



December 14, 2015

Barbara Sabourin Director General
Therapeutics Product Directorate
Health Products and Food Branch
Health Canada
Address Locator: 3106B
Ottawa, Ontario K1A 0K9

Delivered via e-mail to: barbara_sabourin@hc-sc.gc.ca
With copy to: supriya_sharma@hc-sc.gc.ca
jane_philpott@hc-sc.gc.ca
doron.almagor@gmail.com

Dear Ms. Barbara Sabourin,

This past year the Center for ADHD Awareness Canada (CADDAC) and other mental health and neurological organizations met to discuss feedback we were receiving from our patient population base expressing concerns about their medication being substituted by generic medication. The initial coalition who met developed a statement outlining what was currently known and what we were proposing. The statement can be accessed in Appendix A below.

Anecdotal evidence from caregivers, patients and treating physicians, especially for some conditions, indicated a decrease in the degree and length of symptom control and an increase in side effects when patients were switched from brand-name to generic medication. We were unable to access clinical research evidence to gain insight into this potential issue. In order to acquire a better understanding we required a way to quantify the seriousness of this issue for our patient population. To assist with this we developed a survey to gather feedback from our clients, members and constituents on their experiences with generic medications.

Although in earlier interactions between CADDAC and Health Canada, Dr. Sharma through a letter on October the 4th 2010, indicated that only adverse event reports would be recognized, CADDAC felt that sharing this survey's findings in regards to the medication our population base uses was the responsible thing to do. Therefore, I am including a summary of the survey's findings which suggest that a high proportion of the respondents experienced issues when switched to generic medications. Almost half of the respondents reported changes in their ability to function at school, work or home. Of specific concern were the exceptionally high numbers of patients and caregivers reporting issues when switched to a specific generic medication used to treat ADHD.

A summary of the survey's finding including specific examples can be accessed in Appendix B below.

In addition, it is interesting to note that the ODPRN final consolidated report reviewing medications used in the treatment of adult ADHD included this statement "Some physician participants perceived that the generic version of some ADHD medications (e.g., methylphenidate) may be easier to abuse than the brand name version (e.g. Concerta®) and may also be less effective. These comments were found in both the qualitative and environmental

scan draft reports. Since this topic was not under the direct mandate of the ODPRN and the comments were unsolicited yet voiced, one must think that this issue is of significant concern to both patients with ADHD as well as their medical practitioners.

Further exacerbating the problem some provincial governments are now restricting a physician from writing “No Substitution” on a prescription unless a trial has been completed on two generic medications showing adverse events. This situation leads us to an important question that needs to be considered. How would a patient who has a trial on a generic medication know if there was a decrease in efficacy or increase in side effects unless they also had a trial on the brand name medication? The unfortunate result of all this will be that a group of our most vulnerable patients, those who access provincial drug plans, will be undertreated for their medical disorder. This is understandably of great concern to CADDAC.

We hope that Health Canada will review and strengthen the process of assessing for bioequivalence when looking at potential generic ADHD medications, as the FDA did.

I look forward to your response to these serious issues.

Sincerely,

Heidi Bernhardt
President and ED CADDAC

cc: Honourable Jane Philpott, Minister of Health
Dr. Supriya Sharma, Senior Medical Advisor, Office of Assistant Deputy Minister
Dr. Doron Almagor, President CADDRA