



Adverse Reaction Reporting for Natural Health Products

By promptly reporting any adverse reactions your patients experience after taking a natural health product, you can help the government of Canada identify important safety issues.

Naturopathic doctors, as authoritative and trustworthy sources of health information, play a key role in helping Canadians understand and use natural health products safely and effectively. This role is becoming increasingly important as more and more Canadians use natural health products as part of their personal health care regime.

What are Natural Health Products?

Natural health products are defined as vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines such as traditional Chinese medicines, probiotics, and other products like amino acids and essential fatty acids. Natural health products are assigned a Natural Product Number (NPN), an Exemption Number (EN) or a Homeopathic Medicine Number (DIN-HM).

Adverse Reactions to Natural Health Products

Natural health products are assessed by Health Canada for safety, effectiveness and quality before they can be licensed for sale in Canada. Health Canada monitors the safety profile of all health products sold in Canada to ensure that the benefits of using them continue to outweigh the risks that may be associated with their use.

An adverse reaction is a harmful or unintended response to a health product, which may include unintended effect, health product misuse, interaction with other products and unusual lack of therapeutic efficacy.

Adverse Reaction Reports are Key

Naturopathic doctors are a valuable resource to Health Canada for safety monitoring of marketed health products through the detection of adverse reactions and interactions between drugs, natural health products and foods.

Information collected by Health Canada from adverse reaction reports is assessed to determine the most appropriate measures for risk management and intervention. When any changes are made about the conditions of use for a product, or if a product is withdrawn altogether, this information is conveyed to Canadians through communications such as advisories and other resource materials.

You do not have to be certain that the product caused the reaction to report it. All adverse reactions should be reported. A serious adverse reaction is one that:

- Results in a death;
- Is life-threatening;
- Causes congenital malformation or birth defect;
- Results in persistent or significant disability or incapacity;
- Requires in-patient hospitalization or prolongation of existing hospitalization;
- Is medically significant.

When submitting an adverse reaction report, the product label, medicinal and non-medicinal ingredients, lot number and expiry date are all useful in Health Canada's assessment of adverse reactions.

Additional information on natural health products can be found in the *Licensed Natural Health Product Database* as well as in the *Natural Health Products Ingredients Database* available on the Health Canada Web site at www.health.gc.ca

To report and to learn more on adverse reactions, visit www.health.gc.ca/medeffect where you can also access the *Canada Vigilance Adverse Reaction Online Database*.