepcouncil.ca
Kidney Cancer Canada: Catherine Madden	www.kidneycancer canada.org
Lymphoma Foundation Canada: Sue Robson	www.lymphoma.ca
Ovarian Cancer Canada: Monique Beaupré-Lazu re	www.ovariancanada.org
Tourette Syndrome Foundation: Lynn McLarnon	www.tourette.ca

Independent Members:

Lembi Buchanan (BC); Harlon Davey (ON); Marjorie Harris (BC); Katharina Kovacs Burns (AB); Lisa Mortell (BC); Suzanne Nurse (ON); Linda Wilhelm (NB)

For more information:

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Best Medicines Coalition Presenters

Gail Attara

Chair, Best Medicines Coalition (Representing the Gastrointestinal Society)

Gail Attara is the President and Chief Executive Officer of the GI (Gastrointestinal) Society. She began as Executive Director of the organization's sister charity, the Canadian Society of Intestinal Research (CSIR), in 1996, and led the organization from a small BC charity into a national presence, accounting for the largest growth period in its thirty-four year history, before co-founding the GI Society in 2008. Most of the CSIR's activities have transferred to the GI Society, which was formed to provide Canadians with a broader, national range of resources and research funding opportunities in this sorely neglected health area.

Gail's motto, "the patient comes first", directs her resolve for patient-focused healthcare and commitment to increasing awareness about the seriousness of gastrointestinal illnesses. She has been an invited speaker coast-to-coast on more than 30 occasions, to wide-ranging audiences, including doctors, patients, pharmacists, and healthcare decision-makers.

Gail has a solid background in public relations and fundraising and is an active community volunteer in Canada, serving on numerous Boards, and overseas, where she has worked with orphans. Participating as a member of the Best Medicines Coalition since 2005, Gail is now serving a two-year term as Chair. Her goal is to expand the network of knowledgeable patient advocates within the healthcare system.

She is also a published freelance author and artist. With the dynamic support of the Board of Directors, a dedicated group determined to fully realize the GI Society as Canada's gastrointestinal disease and disorder information source, Gail continues to lead the organization into a bright future. www.badgut.org www.mauxdeventre.org

Suzanne Nurse, PhD

Steering Committee, Best Medicines Coalition (Representing the Canadian Epilepsy Alliance)
Member, Safety & Supply Working Group

Suzanne Nurse has been actively involved in epilepsy education and support while working as a staff member with the Epilepsy Support Centre (2008-2012), a grassroots community-based agency in London, Ontario. Suzanne was Executive Director of the Canadian League Against Epilepsy (2009-2011) and has been a member of the Canadian Epilepsy Alliance (CEA) Education Committee (www.epilepsymatters.com). Suzanne was a volunteer Leader with La Leche League Canada for eight years providing breastfeeding information and support to mothers locally and nationally. Suzanne's primary focus is on helping people get access to current, accurate information and support so that they have the knowledge and understanding they need to make informed decisions.

Suzanne currently works as a consultant for non-profit agencies. She volunteers with the CEA on issues related to access to medication and is an Independent Member of the Best Medicines Coalition. Suzanne currently sits on the Neurological Health Charity Canada (NHCC) Implementation Committee, which oversees the National Population Health Study of Neurological Conditions. Suzanne holds a PhD in Medicine with a specialization in neuroscience. She resides in London, Ontario with her husband, Mark, and their three children.