



Health
Canada

Santé
Canada

Your health and
safety...our priority.

Votre santé et votre
sécurité... notre priorité.

Reporting Side Effects From Your Medicine

What You Need to Know...



MedEffect Canada

Together we can improve health product safety

Health Canada is the federal department responsible for helping Canadians maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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Signalement des effets secondaires causés par vos médicaments – Ce que vous devez savoir...

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The Purpose of This Guidebook

This Guidebook is one of several resources to help you learn about the important topic of side effects from medicines. Health Canada also has a slide show on the same subject, and hosts a website called MedEffect where you can find the slide show and even more information.

This Guidebook covers:

- Which medicines to report on
- What kinds of side effects are important to take note of and report
- How to recognize the symptoms of a side effect and keep track of them
- Who to inform when you think a medicine has caused a side effect
- How to complete the Health Canada form for reporting side effects
- How reports about side effects, like yours, are used

This is your Guidebook to keep. Fill in your answers to the learning activities. In doing so you may better understand and learn about reporting side effects from your medicine(s) because you will use your personal experience(s) with taking medicines and having perhaps experienced a side effect.

Practical Learning Activity #1: Identifying Your Objectives

Review the following learning objectives for this Guidebook, and tick off the ones that are most important to you at this time.

Learning Objectives

- To gain a clear idea of the range of medicines that can cause side effects
- To understand how side effects can show up or come about, and what you can do about them
- To recognize when side effects to your medicines can show up
- To learn about easy ways to keep track of your side effects
- To become aware of where you can learn about side effects
- To become familiar with Health Canada's method for reporting side effects

Did You Know: Over 50% of recently surveyed Canadians said they would be much more likely to report a side effect (also called an adverse reaction) if they knew why reporting is important and how to report.

Something to think about...

Your health care team (doctor, dentist, nurse, pharmacist or naturopath) needs to know about your side effect to help you.

Health Canada wants to know about your side effect too. Your information, along with other sources of information, may help make the use of medicines safer for all Canadians.

Side Effects: The Facts

What about Side Effects?

Side effects are troublesome symptoms or feelings that you may not expect that show up when you are taking a medicine. Side effects are sometimes also called **adverse reactions**, especially by doctors and other health professionals.

As new medicines are used by more people, more previously unknown side effects (or adverse reactions) show up.

All medicines have risks, including prescription medicines, non-prescription medicines, and natural health products. Any medicine can cause side effects.

How Side Effects Show Up

Side effects show up in different ways. A side effect could appear soon after you start a medicine, and you might suspect a connection right away. For example, you might start having severe diarrhea shortly after starting a medicine. But, on the other hand, a side effect might take time to develop, and it might be a while before you start wondering if something is going on.

Some side effects come about because medicines can interact with other medicines, or with some foods, or with health conditions like diabetes or heart problems. And sometimes there isn't really a side effect at all; the symptoms could show up because you're developing another illness at the same time, and mistakenly think the medicine was the cause.

Serious Side Effects

Some side effects are not serious and just go away on their own. But other side effects are more troublesome and serious. These side effects might have a big impact on your life or someone else's life.

For example:

- You might have been admitted to a hospital
- A child might have been born with a problem or birth defect after the mother took a medicine while she was pregnant
- You could have developed a severe disability for example, where the side effect caused a significant, persistent, or permanent change, impairment, damage or disruption in your body's function/structure, physical activities or quality of life
- You might have needed additional treatment, for example surgery or another medicine, after using a product
- Your life might have been in danger
- Someone you know might have died as a result of the side effect

Serious side effects like these ones are very important to report on.

Something to think about...

You can learn about known side effects in many ways.

Here's how:

- By asking your health care team (your doctor, naturopath, nurse, pharmacist or dentist)
- By reading the printed information you get from your pharmacist or find in the package or box with the medicine
- By looking at trustworthy websites like Health Canada's MedEffect
- By looking the medicine up in the CPS (*Compendium of Pharmaceuticals and Specialities*, also called the "blue book")
- By contacting the manufacturer of the medicine or by looking up the information on their products on their website



Practical Learning Activity #2: Reflecting on Experience

Have you ever had (or thought you had) a side effect to a medicine? Or maybe someone close to you had such a problem? If so, was the side effect “serious” like the ones described earlier?

What was the name of the medicine (s) you were taking at that time?

What were the signs and symptoms that showed up when you were taking the medicine(s)?

What action did you take, for example, who did you inform about the side effect?

Did You Know: Over 50% of recently surveyed Canadians who experienced a side effect (or adverse reaction) as a result of taking a medicine said they reported it to and/or contacted a physician?

Medicines to Report On

Two Main Types of Medicine

You can report on your side effects from all kinds of medicines you take included in these two main types:

- Prescription medicines — any medicine a doctor has given you a prescription for
- Non-prescription medicines — off-the-shelf products you buy that don't need a prescription

Prescription Medicines

Prescription medicines include any medicines your doctor gave you a prescription for, including antibiotics, birth control, blood pressure and cholesterol medicines, just to mention a few.

Prescription medicines also include biological products such as: therapeutic and diagnostic vaccines (like Mantoux or 'TB test'), Insulin, blood products (for example, albumin or clotting factor products), Botox, and allergenic extracts.

Another category of prescription medicines is radiopharmaceuticals, which are always prepared and given by a health care professional. These are radioactive medicines used to diagnose an illness or to treat a disease like cancer.

Non-Prescription Medicines

You can also report on your side effects from non-prescription medicines. That is, medicines you can buy "off the shelf", without a prescription, for example antacids, laxatives, nicotine replacement products, pain relievers, cough and cold medicines, and many others.

Natural Health Products

There are also non-prescription medicines that Health Canada calls Natural Health Products. These products are what some Canadians might call alternative or homeopathic medicines or herbal remedies. There are a number of products that are considered to be Natural Health Products for which you can report side effect to.

Some examples are:

- Vitamins
- Minerals, like calcium and magnesium
- Herbs, such as Echinacea and St. Johns' Wort
- Probiotics, like Lactobacillus acidophilus
- Amino acids like lysine
- Essential fatty acids, for example, alpha-linolenic acid, which is an omega-3 fatty acid found in vegetable sources like flax seed
- Isolates, like glucosamine
- Homeopathic medicines
- Traditional medicines, including ayurvedic medicines and traditional Chinese medicines

Practical Learning Activity #3: Reviewing your medicines

Most of us don't stop to think about the medicines we take, both prescription and non-prescription. Think about the medicines you have taken in the past month.

List them here:

Prescription Medicines:

Non-prescription Medicines (including natural health products):

Something to think about...

Medicines can interact with each other, that is, the combination of one medicine with another might cause a side effect. Medicines can also interact with some foods, for example grapefruit or its juice can increase, or less commonly decrease, the effect of some medicines.

The printed information your pharmacist gives you inform you of possible problems. The package or bottle can also give you this information.

If you have a side effect, don't overlook what you are eating or what medicines you are already taking.

Keeping Track of Side Effects

Note Your Observations

Most of us don't expect to have a side effect, and so we might overlook one when it starts. Later, we might not remember exactly when the problem began or how long it lasted.

It helps if you keep notes about symptoms and feelings, right from the time you start a new medicine. You can keep track of your symptoms and medicines any way you prefer, say, in a notebook or in a computer file. Another way is to start a log form. You should also note down any other medicines you are taking at the same time, because there could be an interaction between these medicines that results in a side effect.

Sample Log Form

The following is a sample log form you could use. It gives you a place to write down important information, like the date and time you experienced a side effect and what you felt, in other words, a description of your symptoms. You could also describe how strong the symptoms were: mild, medium or severe. You could list any other medicines and other treatment(s) you were using. You could even note whether the symptoms showed up when you ate a certain food.

If you like this approach, you can make copies of this form to keep on hand.

Side Effect Log Form

Name: _____

Medicine Name(s): _____

Medicine Dosage: _____

Scale:

1 = very mild side effect/symptoms to

10 = very bad side effect/symptoms

Side Effects/ Symptoms	Scale	Date & Time Medicine(s) Taken	Other Medicine(s) or Treatment(s) or Food(s)

Additional Notes:

How Your Notes Help

Your notes describing possible side effects can be very helpful in several ways.

First, you can use them to remind you of details that may alert your health care professional(s) (like your doctor, dentist, nurse, pharmacist or naturopath) to a problem.

As well, you will have a record to refer to in the future, in case you are ever prescribed the same or a similar medicine again.

And finally, your notes will help you and your health care professionals, if you decide to complete Health Canada's adverse reaction report form.

Reporting Side Effects

A Team Approach

Reporting side effects is a team effort that starts with you, because you are the one who experienced the side effect, and you know what happened. When you work as a team with your health care professionals, like your doctor, nurse, pharmacist, naturopath, or dentist, you'll have the kind of information Health Canada needs to keep track of the safety of your medicines. Your information helps Health Canada and the product's manufacturer build a complete and accurate picture of the experience Canadians are having with their medicines.

Who to Report To

If you are concerned about a possible side effect, talk to the health care professional(s) you've been seeing. Your doctor, nurse, pharmacist, naturopath, dentist; these are the people who know your case the best. You can report side effects directly to Health Canada yourself too, and if you do, it's still a good idea to involve your health care team. They may be able to give you test results, information about possible interactions between products, and so on, that will make your report even more complete and therefore valuable. You may also want to inform the manufacturer of the medicine about your side effect.

Practical Learning Activity #4: Matching Up Your Medicines

Match the medicines you are using right now with the health care professional who advised you to use them. Beside the team member, jot down the names of the medicines that person recommended.

Beside the last category, “Other Health Products I Take “, list the ones you have decided to take on your own.

Doctor

Dentist

Nurse

Naturopath



Pharmacist

Other Medicines or Health Products I Take

Reporting Side Effects to Health Canada

Health Canada has a form to use to make a report when you think you’ve had a side effect from a medicine. The form, called the **Report of suspected adverse reaction due to health products marketed in Canada**, is the one to use. Note that prescription and non prescription medicines are types of health products.

The form comes in two slightly different versions, a paper version and an online (or electronic) version.

		Canadian Adverse Drug Reaction Monitoring Program		Health Products and Food Branch Direction générale des produits de santé et des aliments	
<p>• The form should be printed and faxed toll free to: 1 866 678-6789 or mailed as per instructions provided. • La version française de ce document est disponible à: http://www.hc-sc.gc.ca/dhp-mps/modelf/report-declaration/form/ar-ei_form_f.html</p>					
<p align="center">Report of suspected adverse reaction due to health products* marketed in Canada</p>				<p align="center">PROTECTED B** (when completed)</p>	
A. Patient Information (See "Confidentiality" section)			C. Suspected Health Product(s) (See "How to report" section)		
1. Identifier	3. Sex <input type="checkbox"/> Male <input type="checkbox"/> Female	4. Height _____ feet _____ cm	5. Weight _____ lbs _____ kgs	1. Name (give labeled strength & manufacturer, if known) # 1 _____ # 2 _____	
B. Adverse Reaction			2. Dose, frequency & route used # 1 _____ # 2 _____		
1. Outcome attributed to adverse reaction (check all that apply) <input type="checkbox"/> Death (yyyy/mm/dd) <input type="checkbox"/> Disability <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital malformation <input type="checkbox"/> Hospitalization <input type="checkbox"/> Required intervention to prevent damage/permanent impairment <input type="checkbox"/> Hospitalization - prolonged <input type="checkbox"/> Other : _____			3. Therapy dates (if unknown, give duration) # 1 From (yyyy/mm/dd) - To (yyyy/mm/dd) # 2 _____		
2. Date of reaction YYYY MM DD		3. Date of this report YYYY MM DD		4. Indication for use of suspected health product # 1 _____ # 2 _____	
4. Describe reaction or problem					
5. Reaction abated after use stopped or dose reduced # 1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply # 2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply					
6. Lot # (if known) 7. Exp. date (if known) # 1 _____ # 1 (yyyy/mm/dd) # 2 _____ # 2 _____					
8. Reaction reappeared after reintroduction # 1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply # 2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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)					
5. Relevant tests / laboratory data (including dates (yyyy/mm/dd))			D. Reporter Information (See "Confidentiality" section)		
6. Other relevant history, including pre-existing medical conditions (e.g. allergies, pregnancy, smoking and alcohol use, hepatic / renal dysfunction)					
1. Name, address & phone number					
2. Health professional? <input type="checkbox"/> Yes <input type="checkbox"/> No		3. Occupation		4. Also reported to manufacturer? <input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the adverse reaction. * Use this form to report suspected adverse reactions to pharmaceuticals, biologics (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health products or radiopharmaceuticals. ** As per the Treasury Board of Canada Secretariat Government Security Policy.</p>					
					

For either version of the form, there are four very important pieces of information that **must** be filled in:

1. A way to identify the patient who experienced the side effect, in **Section A**
2. A description of the side effect, in **Section B**
3. The name of the medicine or other health product you think caused the side effect, in **Section C**
4. The name and mailing address of the person reporting the side effect, in **Section D**

Section A: Identifier

A. Patient Information (See "Confidentiality" section)			
1. Identifier	3. Sex	4. Height	5. Weight
	<input type="checkbox"/> Male	_____ feet	_____ lbs
2. Age at time of reaction	<input type="checkbox"/> Female	or _____ cm	or _____ kgs

In **Section A**, under 'Identifier', you should write a word or code that would remind you in the future who this report is about: yourself, or another person who experienced a side effect. When doctors fill out this report, for example, they might use the patient's chart number as the identifier. In any case, personal information like your name, initials, birth date or social insurance number, should not be used.

The other information in **Section A** (age, gender, height and weight) is also very important, because these factors may affect how the medicine works in different types of bodies.

Section B: Adverse Reaction

In **Section B**, you would check off the results that came about because of the side effect. For example, perhaps you were admitted to the hospital, or you developed a disability.

In **Section B**, you also describe, in your own words, the symptoms you had: what happened and how you were affected. If you were prescribed another medicine to treat the side effect, you can say that here too.

B. Adverse Reaction						
1. Outcome attributed to adverse reaction (check all that apply)						
<input type="checkbox"/> Death _____ (yyyy/mm/dd)				<input type="checkbox"/> Disability		
<input type="checkbox"/> Life-threatening				<input type="checkbox"/> Congenital malformation		
<input checked="" type="checkbox"/> Hospitalization				<input type="checkbox"/> Required intervention to prevent damage/permanent impairment		
<input type="checkbox"/> Hospitalization - prolonged				<input type="checkbox"/> Other : _____		
2. Date of reaction			3. Date of this report			
YYYY	MM	DD	YYYY	MM	DD	
2007	01	15	2007	02	23	
4. Describe reaction or problem						
Very bad diarrhea and blacked out. Went to the hospital and was told I was dehydrated.						

Section C: Suspected Health Product(s)

In **Section C**, Suspected Health Product(s), write the name of the medicine or other health product you think caused the side effect. Two lines are given here in case you suspect more than one health product, but list only the products you suspect most.

You may find it helpful to have the medicine's package or bottle with you when you fill in **Section C**. This will help you give the exact details of the product's name. In some cases, there are different versions of a product, for example, *Zyncofan XD* or *Zyncofan MR*. Those extra letters are important.

C. Suspected Health Product(s) (See "How to report" section)	
1. Name (give labeled strength & manufacturer, if known) # 1 Drug X 50mg # 2	
2. Dose, frequency & route used # 1 50mg daily # 2	3. Therapy dates (if unknown, give duration) # 1 From (yyyy/mm/dd) - To (yyyy/mm/dd) 2007-01-14 to 2007-01-24 # 2

Natural health products sometimes have names that don't really tell much about the ingredients (for example, detox formula or bowel cleaner). Also, there may be several ingredients in one product, like a multi-vitamin that has one name, but may contain up to 30 ingredients. You can attach a photocopy of the product label if you like, or write out as much information about the ingredients as you can. Just as the extra letters are important for drugs, the extra information on the label of a natural health product is important too.

Another piece of important information to include is the dose you were taking of the medicine or health product (for example 50 milligrams twice a day, or two tablets after each meal). In the case of pills, if you don't know the amount of the dose, you can describe what the pills look like.

Section D: Reporter Information

In **Section D**, Reporter Information, include your name, address and phone number, as the person reporting the side effect. That way, if Health Canada needs more information they'll be able to contact you. You can report a side effect that someone else experienced (say, a family member or a friend), and if you do, you should still give your own name and contact information, as you are the person reporting.

Section D also has a place for you to state whether you are a health professional—you may include your occupation here if you wish. If you are also reporting your side effect to the company that makes the medicine or health product, you can say so in this section as well. To send your report to the company, look for the contact information on the medicine's bottle, package or box, in the Manufacturers' Index in the *Compendium of Pharmaceuticals and Specialties* (the 'blue-book'), or look their address up on the internet.

D. Reporter Information (See "Confidentiality" section)		
1. Name, address & phone number 		
2. Health professional? <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation 	4. Also reported to manufacturer? <input type="checkbox"/> Yes <input type="checkbox"/> No

Something to think about...

You can complete and send a report about a side effect someone close to you has experienced. Just be sure to give your own name and contact information as the 'reporter'.

Add More Information about Your Side Effect

The more information you can fill in on the report form, the better.

Time-lines are very important, such as the date the side effect happened, and the dates you started and stopped taking the medicine.

All this information is used by Health Canada to look for a possible link between the medicine and the side effect. So fill in these dates to the best of your knowledge. Here is where your log form or notes about observations comes in handy.

You should also write down any test and lab results you have, and describe what happened when you stopped the medicine, or what happened if you started taking it again. You may find it helpful to involve your health care professional for completing this section if you can.

In the space for “other relevant history” you should write about things like any allergies you have, whether you are pregnant, and so on. If you smoke and drink alcohol, include how often and how much, for instance, one pack of cigarettes a day, or two to four alcoholic drinks a week.

Health Canada / Santé Canada Canadian Adverse Drug Reaction Monitoring Program Health Products and Food Branch / Direction générale des produits de santé et des aliments

* The form should be printed and local toll free no: 1 866 678-6789 or mailed in per instructions provided. / La version française de ce document est disponible à: http://www.hc-sc.gc.ca/medtop/medtop/rapport/declaration/formulaire_fr.html

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

PROTECTED B (when completed)**

A. Patient Information (See "Confidentiality" section)

1. Name: #1 _____ #2 _____
 2. Sex: Male Female
 3. Age at time of reaction: _____
 4. Height: _____ cm _____ in _____ ft _____ in _____ lbs _____ kg
 5. Weight: _____

B. Adverse Reaction (See "Confidentiality" section)

1. Outcome attributed to adverse reaction (check all that apply):
 Death (yyyy/mm/dd) Disability
 Life-threatening Congenital malformation
 Hospitalization Required intervention to prevent damage/permanent impairment
 Hospitalization - prolonged Other: _____

2. Date of reaction: YYY Y MM DD #3. Date of this report: YYY Y 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 labelled strength & manufacturer, if known): #1 _____ #2 _____

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

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

4. Indication for use of suspected health product: #1 _____ #2 _____

5. Reaction abated after use stopped or dose reduced: #1 Yes No (Don't) apply #2 Yes No (Don't) apply

6. Lot # (if known): #1 _____ #2 _____

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

8. Reaction reappeared after reintroduction: #1 Yes No (Don't) apply #2 Yes No (Don'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? Yes No #3. Occupation: _____ #4. Also reported to manufacturer? Yes No

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the adverse reaction.
 * Use this form to report suspected adverse reactions to pharmaceuticals, biologics (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health products or radiopharmaceuticals.
 ** As per the Treasury Board of Canada Secretariat Government Security Policy.

Canada

Other Useful Facts

Health Canada / Santé Canada

Canadian Adverse Drug Reaction Monitoring Program

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

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

* The form should be printed and faxed toll free to: 1 866 678-6789 or mailed as per instructions provided.
 * Le formulaire doit être imprimé et déposé par télécopieur à: 1 866 678-6789 ou par la poste en suivant les instructions.

http://www.hc-sc.gc.ca/drugs/rdmt/rdmt/rdmt-report-dre/declaration-form-fr-01_faxm_01.html

PROTECTED B**
 (when completed)

A. Patient Information (See "Confidentiality" section)		C. Suspected Health Product(s) (See "How to report" section)	
1. Identifier	3. Sex <input type="checkbox"/> Male <input type="checkbox"/> Female	4. Height feet _____ or _____ cm	5. Weight lbs _____ or _____ kg
B. Adverse Reaction 1. Outcome attributed to adverse reaction (check all that apply): <input type="checkbox"/> Death (yyyy-mm-dd) <input type="checkbox"/> Disability <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital malformation <input type="checkbox"/> Hospitalization <input type="checkbox"/> Required intervention to prevent damage/permanent impairment <input type="checkbox"/> Hospitalization - prolonged <input type="checkbox"/> Other: _____		2. Dose, frequency & route used #1 _____ #2 _____	3. Therapy dates (if unknown, give duration) #1 From (yyyy-mm-dd) - To (yyyy-mm-dd) #2 _____
2. Date of reaction YYYY MM DD	3. Date of this report YYYY MM DD	4. Indication for use of suspected health product #1 _____ #2 _____	5. Reaction abated after use stopped or dose reduced #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> (Doesn't apply) #2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> (Doesn't apply)
4. Describe reaction or problem		6. Lot # (if known) #1 _____ #2 _____	7. Exp. date (if known) #1 (yyyy-mm-dd) #2 _____
5. Relevant tests / laboratory data (including dates) (yyyy-mm-dd)		8. Reaction reappeared after reintroduction #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> (Doesn't apply) #2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> (Doesn't apply)	
6. Other relevant history, including pre-existing medical conditions (e.g. allergies, pregnancy, smoking and alcohol use, hepatic / renal dysfunction)		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 (medication and / or other therapy), include dates (yyyy-mm-dd)	
		D. Reporter Information (See "Confidentiality" section)	
		1. Name, address & phone number	
		2. Health professional? <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation
		4. Also reported to manufacturer? <input type="checkbox"/> Yes <input type="checkbox"/> No	

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the adverse reaction.
 * Use this form to report suspected adverse reactions to pharmaceuticals, biologics (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health products or radiopharmaceuticals.
 ** As per the Treasury Board of Canada Secretariat Government Security Policy.
 HC/SC 5000 (06/06)

← Reaction abated

← Concomitant health products

In the section called **Concomitant health products**, list anything else you were taking at the same time as the medicine you are suspicious about. Don't overlook things like vitamins, supplements and herbs. If you have nothing to report here, it's good to write "nothing else taken" rather than leaving this space blank.

In the section that asks about whether the "reaction abated" (that is, became less intense when you stopped the medicine or reduced the dose), answer "yes" or "no", if it applies. If you tried the medicine again, you could state whether you had the same side effect or reaction again.

How Health Canada Works with Your Report

What does Health Canada do with the reports people send in? Reports are first checked over to make sure the basic information is complete. There must be an identifier for the patient, a description of the side effect (or adverse reaction), the name of the medicine, and the reporter's name and contact information. Without this information, reports cannot be processed.

The reports are then entered into an electronic database.

The seriousness of the suspected reaction is assessed, by considering whether the person was admitted to the hospital, whether a severe disability resulted, and so on. A standard international medical terminology is used to classify the information, which helps to make sure that the same term is used when similar experiences are reported.

The information from the reports, along with other information, is used to check for new safety concerns about a product.

Health Canada shares non-confidential details on the internet to make it possible for manufacturers to be aware and take proper action(s).

Will Health Canada contact me?

Will you hear back from Health Canada once you have reported on a side effect, or in other words, an adverse reaction?

Yes, Health Canada sends a letter thanking people who report on side effects. The letter also gives you a tracking number for your report. This number should be used if you have follow-up information to give later, or if Health Canada needs to contact you for more information.

How to Obtain and Send a Report Form

The Adverse Reaction report form is available from a number of sources.

Internet

Health Canada's MedEffect website includes the report form, which you can fill out and submit online.

www.healthcanada.gc.ca/medeffect



Telephone (toll-free)

You can also get the form, or make a report immediately, by phoning Health Canada's toll-free number. Call: 1-866-234-2345, and ask to have the form sent or give your report in person.

CPS

You can photocopy the form from the back of the "blue book," which is titled The Compendium of Pharmaceuticals and Specialties. This book, produced each year by the Canadian Pharmacists Association, includes product information on many but not all products authorized by Health Canada for sale in Canada

By Mail

When you get to the main MedEffect page, click on "Adverse Reaction Reporting", and then on "Regional Adverse Reaction Monitoring Offices". From here if you scroll down you will find a list of Regional Office Addresses. You can then mail your stamped envelope to your nearest Regional Office.

MedEffect Offers More

When you go to MedEffect's main page you will find many more topics you can explore to increase your knowledge about side effects. Here is just a sample list:

- You can receive the Canadian Adverse Reaction Newsletter (CARN) along with health product advisories free by e-mail simply by joining MedEffect's mailing list.
- You can read back issues of the Newsletter and Advisories too.
- You can link to the Drugs & Health Products section on Natural Health Products and on Veterinary Drugs. If you go to the Veterinary Drugs section you will learn, for example, about reporting side effects that you, yourself, might have had from handling veterinary products used to treat animals.
- You can find reports and publications about a wide range of subjects, like surveys approved by Health Canada.



These are only a few examples of the many sources and resources MedEffect offers you to add to your knowledge about side effects.

Specialized Report Forms

Vaccines

Vaccines that prevent infectious diseases like flu or measles use a different form. If you experience an adverse reaction after immunization, ask your health care professional (like your doctor, pharmacist, dentist or nurse) to complete the form called ***Adverse Events Following Immunization***. This form is sent to the local health department or directly to the Public Health Agency of Canada. Find this form at:

http://www.phac-aspc.gc.ca/im/ae-fi-form_e.html

Medical Devices

Reactions to medical devices (like tampons, condoms or contact lenses, just to mention a few) are reported to the Health Products and Food Branch Inspectorate of Health Canada. A special form is used to report side effects to these products. Find this form when you click on the “Compliance and Enforcement” section on MedEffect’s main page, followed by “Problem Reporting”.

If you are not sure which form to use, simply use the report form for reporting side effects from medicine(s). Health Canada will reroute the information.

Your Report is Important!

Your report is kept in Health Canada's electronic database, and used to build an understanding of possible side effects. Health Canada may also look to other sources of information about side effects too, **for example:**

- Medical publications may carry reports of side effects that doctors, pharmacists, and other professionals think they have come across.
- Other countries share the information they have about possible side effects.
- Regulatory agencies in other countries that oversee certain aspects of health and safety may share their information.
- The companies that make a medicine or health product also provide reports about their products.

It is usually a review of a combination of these sources of reports that detects a sign or trend about a possible problem with a particular medicine.

Practical Learning Activity #5: Assessing Your Learning

At the beginning of this Guidebook, you ticked off the items you wanted to learn about. Review the list again, this time assessing whether you achieved your learning goals.

- To gain a clear idea of the range of medicines that can cause side effects
- To understand how side effects can show up or come about, and what you can do about them
- To recognize when side effects to your medicines can show up
- To learn about easy ways to keep track of your side effects
- To become aware of where you can learn about side effects
- To become familiar with Health Canada's method for reporting side effects

Remember, the MedEffect site can help you continue your learning if you want to learn more about side effects and the actions you can take.

Notes

www.healthcanada.gc.ca/medeffect
1-866-234-2345

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