CADDAC
CENTRE FOR ADD/ADHD ADVOCACY, CANADA

September 1st, 2010

Dr. Supriya Sharma
Director General
Therapeutics Product Directorate
Health Products and Food Branch
Health Canada
Holland Cross, Tower B
1600 Scott Street
Ottawa, Ontario K1A 1B6

Dear Dr. Supriya Sharma,

We would like to thank your office and Director Andrew Adams for your response to our initial contact in February of this year regarding our concern of the interchangeability of Novo-Methylphenidate-ER-C and Concerta™.

While we are aware that your province has already decided to make Novo-Methylphenidate-ER-C interchangeable with Concerta™, we would encourage you to continue to closely monitor the impact of this decision on patients who have been negatively affected.

With the return to school, many of the students with ADHD that we support will be starting back on their medication routine.

Since our letter sent to your Ministry on February 22, 2010 (copy enclosed), we have been receiving feedback from patients whose children have been switched to Novo-Methylphenidate-ER-C.

As a result, our concern has only been strengthened that some patients who are currently being successfully treated with Concerta™, are being switched with or without their knowledge or permission, to a generic medication that does not offer identical coverage for their child. Inadequately treated ADHD offers a host of well documented risks, especially if the risk is not being adequately monitored due to an unrecognized change in medication.

We would like to strongly reiterate that CADDAC certainly does not have an issue with generic medications if they are shown to be as effective as the brand name medication. In fact, for many families that we support, a lower cost alternative would relieve a financial burden.

It is our belief that the safety, efficacy and effectiveness of ADHD medication must be unequivocally demonstrated scientifically prior to children and adolescents having access to them. The long-term

consequences of inadequate treatment are too high from a societal point of view.

Substituting generic medication without first confirming the medication has the same clinical impact and can be used safely (vis-à-vis abuse potential) is irresponsible.

Our concerns are:

- The mechanism of action (release mechanism) of Novo-Methylphenidate ER-C and a granular understanding of the profile of action are unknown.

- The abuse potential of Novo-Methylphenidate ER-C is unknown.

- There is currently no evidence to show the comparability of the two products throughout the school day for children. In fact, no trials have been done on children.

Choosing the appropriate and best medication for ADHD is not a quick and simple matter as many physicians and parents will tell you. As with antidepressant medications it is not a case of one size fits all. Some families have to struggle for months and possibly more than a year to find the best medication and dose for optimum efficacy and the least amount of side effects.

Although Novopharm has met the threshold for bioequivalence set out by Health Canada, the method to demonstrate bioequivalence was devised before new technology used in some time-released medications was available. Health Canada's various guidance on bioequivalence did not anticipate such a product and therefore, the requirements do not necessarily apply in this case from a scientific point of view.

CADDAC is well aware of Health Canada's position on this issues and was present in Ottawa for the review of these issues on June the 11th.

At this time, we would like to share with you a sample of some of the feedback that we have been receiving from our membership in the hopes that this will serve as an example of why we continue to be concerned.

We would be very interested in discussing these issues with your Ministry over a conference call at your convenience.

Sincerely,

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