Health Canada / Santé Canada

Therapeutic Products Directorate
Holland Cross, Tower "B"
6th Floor, 1600 Scott Street
Address Locator # 3106B
OTTAWA, Ontario
K1A 0K9

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16-100151-854

Heidi Bernhardt
President and ED
CADDAC
3950 14th Avenue, Suite 604
Markham, Ontario
L3R0A9

Dear Ms. Bernhardt:

Thank you for your letter of December 14, 2015, regarding the results of a survey the Centre for ADHD Awareness Canada conducted on the substitution of brand name drugs with generic drugs. I want to thank you for bringing your concerns and these study results to my attention. The Department is aware more generally of concerns that have been raised regarding the efficacy of ADHD medications.

It is important to know that the quality standards Health Canada has established for brand name drugs and generic drugs are the same. The ingredients, manufacturing processes and facilities for all drugs must meet the federal guidelines for Good Manufacturing Practices. As well, all drug manufacturers must perform a series of tests, both during and after production, to show that every drug batch made meets the requirements for that product.

Furthermore, the generic drug must contain the same amount of medicinal ingredient as the brand name reference product. However, non-medicinal ingredients, like fillers and ingredients that colour the drug, may be different from those of the brand name product. The generic manufacturer must provide studies showing that the different non-medicinal ingredients have not changed the quality, safety or effectiveness of the generic drug.

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To prove that their products are safe and effective, generic drug manufacturers must demonstrate that the generic drug performs similarly to the brand name drug. The studies that compare the generic drug with the brand name drug are called "comparative bioavailability" studies. In these studies, the level of a medicinal ingredient in the blood of healthy human volunteers is measured. During the studies, each volunteer gets the brand name drug and the new generic drug. The generic drug must show that it delivers the same amount of medicinal ingredient at the same rate as the brand name drug.

Sponsors of the generic medications for ADHD you referenced in your correspondence would have all provided sufficient evidence of the safety, efficacy and quality of these products compared to their respective brand name reference products prior to them being authorized for sale by the Department.

As Dr. Sharma previously indicated, it is important for Health Canada to have a thorough record of any problems with a drug, including a lack of efficacy, and so we would encourage you to recommend that, with the help of their doctor, patients file a report with the Canada Vigilance Program, accessible on the Health Canada website at http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php. Consumers are encouraged to complete reports in conjunction with their health professional, so that additional information about their medical history can be included in order to make the reports more detailed and scientifically valid.

As was outlined in Appendix A of the Survey Overview you provided, adverse reactions of variable frequency and severity are possible with the administration of any health product. Risks associated with a health product's use may arise from several factors including: the properties of the product itself, the disease or condition being treated, the combination with other health products, unpredictable allergic and other individual reactions to a product, inappropriate use of the product or the underlying genetic make-up of the individual which may predispose him/her to certain reactions.

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The process of drug substitution is based on the principles of drug interchangeability and is defined by the various provincial/territorial authorities of health and not Health Canada. The lists of products that are interchangeable and may be legally substituted are usually defined in provincial drug formularies. The provinces and territories determine whether brand and generic drug products are interchangeable and whether they may be substituted without consultation with the prescriber. Health Canada encourages patients to consult their doctors in regards to any changes in their treatment.

The Department continues to monitor the safety profile of all health products once they are marketed to ensure that the benefits of a product continue to outweigh its risks. Any new safety information on a product is communicated to Canadians, so they can make informed decisions about their health. In addition, I can assure you that the Department continuously monitors foreign regulatory activity and considers any new information or actions taken by trusted regulatory partners to determine whether our guidances or policies may need to be revised.

Thank you again for writing and bringing your concerns to my attention.

Sincerely,

Barbara J. Sabourin
Director General

c.c.: Honourable Jane Philpott, Minister of Health
Dr. Supriya Sharma, Senior Medical Advisor, Assistant Deputy Minister's Office
Dr. Doron Almagor, President, CADDRA