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Adverse Reaction Reporting for Health Care Providers and Consumers

ABOUT THIS GUIDANCE DOCUMENT

In 1998, the House of Commons Standing Committee on Health, which had studied how existing legislation and regulations covered natural health products, released a report that set out a number of recommendations for regulating these products. The Committee recommended that "the level of post-market monitoring [of natural health products] be based on the margin of safety associated with the product and include an adverse reaction reporting system for industry and an adverse reaction hotline for practitioners and the general public" [see **http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/nhp_53_recommendations_e.html**]. In response, Health Canada's Natural Health Products Directorate developed a regulatory framework that includes adverse reaction reporting under the new *Natural Health Products Regulations*. A complete version of the regulations is available on the Internet [see **http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/regs_cg2_cp_e.html**].

This guidance document outlines the information that health care providers and consumers need in order to voluntarily submit a case report, to Health Canada, about an adverse reaction to a natural health product.

Health Canada requires this information so it can ensure that Canadians have access to natural health products that are safe, effective and of high quality.

The definitions of terms used in this guidance document are provided in the Glossary.

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1.0 REPORTING OF ADVERSE REACTIONS TO NATURAL HEALTH PRODUCTS

Health Canada has established an adverse reaction reporting system for the collection and evaluation of information relevant to the safe use of medicinal products, including natural health products.

An adverse reaction is a noxious and unintended response to a natural health product that occurs at any dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying an organic function.

Continued monitoring of adverse reactions is essential to maintaining a comprehensive safety and effectiveness profile of the products that are made available to Canadians. In Canada, the legislative requirements for the post approval surveillance of natural health products are covered under the *Natural Health Products Regulations*. These may be accessed at: **http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/regs_cg2_cp_e.html**.

2.0 WHAT TO REPORT

Adverse reaction reports, for the most part, are only suspected associations. A temporal or possible association is sufficient for a report to be made. However, reporting an adverse reaction does not imply a causal link.

Health care providers and consumers may report all adverse reactions including adverse reactions due to natural health product abuse, overdoses, and interactions (e.g. drug-natural health product interactions).

Health care providers and consumers should report all suspected adverse reactions that are:

- **serious**, whether expected or not; or
- **unexpected**, regardless of their severity i.e. not consistent with product information or labeling.

A serious adverse reaction is a noxious and unintended response to a natural health product that occurs at any dose and that requires in-patient hospitalization or a prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity, that is life threatening or that results in death.

A serious unexpected adverse reaction is a serious adverse reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the natural health product.

3.0 HOW TO REPORT

Reports on adverse reactions, from health care providers and consumers, can be made to Health Canada by completing the template provided in **Appendix 2** or they may use the Health Canada reporting form (HC/SC 4016 (04-02)).

The Health Canada reporting form may be obtained from any of the regional centres or from the National AR Centre (see **Appendix 3**), is included in the Compendium of Pharmaceuticals and

Specialities (CPS), and is also available from the following site: **http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adverse_e.html**.

The reporter is encouraged to complete all relevant sections of the form, using a separate form for each person. Additional pages may be attached if more space is required. The success of the program depends on the quality and accuracy of the information sent in by the reporter.

All the information required in the adverse reaction reporting form for evaluation by Health Canada may not be obtainable at the time the report is made, nevertheless, the report should still be submitted.

Appendix 1 sets out the key data elements that appear on the reporting form and provides additional information and requirements that will allow Health Canada to perform a complete and accurate assessment.

Any follow-up information for an adverse reaction that has already been reported can be sent using another adverse reaction reporting form, or it can be communicated by telephone, fax or e-mail to the appropriate region (see **Appendix 3**).

It is very important that follow-up reports are identified and linked to the original report. The follow-up report should include the specific references in the initial report. For example, it should refer to the same product licence number, original patient, the original reporter, and the date of the initial report. It is recommended that all reporting forms be clearly labelled as "initial" or "follow-up" reports.

Health care providers and consumers may also report adverse reactions to natural health products to the licencee. If this is the case, indicate on the adverse reaction reporting form sent to Health Canada that the case was also reported to the licencee.

4.0 WHERE TO SEND THE REPORT OR TO OBTAIN MORE INFORMATION

The adverse reaction reporting forms should be sent to an appropriate regional centre as listed in **Appendix 3**.

Health care providers and consumers may also report adverse reactions toll free to Health Canada at:

- Telephone: **1-866 234-2345**; or
- Fax: **1-866 678-6789**

The call will be directed to the appropriate adverse reaction regional centre.

For more information on the Health Canada adverse reaction-monitoring program, for additional copies of adverse reaction reporting forms or for further clarification on how to report an adverse reaction, health care providers and consumers are invited to contact the appropriate regional centre (see **Appendix 3**).

GLOSSARY

Adverse Reaction. A noxious and unintended response to a natural health product that occurs at any dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying an organic function.

Brand Name. A name in English or French, whether or not it includes the name of a manufacturer, corporation, partnership or individual (*a*) that is used to distinguish the natural health product; and (*b*) under which a natural health product is sold or advertised.

Common Name. For any medicinal or non-medicinal ingredient contained in a natural health product, the name by which it is commonly known **and is designated in a scientific or technical reference**..

Lot number. Any combination of letters or figures or both by which a natural health product can be traced during manufacturing and identified during and after distribution.

Natural health product. A substance listed in Schedule 1, or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in:

- the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- restoring or correcting organic functions in humans; or
- modifying organic functions in humans to, such as modifying those function in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

NPN/DIN-HM: Natural Product Number is an eight (8) digit numerical code assigned to each natural health product approved to be marketed under the *Natural Health Products Regulations*. DIN-HM is an eight (8) digit numerical code assigned to each homeopathic medicine approved to be marketed under the *Natural Health Products Regulations.*

Serious Adverse Reaction. A noxious and unintended response to a natural health product that occurs at any dose and that requires in-patient hospitalization or a prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity, that is life threatening or that results in death.

Serious Unexpected Adverse Reaction. A serious adverse reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the natural health product.

APPENDIX 1: KEY DATA ELEMENTS FOR ADVERSE REACTION REPORTS

Patient Details	**Patient History**
• Initials or other relevant identifier • Age/date of birth • Sex • Weight/height	• Allergy • Drug or alcohol abuse • Family history • Previous reaction(s) • Tobacco use • Disease states (e.g. diabetes)
Suspected Natural Health Product	**Concomitant Medicinal Products**
• Brand (or trade) name • NPN/DIN-HM • Common name • Lot (or batch) number • Indication(s) of use • Dosage form and strength • Daily dose and regimen • (specify units, e.g. mg, mL, mg/kg) • Route of administration • Start date • Stop date or duration of treatment	• Include for example, prescription products, over-the-counter (non-prescription) medicinal products and non-medicinal product therapies • Provide the same information as for the suspected natural health product
Details of Adverse Reaction(s)	**Outcome**
• Full description of reaction(s), including body site and severity, as well as the criteria for regarding the report as serious. • Start date of onset of reaction • Stop date or duration of reaction • Dechallenge and rechallenge information, if relevant	• Information on recovery and any sequelae (consequence); tests or treatment required • Hospitalization • In case of death, state cause (include autopsy or other postmortem findings when available and date of death) • If unknown, state “unknown”
Details of Reporter of AR	**Administrative and Licensee Details**
• Name • Address • Telephone number • Profession (speciality)	• Source of report: spontaneous (e.g. consumer, health care provider), literature, other • Date report was received by licensee • Country in which the reaction occurred • Type of report: initial vs. follow-up • Name and address of licensee • Name, address, telephone number, fax number and email address of contact person from licensee • Identification for the case (this must be the same for both the initial and follow-up reports)*

*The follow-up report should include the specific references in the initial report. For example, it should refer to the same product licence number, licensee and the original reporter.

APPENDIX 2: ADVERSE REACTION REPORTING FORM TEMPLATE

Report of suspected adverse reaction due to natural health products marketed in Canada

A. Patient Information

1. Patient Identifier	2. Age at time of reaction	3. Sex	4. Height	4. Weight
	_____ or	❑ Male	_____ feet	_____ lbs
Chart Number	**Date of Birth** _____ (dd / mm / yyyy)	❑ Female	**or** _____ cm	**or** _____ kgs

B. Adverse Reaction

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

- ❑ Death _____ (dd / mm / yyyy)
- ❑ Life-threatening
- ❑ Hospitalization
- ❑ Hospitalization – prolonged
- ❑ Other: _____
- ❑ Disability
- ❑ Congenital malformation
- ❑ Required intervention to prevent damage / permanent impairment

2. Date and time of reaction		3. Date of this report
_____ (dd / mm / yyyy)		_____ (dd / mm / yyyy)

4. Describe reaction or problem

5. Relevant tests / laboratory data (including dates (dd / mm / yyyy))

6. Other relevant history, including pre-existing medical conditions
(e.g. allergies, pregnancy, smoking and alcohol use, hepatic / renal dysfunction)

C. Suspected natural health product(s)

1. Name (give labelled strength & manufacturer, if known)
#1 _____ **NPN/DIN-HM:** _____
#2 _____ **NPN/DIN-HM:** _____

2. Dose, frequency & route used
#1 _____
#2 _____

3. Indication for use of suspected natural health product
#1 _____
#2 _____

4. Lot number (if known)
#1 _____ #2 _____

5. Exp. date (if known) (dd / mm / yyyy)
#1 _____ #2 _____

6. Therapy dates (if unknown, give duration)
#1 _____ - _____
#2 _____ - _____
From (dd / mm / yyyy) – To (dd / mm / yyyy)

7. Reaction abated after use stopped or dose reduced
#1 ❑ Yes ❑ No ❑ Doesn't apply
#2 ❑ Yes ❑ No ❑ Doesn't apply

8. Reaction appeared after reintroduction
#1 ❑ Yes ❑ No ❑ Doesn't apply
#2 ❑ Yes ❑ No ❑ Doesn't apply

9. Concomitant medicinal products (name, dose, frequency and route used) and therapy dates (dd / mm / yyyy) (exclude treatment of reaction)

10. Treatment of adverse reaction (medicinal products and / or therapy), **including dates** (dd / mm / yyyy)

D. Reporter *

1. Name, address & phone number

2. Health professional?	3. Occupation	4. Also reported to manufacturer?
❑ Yes ❑ No		❑ Yes ❑ No

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the adverse reaction.

*** Any information related to the reporter and patient identifiers is kept confidential.**

APPENDIX 3: REGIONAL CENTRES

British Columbia

British Columbia Regional AR Centre
c/o BC Drug and Poison Information Centre
1081 Burrard St.
Vancouver BC V6Z 1Y6
Tel: (604) 806-8625; Fax: (604) 806-8262;
E-mail: adr@dpic.ca

Saskatchewan

Saskatchewan Regional AR Centre
c/o Saskatchewan Drug Information Service
College of Pharmacy and Nutrition
University of Saskatchewan
110 Science Place
Saskatoon SK S7N 5C9
Tel: (306) 966-6329; Fax: (306) 966-2286;
E-mail: AR@usask.ca

Ontario

Ontario Regional AR Centre
c/o LonDIS Drug Information Centre
London Health Sciences Centre
339 Windermere Road
London ON N6A 5A5
Tel: (519) 663-8801; Fax: (519) 663-2968;
E-mail: adr@ihsc.on.ca

Québec

Québec Regional AR Centre
c/o Drug Information Centre
Hôpital du Sacré Coeur de Montréal
5400, boul. Gouin ouest
Montréal QC H4J 1C5
Tel: (514) 338-2961; Fax: (514) 338-3670;
E-mail: pharmacovigilance.hsc@ssss.gouv.gc.ca

Atlantic

Atlantic Regional AR Centre
For New Brunswick, Nova Scotia, Prince Edward Island and Newfoundland
c/o Queen Elizabeth II Health Sciences Centre
Drug Information Centre
1796 Summer St., Room 2421
Halifax NS B3H 3A7
Tel: (902) 473-7171; Fax: (902) 473-8612;
E-mail: adr@cdha.nshealth.ca

All other Provinces and Territories

National AR Centre
Marketed Health Products Safety and
Effectiveness Information Division
Marketed Health Products Directorate
Tunney's Pasture
AL 0701C
Ottawa ON K1A 0K9
Tel: (613) 957-0337; Fax: (613) 957-0335;
E-mail: cadrmp@hc-sc.gc.ca