

Health Canada - Adverse Reaction - Form & Guide

Guide to Filling out the Health Canada Adverse Reaction Reporting Form

*Click this link to access Health Canada's reporting site: <http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php#a2>

Adverse events, or a serious adverse reaction to taking a medication should be reported to Health Canada using this reporting site. While physicians are the ones who primarily report these events, it should be noted that patients may and should also do so. The form provides examples of an Adverse Reaction, such as, *Death, Hospitalization, Disability*, etc, however Health Canada has informed CADDAC that a decrease in the effectiveness, (the length of duration, the rate of symptom control etc and/or an increase of side effects or adverse reactions) with Generic medications, that are deemed to be equivalent, should also be reported as an adverse event.

Using medication that does not perform as well as the brand name is an adverse reaction, which can affect a persons' day to day life dramatically. Health Canada has informed us that they will not review their decision regarding the approval of the “bioequivalency” (similar amounts of the same medication found in the blood stream) of the generic medications unless enough reports of adverse reactions are received. It is this approval of “bioequivalency” that allows provinces to approve direct substitution of the generic medication for a brand name medication.

Since the reporting on this type of adverse event is less clear we have provided some information to assist you.

We have noted two areas to help you fill out this form with respect to reporting an adverse reaction to Generic Medication.

On section “**B: Adverse Reaction**”

1.Outcome attributed to adverse reaction (select all that apply)

Other: _____

**If you/the patient experienced less effectiveness with the Generic Medication, you may fill it in as “Less Effective” and state why, (effective for a shorter duration, less symptom control etc.) or simply state the side effect.

Below this area, still under B., section

“4. Describe reaction or problem”

Examples that we received of this are;

“After a few weeks we noticed that the pill took a long time to kick in and that it wore off sooner than the brand name Concerta.”

“... we switched to the Generic. Within that first week, I received a call from his teacher reporting that his ability to focus wasn't the same, and he was not getting any work done. I think it is important to note that we did NOT tell the school that we had switched his meds.”

“My son has been on Concerta for about the last five years without incident....recently without our knowledge or consent we were switched to the generic. My son now complains of not feeling like himself and argues about taking his medication. This has never been an issue before.”

“The generic medication does not last as long as Concerta. I notice that his symptoms reappear 2-3 hours earlier when on the generic medication, which limits his abilities in academics, sports and socialization in the early evening. We have gone back to Concerta and have noticed an improvement.”

“My girls were switched to the generic version and from the 1st day it has not worked. Their various symptoms were:

Daily complaints of not feeling "right", loss of focus all day long, meds wearing off after 3 or 4 hours therefore not getting them to their last class of the day, fatigue, hunger, irritability, hyper active (not a usual component of my ADD girls), unable to attend during class lessons, constant bickering with twin sister (both), brain not quiet at any time of the day, overly emotional, easily stressed, becoming very anxious and worried all the time about school work and inability to complete tasks, disorganized to the point of accomplishing very little and extreme frustration, odd aches and pains throughout their bodies etc.”

It is important to stick to the facts when submitting this form. We all know what an emotional roller coaster it can be to have a history of reliable medication and then suddenly have less favourable affects from a new one, but try to keep your statement as close to the simple facts as possible for the best consideration. Use Who, What, When, How type answers.

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***Click here to access a copy of the Health Canada Adverse Reaction [Form](#)**

*Click here to access the Health Canada Adverse Reaction [Fact Sheet](#)