Health Canada / Santé Canada

APPENDIX - J

The form should be printed and faxed toll free to:
56 678-6789 or mailed as per instructions provided.

Canada Vigilance

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

Health Products and Food Branch
Direction générale des produits de santé et des aliments

PROTECTED B**
(when completed)

La version française de ce document est disponible à: http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-fra.php

A. Patient Information (See " Confidentiality" section)

1. Identifier	3. Sex	4. Height	5. Weight
2. Age at time of reaction	☐ Male ☐ Female	____ feet or ____ cm	____ lbs or ____ kgs

B. Adverse Reaction

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

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

2. Date of reaction			3. Date of this report		
YYYY	MM	DD	YYYY	MM	DD

4. Describe reaction or problem

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

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

C. Suspected Health Product(s) (See "How to report" section)

1. Name (give labeled strength & manufacturer, if known)

#1

#2

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
#1	#1 From (yyyy/mm/dd) - To (yyyy/mm/dd)
#2	#2

4. Indication for use of suspected health product	5. Reaction abated after use stopped or dose reduced
#1	#1 ☐ Yes ☐ No ☐ Doesn't apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't apply

6. Lot # (if known)	7. Exp. date (if known)	8. Reaction reappeared after reintroduction
#1	#1 (yyyy/mm/dd)	#1 ☐ Yes ☐ No ☐ Doesn't apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't apply

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

10. Treatment of adverse reaction (medications and / or other therapy), **include dates** (yyyy/mm/dd)

D. Reporter Information (See " Confidentiality" section)

1. Name, address & phone number

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

Canada

Return this form to the appropriate Canada Vigilance Regional Office listed below

APPENDIX I VOLUNTARY ADVERSE REACTION (AR) REPORTING GUIDELINES

Confidentiality of adverse reaction information
Any information related to the identity of the patient and/or the reporter of the AR will be protected as per the *Privacy Act*. For the "identifier" box, provide some type of identifier that will allow you, the reporter, to readily locate the case if you are contacted for more information; do not use the patient's name.

Privacy Notice Statement:
Information related to the identity of the patient and/or reporter will be protected as per the *Privacy Act*, including in the case of an access to information request. Suspected health product-related AR information that is submitted on a voluntary basis is maintained in a computerized database. AR information is used for the monitoring of marketed health products, and may contribute to the detection of potential product-related safety issues as well as to the benefit-risk assessments of these products. For more details with regard to personal information collected under this program, visit the Personal Information Bank; Health Canada; Health Products and Food Branch; Branch Incident Reporting System; PIB# PPU 088 at: http://infosource.gc.ca/inst/shc/fed07-eng.asp.

What to report?
ARs to Canadian marketed health products, including prescription and non-prescription pharmaceuticals, biologics (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health products and radiopharmaceuticals are collected by the Canada Vigilance Program. An AR is a harmful and unintended response to a health product. This includes any undesirable patient effect suspected to be associated with health product use. Unintended effect, health product abuse, overdose, interaction (including drug-drug and drug-food interactions) and unusual lack of therapeutic efficacy are all considered to be reportable ARs.

AR reports are, for the most part, only *suspected* associations. A temporal or possible association is sufficient for a report to be made. Reporting of an AR does not imply a definitive causal link.

All suspected adverse reactions should be reported, especially those that are:
- **unexpected**, regardless of their severity, i.e., not consistent with product information or labeling; or
- **serious**, whether expected or not; or
- reactions to **recently marketed health products** (on the market for less than five years), regardless of their nature or severity.

What is a serious adverse reaction?
A serious AR is one that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death. ARs that require significant medical intervention to prevent one of these listed outcomes are also considered to be serious.

How to report?
To report a suspected AR for health products marketed in Canada, health professionals or consumers (preferably in conjunction with their health professional, so that information about medical history can be included in order to make the reports more complete and scientifically valid) should complete a copy of the Report of Suspected Adverse Reaction Due to Health Products Marketed in Canada (HC/SC 4016). This form may be obtained from the Internet at http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php, from your Canada Vigilance Regional Office (see contact information below), and is also available in the appendices of the Compendium of Pharmaceuticals and Specialities (CPS).

All applicable sections of the Canada Vigilance Reporting Form should be filled in as completely as possible. Use a separate form for each patient. Up to two suspected health products for a particular AR may be reported on one form. Attach an additional form if there are more than two suspected health products for the AR being reported. Additional pages may be attached if more space is required. The success of the program depends on the quality and accuracy of the information provided by the reporter.

To report an Adverse Event following an Immunization (AEFI) for a vaccine used in the prevention of infectious disease, the same criteria as stated in these guidelines are used. Health professionals should complete a copy of the AEFI reporting form. This form is available on the Internet at http://www.phac-aspc.gc.ca/im/aefi-form-eng.php, or in the appendices of the CPS. These forms also exist as customized Provincial/Territorial adverse event forms which can be obtained either from local public health departments or from the Provincial/Territorial health authorities.

For more information on the Canada Vigilance Program, additional copies of the Canada Vigilance Reporting Forms or to report an AR, health professionals and consumers are invited to contact a Canada Vigilance Regional Office as listed below. The following toll-free numbers may be used by health professionals and consumers. Calls will be automatically routed to the appropriate Canada Vigilance Regional Office based on the area code from which the call originates.
Toll-free telephone: 1-866-234-2345 **Toll-free fax: 1-866-678-6789**

British Columbia and Yukon: Canada Vigilance Regional Office - BC and Yukon, 400-4595 Canada Way, Burnaby, British Columbia, V5G 1J9
CanadaVigilance_BC@hc-sc.gc.ca

Alberta and Northwest Territories: Canada Vigilance Regional Office - Alberta and Northwest Territories, Suite 730, 9700 Jasper Avenue, Edmonton, Alberta, T5J 4C3
CanadaVigilance_AB@hc-sc.gc.ca

Saskatchewan: Canada Vigilance Regional Office - Saskatchewan, 4th floor, Room 412, 101 - 22nd Street East, Saskatoon, Saskatchewan, S7K 0E1
CanadaVigilance_SK@hc-sc.gc.ca

Manitoba: Canada Vigilance Regional Office - Manitoba, 510 Lagimodière Blvd, Winnipeg, Manitoba, R2J 3Y1
CanadaVigilance_MB@hc-sc.gc.ca

Ontario and Nunavut: Canada Vigilance Regional Office - Ontario and Nunavut, 2301 Midland Avenue, Toronto, Ontario, M1P 4R7
CanadaVigilance_ON@hc-sc.gc.ca

Québec: Canada Vigilance Regional Office - Québec, 1001 Saint-Laurent Street West, Longueuil, Québec, J4K 1C7
CanadaVigilance_QC@hc-sc.gc.ca

Atlantic: Canada Vigilance Regional Office - Atlantic, For New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, 1505 Barrington St., Maritime Centre, Suite 1625, 16th floor, Halifax, Nova Scotia, B3J 3Y6
CanadaVigilance_ATL@hc-sc.gc.ca

How to deal with follow-up information for an AR that has already been reported?
Any follow-up information for an AR that has already been reported can be submitted using a new Canada Vigilance Reporting Form. It can be communicated by telephone, fax or e-mail to the appropriate Canada Vigilance Regional Office (see contact information above). In order that this information can be matched with the original report, indicate that it is follow-up information, and if known, the date of the original report and the case report tracking number provided in the acknowledgement letter. It is very important that follow-up reports are identified and linked to the original report.

What about reporting ARs to the Market Authorization Holder (manufacturer)?
Health professionals and consumers may also report ARs to the market authorization holder (MAH). Indicate on your AR report sent to Health Canada if a case was also reported to the product's MAH.