The College of Naturopaths of Ontario

Regulatory Guidance

Reporting Adverse Reactions and Side Effects to Health Canada

Health care providers, including naturopathic doctors, can voluntarily report adverse reactions or side effects of health products to the Canada Vigilance Program. Please note that the patient's name is not required when making a report to the Canada Vigilance Program.

The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions and side effects of health products marketed in Canada. Post-market surveillance enables Health Canada to monitor the safety profile of health products once they are marketed to ensure that the benefits of the products continue to outweigh the risks.

Health products include:

- prescription and non-prescription medications,
- natural health products,
- biologically derived products such as vaccines and fractionated blood products,
- cells, tissues and organs,
- radiopharmaceuticals, and
- disinfectants and sanitizers with disinfectant claims.

Adverse reactions for the purpose of reporting to Health Canada are defined as "noxious and unintended effects to health products." Health Canada has also determined 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.

Reportable adverse reactions may:

- occur under normal use conditions of the product,
- be evident at any time, from minutes to years, after exposure to the product,
- range from minor reactions like a skin rash, to serious and life-threatening events such as a heart attack or liver damage.

The registrant does not have to be certain that the health product caused the reaction in order to report it. Most adverse reaction reports are in relation to suspected

associations between the side effects and the health product.

The reporting of adverse reactions and side effects contributes to the ongoing collection of information that occurs once health products are on the market. Reports can lead to:

- the identification of previously unrecognized rare or serious adverse reactions,
- changes in product safety information,
- the withdrawal of a product from the Canadian market,
- increasing the international data regarding benefits, risks or effectiveness of health products, and
- improved safety of health products.

Health Canada is interested in knowing about all suspected adverse reactions and side effects, but especially if they are:

- unexpected (not consistent with product information or labeling), regardless of severity,
- serious, whether expected or not,
- related to a health product that has been on the market less than 5 years.

If a registrant reports an adverse reaction, they will be asked to provide information about themselves and the patient (however as noted above, the patient's name is not required). Information about the patient (such as age, gender, weight, etc.) and the registrant is kept confidential in accordance with the *Privacy Act, 1985*.

The adverse reactions data collected by the program can be accessed through the Canada Vigilance Online Database.

The registrant should document all disclosures in the patient chart.

Additional resources:

Adverse Reaction Reporting and Health Product Safety Information

Canada Vigilance Program

Instructions to Complete the Side Effects Reporting Form

Online form to Report a Side Effect