CADDAC
CENTRE FOR ADHD AWARENESS, CANADA

Generic Medication Substitution

Please note that the medication substitution may work very well for you or your child. We are not suggesting that there will be a problem for all, or even for most people, but we believe patients have a right to know about this situation.

Several generic medications have been approved by Health Canada to be "bioequivalent" or interchangeable for brand name ADHD medication. There are approved generic forms of Strattera, Adderall XR and several versions of generic forms of Concerta. To-date, there have been no significant issues found with the generic versions of Adderall XR or Strattera. However, since soon after its release in 2010 CADDAC has been receiving feedback on issues with generic forms of Concerta, in particular with Teva-Methylphenidate ER-C.

The actual delivery mechanism is not the same as Concerta and - despite attempts to find out more – we have been unable to obtain additional details on the delivery system of this medication. The visual appearance of the medication is very similar to Concerta. However, unlike ConcertaTM, Teva-Methylphenidate ER-C can easily be divided, crushed and powdered, which could potentially increase its abuse potential.

As with all other generic products, Teva-Methylphenidate ER-C was made available in Canada after demonstrating bioequivalence to ConcertaTM according to Health Canada criteria. Simply put, the criteria requirement is that - at any given time - the amount of medication (methylphenidate) in the bloodstream must be 80% to 125% of the amount of the same medication that would be in the blood stream if ConcertaTM was taken. Health Canada made their decision in this case based on blood levels recorded in 25 healthy adults.

However, bioequivalence does not always mean equal therapeutic effect. What we do know is that the time necessary to obtain the maximal concentration (Tmax) is less for Novo-Methylphenidate ER-C than ConcertaTM. ConcertaTM peaks at 7.6 hours and Novo-Methylphenidate ER-C peaks at 4.6 hours.

At this time, pharmacists have the right to substitute an innovative or original product for a generic product and in many provinces this can be done without notifying the patient or caregiver. Many private health insurance companies have requested that this new generic medication be substituted for the brand name medication. Many provincial health plans have done the same. Physicians need not be notified that a medication substitution has occurred.

It is logical that close follow-up should occur when a medication is being substituted. However, in some cases, the patient may not even be aware that a substitution has occurred and could therefore not alert their physician to this.

A patient has the option to reject the proposed substitution. However, if the patient is covered by a

public medication insurance program or in certain cases a private insurance program, he or she will be required to pay more for the original product. Physicians may decide to write *"do not substitute*" on the prescription, but there may be restrictions around this in some jurisdictions.

If you have had issues with a generic form of a medication, this included a decrease in effectiveness or increase in side effects please fill out the Health Canada Adverse Event form and encourage your physician to do the same. Please access Adverse Event Reporting.