Editorial



# Governments need to act on cancer drug shortages affecting public health

## Editorial

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Alan Viau
Financial Management, Strategic Advisor, Public Works and Government Services, Canada

**Correspondence:** Alan Viau, Financial Management, Strategic Advisor, Public Works and Government Services, Canada, Email dralanviau@gmail.com

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Worldwide drug shortages have been widely publicized. The large majority of drug shortages seem to originate from generic drug manufacturers. Is the uncertainty of drug availability affecting treatment options for patients and therefore public health? What remedies can be sought from a country perspective?

It has happened to me more than once. I go to re-fill a prescription for a generic drug and I am told it is on back-order. If I am lucky the pharmacist can call other drug stores to see if anyone has supply. Alternatively, I may need to switch medication–which means a call to the doctor for equivalency. Sure enough, I check to Drug Shortages Database[1] for Canada and discover that it is indeed in shortage.

The results of these on-going drug shortages are manifold. First and foremost is the effect on public health. Not have the medication will definitely affect treatment. Switching brands may also result in some effects. Secondly is the impact on the effectiveness of the health care system. With pharmacists running around to fill orders and doctors finding equivalent treatments, the added work diminishes their effectiveness. Both increase the cost burden of treatments.

Although for most common cases like mine an equivalent can be found, it is more crucial in the treatment of cancer. Michael Link, MD,[2] The Past President of the American Society of Clinical Oncology (ASCO) commented in 2011.

*"Starting at the beginning of the 21st century, there has been a crescendo effect of the number of drugs in short supply. We're on track this year to have a shortage of almost 300 drugs -- including cancer drugs. For antibiotics, for example, there are usually -- although not always -- alternatives. There is often a work-around.... But when you look at the treatment of leukemia, there are really not that many alternatives. And for certain types of the disease, the shortage of drugs such as daunorubicin and cytarabine basically make it impossible to treat leukemia in both children and adults. That really makes the impact on oncology devastating because it really is a matter of life or death to patients. That is the most deplorable situation. We know that we have the wherewithal to cure these diseases, but with drugs unavailable, we can't deliver".*

When specifically applied to cancer treatment, shortages affect the healthcare system in four ways:

a. Health care providers trying to get drugs that are needed to treat patients may delay planned procedures if a drug is shortage.

b. Hospital administrators are worried how they can reliably run an oncology center when medications needed to provide treatment are in shortage.

c. Hospital financial officers are concerned about the pharmacy drug budget, because drug shortages create higher than expected costs for alternatives.

d. Physicians are concerned that replacement with alternatives may lead to errors and adverse events.

The availability of cancer drugs remains of concern for many health professionals and patients. The impact of a shortage of anticancer drugs is probably worse than for other classes of drugs. This is because of the lack of alternatives. For example, for antibiotics, there are usually, but not always, alternatives. When we look at the treatment of leukemia, there are really not many alternatives. If there are alternatives, there may be therapeutic impacts with an alternative drug (generic or otherwise) in the midst of treatments.

The CML Advocates Network, which unites chronic myeloid leukaemia patient groups across the world is one group that is keeping a close watch on 'mission critical' cancer generics. In August 2014, CML Advocates Network welcomed the greater patient access that multiple generics can bring, but issue a statement "about the impact on their cancer when switched between different products for non-medical reasons, if these products' equivalence in terms of quality and efficacy is uncertain".

Their statement called on governments, health authorities and healthcare professionals to minimise potential uncertainties and risks for patients with the following five measures:

a. Provision of reliable proof of quality and equivalence of pharmacokinetics and bioavailability

b. Collection of comparative clinical data to ensure comparable efficacy

c. No switching for non-medical reasons if a patient is responding optimally and tolerating well

d. No switching between products of the same compound more frequently than once a year to allow consistent follow-up, and in case of loss of response or increased toxicity, switch back or switch treatment

e. More frequent monitoring (obligatory: PCR tests; optional: plasma level testing).

Faced with the realities of possible drug shortages what can countries do to protect their public health for 'mission critical' drugs? We can look at two efforts.

In one example, the Indian Patent Office in 2012[3] announced

that it had issued its first compulsory license to a domestic generic drug-maker. Compulsory licensing happens when a government authorizes another party other than the patent owner to produce the patented product or process, without the patent owner's consent. This occurred because the right-holder, Bayer, failed to supply the cancer drug (sorafenib tosylate) at affordable prices and in sufficient quantities. The generic drug was supplied at a 97 percent price cut.

Another effort to ensure supply is seen in New Zealand. The worldwide market share of drugs for New Zealand is small. Yet how can they make their market attractive to generic drug-makers and ensure sufficient supply. In their case, drug-manufacturers are asked to submit not only scientific data to verify pharmaceutical equivalence, bioavailability and bioequivalence. A pricing plan is also required. The company who meets the scientific requirements at the best cost gets exclusive access to the whole New Zealand market. The second company is considered the alternative back up supplier. This creates an incentive to keep the market supplied.

These two examples serve to illustrate that when faced with a public health issue, governments cannot be perceived as being satisfied by letting the law of supply and demand reign–especially when it impacts public health. Currently, the U.S and Canadian governments are monitoring the drug shortages only. Governments are currently struggling to balance pricing and availability against legitimate concerns from stakeholders, e.g. the patients, oncologists, and the hospital system. There will be a time for the governments to enact requirements to ensure supply for the overall betterment of public health.

## Acknowledgements

None.

## Conflict of interest

The author declares no conflict of interest.

## References

1. http://www.drugshortages.ca/drugshortages.asp
2. Michael Link, MD.
3. http://www.ictsd.org/bridges-news/bridges/news/india-grants-first-compulsory-license-to-generic-drug-producer

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