Health Canada / Santé Canada
Health Products and Food Branch / Direction générale des produits de santé et des aliments

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Heidi Bernhardt
National Director
Centre for ADHD Advocacy Canada
40 Windford Drive, Suite 3048
TORONTO, Ontario
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Dear Ms. Bernhardt,

I am responding to your letter of September 1, 2010 to the Minister of Health regarding the interchangeability of Concerta™ with Novo-Methylphenidate-ER-C.

In your letter you have given several examples of situations in which the interchangeability is thought to have caused ineffective treatment of ADHD in children. I ask that you encourage the physicians, in conjunction with the parents, to report these observations to us through the adverse drug reporting system at Health Canada. This is the only way we can get accurate reporting rates concerning ineffective drugs.

Furthermore, as you point out in your letter, it is very important for physicians to monitor their patients especially when a change in medication occurs. A switch of any medication has the potential to change the control of a disease whether it be brand to generic or even generic to brand. This is an important message to convey to your audience.

Finally, as you are aware, the recommendations from the Scientific Advisory Panel stated that, given the information they reviewed, no special bioequivalence parameters were warranted for generics of Concerta™. Health Canada is

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currently reviewing comments received through the consultative process on the draft bioequivalence guidances which are to be finalised shortly.

Yours sincerely,

Supriya Sharma, MD MPH FRCPC
Director General