

The slide features a blue header with the Health Canada logo and the slogan "Your health and safety...our priority. / Votre santé et votre sécurité... notre priorité." Below this, the text "Helping the people of Canada maintain and improve their health" is paired with its French equivalent "Aider les Canadiens et les Canadiennes à améliorer leur état de santé". The main title "Reporting Side Effects from your Medicine: what you need to know" is centered, followed by the subtitle "Consumer Adverse Reaction Reporting Education Module" and a speaker icon. The bottom section includes the "MEDeffect" logo, the slogan "Together we can improve health product safety", and the "Canada" logo.

Health Canada Santé Canada Your health and safety...our priority. Votre santé et votre sécurité... notre priorité.

Helping the people of Canada maintain and improve their health Aider les Canadiens et les Canadiennes à améliorer leur état de santé

**Reporting Side Effects from your Medicine:
what you need to know**

Consumer Adverse Reaction Reporting Education Module

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Canada

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

If you think you've had a side effect from your medicine, Health Canada wants to hear about it so we can work toward making the medicines you use safer and more effective for everyone.

This slide show will teach you important facts on reporting side effects from your medicine(s). There is also a guide book on the same topic, which you will be able to print out at the end of the slide show.

Side effects = adverse reactions

Side effects may be:

- troublesome
- unexpected

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AUDIO SCRIPT: Side effects are sometimes also called “adverse reactions,” especially by doctors and other health professionals. Both terms mean the same thing, that is: troublesome symptoms or feelings that you may not expect, that show up when you are taking a medicine.

Reporting side effects: what you need to know

- Which medicines?
- What kinds of side effects?
- How to recognize and keep track of your symptoms?
- Who to inform?
- How to complete Health Canada's report form?
- How are reports used?

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AUDIO SCRIPT: To report side effects to your health care professional or Health Canada, you need to know:

- Which medicines you should report on
- The types of side effects you should be reporting
- How you would recognize the symptoms of a side effect and keep track of them
- Who you should inform about side effects
- How to make a report about a side effect to Health Canada
- How Health Canada uses reports about side effects

Medicines to report on

Prescription medicines.....need a prescription

- For example:
 - antibiotics, birth control, blood pressure and cholesterol medicines etc.
- Other examples:
 - biological products (therapeutic and diagnostic vaccines [Mantoux or 'TB test'], Insulin, blood products [albumin, clotting factor products], Botox, allergenic extracts
- Another category:
 - radiopharmaceuticals (radioactive drugs to diagnose or treat disease like cancer)



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AUDIO SCRIPT: You can report on your side effects from all types of medicines. To begin with:

• Prescription medicines – that is, any medicine a doctor has given you a prescription for

For example:

• antibiotics, birth control, blood pressure and cholesterol medicines just to mention a few

Other examples of prescription medicines are Biological products – There are many of these medicines. Therapeutic and diagnostic vaccines, like the Mantoux (also called the TB test) is one example. Insulin is another. So are blood products like albumin or any of the clotting factor products. And Botox and Allergenic Extracts for treating allergies are other examples.

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.

Medicines to report on

Non-prescription medicines...off-the-shelf/ no prescription

- antacids, laxatives, nicotine replacement products, pain relievers, and cough and cold medicines, etc.
- natural health products

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AUDIO SCRIPT: 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.

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 effects to. The next slide gives you some examples.

Medicines to report on

- **Natural health products**

- vitamins
- minerals
- herbs
- probiotics
- amino acids
- essential fatty acids
- isolates
- homeopathic medicine
- traditional medicines



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AUDIO SCRIPT: Natural health products include:

- 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 seeds
- Isolates, like glucosamine
- Homeopathic medicines, and
- Traditional medicines, including ayurvedic medicines and traditional Chinese medicines

Side effects vary

- Some side effects start soon
- Others take time to develop
- Interaction with other medicines, foods, or health conditions
- May not actually be a side effect at all



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AUDIO SCRIPT: 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 that result in

- Hospitalization
- Malformation
- Disability
- Further treatment
- Life-threatening
- Death

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AUDIO SCRIPT: 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 or one that lasted for a long time
- You might have needed additional treatment, for example surgery or another medicine, after using a product
- Your life might have been in danger, or
- Someone you know might have died as a result of the side effect

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

Some side effects are known

- Talk to your health professional
- Read the information sheets
- Look at the CPS or “blue book”
- Contact the manufacturer
- Visit MedEffect and other reliable Websites



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AUDIO SCRIPT: As we saw, all medicines have risks or possible side effects. You can learn about known side effects a number of ways:

- You can talk to any of your health care team, like your doctor, pharmacist, nurse, naturopath or dentist.
- You can read the information sheet your pharmacist gives you with your prescription, or the one that sometimes comes in the package or box with the medicine.
- You can look up your medicine in the Compendium of Pharmaceuticals and Specialties, or CPS, also called the *blue-book*.
- You may want to contact the manufacturer of the medicine or look up information on their product on their Website.
- Trustworthy Websites like Health Canada’s MedEffect Website carry good information about previously reported side effects.

Keeping track of side effects

- Note your observations
 - when a side effect started
 - how long the side effect lasted
- Note your medicines
- Use a notebook or computer file or log form



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AUDIO SCRIPT: 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 your 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

Side Effect Log Form


Name: _____

Medicine Name(s) _____

Medicine Dosage: _____

Scale: 1 = very mild side effect/symptom 10 = very bad side effect/symptom

Side Effect/Symptoms	Scale	Date & Time Medicine(s) Taken	Other Medicine(s) or Treatments or Food(s)



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AUDIO SCRIPT: Here 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 print this form out at the end of this slide show and make copies of it to keep on hand.

How your notes help

- May alert health care professionals to a problem
- Can be a useful record for the future
- Can help you complete an adverse reaction report



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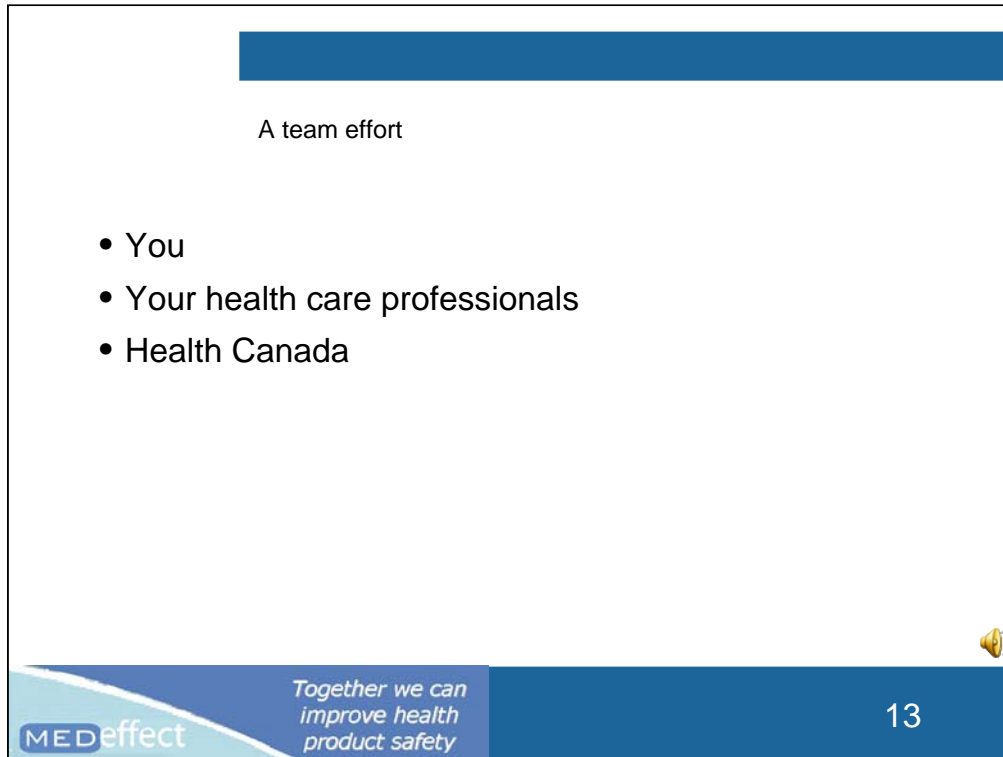
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AUDIO SCRIPT: Your notes describing possible side effects can be very helpful:

- The symptoms you've described may alert your health care professional(s) to a problem.
- You'll have a record to refer to in the future, in case you are ever prescribed the same or a similar medicine again.
- Your notes will help you and your health care professionals, if you decide to complete Health Canada's adverse reaction report form.

The information on these adverse reaction reports, along with other sources of information, may help make the use of medicines safer.



A team effort

- You
- Your health care professionals
- Health Canada

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The slide features a blue header bar at the top. Below it, the text "A team effort" is centered. A bulleted list follows, listing "You", "Your health care professionals", and "Health Canada". At the bottom, there is a blue footer bar with the "MEDeffect" logo on the left, the slogan "Together we can improve health product safety" in the center, and the number "13" on the right. A small yellow speaker icon is located in the bottom right corner of the slide area.

AUDIO SCRIPT: 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 professional(s) 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.

Concerned about a possible side effect?

- Inform your health care professional(s)
 - doctor, nurse, pharmacist, naturopath or dentist
- Report to Health Canada
- Report to the manufacturer of the medicine



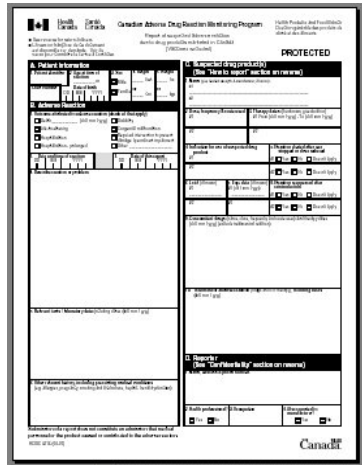
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AUDIO SCRIPT: If you are concerned about a possible side effect, talk to the health care professional(s) you've been seeing. Your doctor, nurse, pharmacist, naturopath, dentist; these are the people who know your case the best. You can report side 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.

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



- Identifiable patient
- Description of the side effect/reaction
- Suspected medicine/health product
- The reporter's name and address

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AUDIO SCRIPT: The next several slides explain how to complete a written report about a side effect.

This 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. Both versions have four very important pieces of information that **must** be filled in:

A way to identify the patient who experienced the side effect, in Section A

A description of the side effect, in Section B

The name of the medicine or other health product you think caused the side effect, in Section C

The name and mailing address of the person reporting the side effect, in Section D.

The information in sections A and D, about a person's identity, is kept confidential. Its use is covered by the *Access to Information Act* and the *Privacy Act*. It's only looked at by Health Canada employees who need it to do their job, which may require follow up work.

We'll now look at each of these four sections in more detail.

Section A: Patient Information

A. Patient Information (See "Confidentiality" section below)			
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

- Identifier
- Age, gender, height, weight



AUDIO SCRIPT: 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

- Check off the results of the side effect
- Describe what happened

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
2006	01	15	2006	02	23
4. Describe reaction or problem					
Very bad diarrhea and blacked out. Went to the hospital and was told I was dehydrated.					

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AUDIO SCRIPT: In Section B, you should 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.

Section C: Suspected Health Product(s)

- Name of the medicine or health product you suspect
- List only the one(s) you suspect most
- Ingredients
- Dose

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	50 mg daily
3. Therapy dates (if unknown, give duration)	
# 1 From (yyyy/mm/dd) - To (yyyy/mm/dd)	2006-01-14 to 2006-01-24
# 2	# 2

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AUDIO SCRIPT: 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.

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

- Give your name, address and phone number
- You can report for someone else
- Health professional?
- Occupation
- Reported to manufacturer?



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AUDIO SCRIPT: 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 up their address on the Internet.

More information about your side effect

- Time-lines
 - date of side effect/reaction
 - date started the medicine
 - date stopped the medicine
- Tests/Lab results
- Other relevant history:
 - allergies, pregnancy, smoking and alcohol

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

Time-lines are very important. 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 come 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.

Other useful facts

The image shows a Canadian Medication Event Reporting Form (MERRF) with several green arrows pointing to specific sections. The arrows point to the 'Concomitant health products' section, the 'Reaction abated' section, and the 'Reaction reappeared after reintroduction' section. The form includes fields for patient information, medication details, and a detailed description of the event.

- Concomitant health products
 - means anything else you were taking
- Reaction abated
 - means your side effect let up after use stopped or dose was reduced
- Reaction reappeared after reintroduction

AUDIO SCRIPT: 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.

What does Health Canada do with the report?



- Reports are received and checked
- Report information is entered into a database
- Seriousness is assessed
- Medical terminology is applied
- Check for new safety concerns
- Share non-confidential details



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AUDIO SCRIPT: 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?

- You will get a letter
 - to say thank you
 - to give you a tracking number



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AUDIO SCRIPT:

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.

Where to get the adverse reaction report form

Internet

- Health Canada
 - MedEffect Program

Telephone (toll-free)

- 1-866-234-2345

CPS

- Photocopy back of the Compendium of Pharmaceuticals and Specialties (CPS) or “blue book”



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AUDIO SCRIPT: The Adverse Reaction report form is available from a number of sources. You can get it on the Internet from Health Canada's Website in a section called MedEffect. You can also get the form by phoning Health Canada's toll-free number and asking to have it sent.

Or, you can photocopy the form from the back of the “blue book,” which is titled The Compendium of Pharmaceuticals and Specialties: a book made every year by the Canadian Pharmacists Association which includes product information on many but not all products authorized by Health Canada for sale in Canada.

Contact information like phone numbers and Websites will be given again in a moment.

If you think you've had a side effect from a medication

Please report it!



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AUDIO SCRIPT: If you experienced a side effect, take an active role. Please report it to your health care professional, like your doctor, pharmacist, nurse, naturopath or dentist, or to Health Canada.

Do you need more information about...

- Which medicines?
- What kinds of side effects?
- How to recognize and keep track of your symptoms?
- Who to inform?
- How to complete Health Canada's report form?
- How reports are used?
- [Click here for the Guidebook](#)



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AUDIO SCRIPT: You've heard and seen a lot of information about reporting side effects in this slide show. Look over the list of topics you learned about. Do you feel you'd like more information about some of these areas? If you'd like to continue your learning, there is a handy guidebook you can print out, where you will find more information and activities to delve into.

Health Canada thanks you for taking the time to inform yourself about this important subject: reporting side effects. Together we can make the use of medicines safer for all Canadians.

To make a report

www.healthcanada.gc.ca/medeffect

- Online reporting
- Paper copy report form
 - toll-free fax: 1-866-678-6789
 - mail (stamped envelope)
- Toll-free phone: 1-866-234-2345



AUDIO SCRIPT:

The Web address shown here will take you to the main MedEffect page. When you get to this page, click on Adverse Reaction Reporting and you will find instructions on how to report online, how to report on a paper copy of the form should you want to fax or mail your report to Health Canada, and instructions on phoning a Regional Adverse Reaction Monitoring Office using a toll-free number.

Sample log form: click & print

Side Effect Log Form


Name: _____

Medicine Name(s) _____

Medicine Dosage: _____

Scale: 1 = very mild side effect/symptom 10 = very bad side effect/symptom

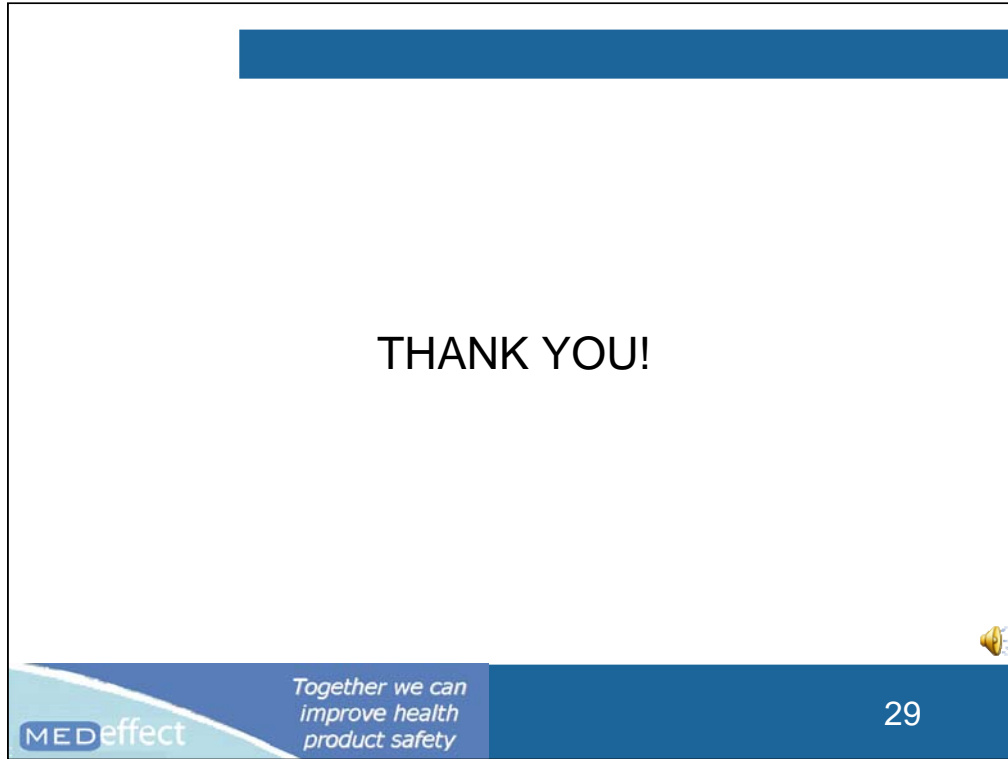
Side Effect/Symptoms	Scale	Date & Time Medicine(s) Taken	Other Medicine(s) or Treatments or Food(s)



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AUDIO SCRIPT: Simply click on the form to print.



AUDIO SCRIPT: Thank you!