

Your health and safety... our priority.

Adulteration of Natural Health Products

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# IT'S YOUR HEALTH

# **Adulteration of Natural Health Products**

### The Issue

Many natural health products (NHPs) have a history of safe use. But some products marketed or represented as NHPs have been adulterated. Products that



are adulterated contain substances that are not declared on the label, including prescription medications or other potentially dangerous ingredients. If you use one of these products, you will be exposed to the added drugs or substances without your knowledge, which may present serious risks to your health.

# Background

"Natural health product" (NHP) is an expression used in Canada to refer to a group of health products, including:

- vitamin and mineral supplements
- herbal and other plant-based health products

- traditional medicines (like Traditional Chinese medicines and Ayurvedic or East Indian medicines)
- homeopathic medicines
- omega-3 and other essential fatty acids
- amino acid supplements
- probiotics
- some personal care products like toothpastes and mouthwashes with fluoride, and anti-perspirants.

Health Canada assesses NHPs for their safety, effectiveness and quality before they are authorized for sale in Canada. NHPs that have been licensed by Health Canada are labelled with either a Natural Product Number (NPN) or a Homeopathic Medicine Number (DIN-HM).

Despite this licensing process, it is still possible to get unauthorized NHPs through retail stores or other routes (like the Internet and/or importing them from other countries). Buying unauthorized products may increase your chances of being exposed to products that have not been regulated and verified for safety and quality.



The adulteration of health products that are promoted as "natural" but contain prescription and nonprescription drugs have become a worldwide problem, especially those promoted for weight loss, body building, erectile dysfunction, sleep problems, inflammatory conditions and treatment of diabetes.

## Health Risks of Adulterated Health Products

There are several potential health risks if you use products containing undeclared drugs (or other substances):

The adulterated product is promoted as "safe," "natural" and without side effects, when in reality, the undeclared drug has

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known side effects.

- The undeclared drug may not be recommended for the disease or health condition you have.
- You may be allergic to the undeclared drug.
- The adulterated product may contain a dose that exceeds the maximum daily recommended dose for the drug ingredient.
- The undeclared drug may not be authorized for sale in Canada, or no longer sold in Canada because of related health concerns.
- There may be more than one undeclared drug in the product, increasing the risk of possible

drug interactions and serious health effects.

- The undeclared drug may interact with certain foods and/or other health products that you may be using.
- In some cases, the undeclared drug(s) may be analogues, which are chemical compounds similar in structure to prescription drugs. The safety of these compounds may not be known or have been assessed by Health Canada, and may present a health risk.

The following are examples of drugs that have been found in unauthorized "herbal" or "natural" health products promoted for weight loss, erectile dysfunction, sleep problems and inflammatory conditions.

Drugs that have been found in products promoted as NHPs for **weight loss**:

- Sibutramine a drug previously used to treat obesity. This drug was withdrawn from the Canadian market because of an increased risk of serious cardiovascular side effects. Other side effects related to sibutramine include increased blood pressure and heart rate, dry mouth, difficulty sleeping and constipation.
- Fenfluramine a drug previously used to treat obesity. It is no longer authorized for sale in Canada because of its association with severe lung disease and heart valve disease. Other side effects related to fenfluramine include headache, drowsiness, dizziness, palpitation, diarrhea and dry mouth.



 Phenolphthalein – a drug previously used as a laxative. It is no longer authorized for sale in Canada because it may cause cancer. Other side effects related to phenolphthalein include decreased blood pressure, skin rash and gastrointestinal bleeding.

Drugs that have been found in products promoted as NHPs for **erectile dysfunction/sexual enhancement**:

- Sildenafil, Tadalafil, Vardenafil these are prescription drugs used to treat erectile dysfunction. They should never be used by people taking any kind of nitrate drug (like nitroglycerine), as lifethreatening low blood pressure may result. For people with heart problems, there is an increased risk of side effects like heart attack, stroke, chest pain, high blood pressure, and abnormal heart beat. Other side effects include headache, facial flushing, indigestion, dizziness, abnormal vision and hearing loss.
- An increasing problem with "herbal" or "natural" unauthorized products promoted for erectile dysfunction is that they contain analogues of erectile dysfunction drugs. Analogues are compounds that are structurally similar to the original drug compound, (like sildenafil, tadalafil, or vardenafil). Although they may have side



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effects similar to the original drug compound, they may also have slightly or entirely different side effects and/or interactions. Analogues of erectile dysfunction drugs have not been reviewed for their safety, effectiveness or quality, and have not been authorized for sale in Canada.

Drugs that have been found in products promoted as NHPs for **sleep problems**:

 Benzodiazepines – these are a class of prescription drugs (including estazolam and clonazepam) used to treat conditions like insomnia, anxiety, seizures, muscle spasms and alcohol withdrawal. Side effects may include drowsiness, dizziness, slurred speech, headache, depression and fatigue. Also, people with certain diseases (like glaucoma and myasthenia gravis) should not use benzodiazepines.

Drugs that have been found in topical products (products used on the skin) and promoted as NHPs for **inflammatory conditions**:

 Corticosteroids – these are steroidal prescription drugs used to treat inflammatory conditions, like arthritis, allergies, and skin problems like psoriasis and eczema. Side effects include irregular heartbeat, increased blood pressure, stomach ulcer, blood disorders, skin, muscle and bone damage, and nervous system disorders. Abruptly stopping the use of corticosteroids may cause symptoms of withdrawal, so it is important to talk to your health care provider before doing so.

It is important to remember that ingredients licensed for sale in Canada as prescription drugs should only be used under the supervision of a health care provider. You should never use drugs not authorized for sale in Canada (not licensed as a prescription drug or over-the-counter product, withdrawn from the market, or analogue).

#### **Minimizing Your Risk**

The following steps will help you minimize your potential risk:

Choose NHPs that have been
reviewed and authorized for sale by
Health Canada. They will have an
eight-digit Natural Product Number
(NPN) or a Homeopathic Medicine
Number (DIN-HM) on the label. This
is particularly important if you
choose to buy NHPs over the
Internet.



Canada

- Tell your health care provider about all health products you are using, including NHPs.
- If you think you are having a side effect (adverse reaction) to an NHP, talk to your health care provider. Be sure to mention the other health products and substances you are using, including prescription and overthe-counter drugs, other NHPs, alcohol and special foods. This will help avoid potentially harmful interactions.
- Report side effects (adverse reactions) to Health Canada.
- Check out Health Canada's *O gf Gllgev/Ecpcf c* website (see the link in the Need More Info? section below) to report a side effect and for new safety information, including warnings and advisories. You can also subscribe to the *O gf Gllgev* e-Notice.

• If you choose to buy NHPs online, avoid doing business with a website that:

- > refuses to give you a street address and telephone number
- > claims to have a "miracle cure" for any serious condition
- > sells NHPs that do not have either a Natural Product Number (NPN) or a Homeopathic Medicine Number (DIN-HM) on the label

### Health Canada's Role

Health Canada helps to make sure Canadians have ready access to NHPs that are safe, effective and of high quality. As part of this work, Heath Canada assesses the benefits and risks of natural health products, monitors and assesses side effects (adverse reactions), and communicates information about risks to health professionals and the public.

#### Need More Info?

To report an adverse reaction or interaction involving any health product, contact Health Canada at 3/866-234-2345 (toll free in Canada), or visit the *O gf GhgevEcpcf c* web section at:

www.health.gc.ca/medeffect

For more information about Natural Health Products and the safe use of medicines, see the following Health Canada web sections:

- Informing You About Natural Health Products: Information Sheet (#5) for Consumers at: www.hc-sc.gc.ca/dhp-mps/ alt\_formats/pdf/prodnatur/ fiche\_info\_sheets\_5-eng.pdf
- Patient Guide for Reporting Side Effects from Health Products at: www.hc-sc.gc.ca/dhp-mps/pubs/ medeff/\_fs-if/2009-ar-ei-guidepatient/index-eng.php

#### Køu'[ qwt ''J gcnj articles:

• Safe Use of Natural Health Products at: www.hc-sc.gc.ca/hl-vs/iyh-vsv/ med/nat-prod-eng.php

- Safe Use of Health Products for Weight Loss at: www.hc-sc.gc.ca/hl-vs/iyh-vsv/ med/weight-amaigr-eng.php
- Buying Drugs over the Internet at: www.hc-sc.gc.ca/hl-vs/iyh-vsv/ med/internet-eng.php
- Safe Use of Natural Health Products During Menopause at: www.hc-sc.gc.ca/hl-vs/iyh-vsv/ med/menopause-eng.php
- Safe Use of Medicines at: www.hc-sc.gc.ca/hl-vs/iyh-vsv/ med/safe-secure-eng.php

For safety information about food, health and consumer products, visit the Safe Consumers website at: www.health.gc.ca/consumer

For more articles on health and safety issues, go to the *Kat'[ qwt 'J gcnj* web section at:

www.healthcanada.gc.ca/iyh

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*.

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