**Comparing Treatment Results in Adults Switched to Generic ADHD Medication**

Results of a recently published study, "A randomized, double-blind, cross-over, phase IV trial of oros-methylphenidate (CONCERTA®) and generic novo-methylphenidate ER-C (NOVO-generic)" confirms concerns expressed to CADDAC over the past number of years by adults with ADHD, parents of children with ADHD and physicians treating patients with ADHD who have been switched to a generic medication. The objective of this study was to evaluate adult ADHD subject outcomes when they were switched from a stable dose of CONCERTA® to the same dose of generic Novo-methylphenidate ER-C®.
The small study consisted of 20 participants with a primary diagnosis of ADHD. It consisted of two phases; 3 weeks of treatment with CONCERTA or generic Novo-Methylphenidate ER-C, followed by 3 weeks where participants were crossed-over to receive the other treatment. The effectiveness of each treatment was assessed through the use of the Treatment Satisfaction Questionnaires for Medication, Version II (TSQM-II).

A pharmacist, outside of the physician's office was used to produce the medication. In order to maintain the "blind", both CONCERTA® and novo-methylphenidate ER-C were put into a white opaque capsule. Neither the investigator, research team, nor the participant knew which medication was being taken during which three week period.

Results:

The participants treated with CONCERTA® were more satisfied in terms of the medication's effectiveness and lack of side effects, than those receiving an equivalent dose of the generic version novo-MPH. These results were also supported by the physician-reported Clinical Global Impression (CGI) outcomes. The Clinical Global Impression – Severity scale (CGI-S) allows a clinician to rate the severity of a patient's illness. All study subjects chose to return to treatment with CONCERTA® at the conclusion of the trial. The researcher's interpretation of these results was that the adults with ADHD were satisfied and feeling better with CONCERTA ® treatment than with the generic form of the medication.

The paper explains that when a generic medication is deemed to be bioequivalent by Health Canada it is assumed that it will provide patients the same therapeutic effect and the same level of tolerability (number and degree of side effects) as the branded drug. The paper then goes on to explore a potentially serious issue, since the generic medication was deemed to be bioequivalent by Health Canada - if the study's results indicate clinical differences between the generic and brand medication, at least for those patients who have been stabilized on the brand medication, is the current method of determining bioequivalency sufficient to ensure equivalent treatment when switching a person to the generic product? At this time, the only criteria requirement for bioequivalency is that - at any given time - the amount of medication in the bloodstream must be 80% to 125% of the amount of the same medication that would be in the blood stream if the brand medication was taken. Differences in the delivery system of the medications are not taken into account when determining bioequivalency.

The paper also looks at the risk of substitution with a generic product when only comparing cost benefits of generic medications. Things such as costs of increased doctor and emergency room visits, and nonadherence to the treatment may cost much more in the long run. The paper closes with a call for further investigation into all these questions and concerns.